# KG November-December 18’ Price Controls

Cut https://thehill.com/blogs/pundits-blog/healthcare/332145-the-tragic-toll-of-drug-price-controls

**Resolved: The United States federal government should impose price controls on the pharmaceutical industry.**

## Topic Analysis

### Timeline

### Background

### Definitions

**United States Federal Government: The Federal Government of the United States is the national government of the United States, a federal republic in North America, composed of 50 states, a federal district, five major self-governing territories, and several island possessions.** (<https://www.usa.gov/>)

**Impose: to establish or apply by authority** (https://www.merriam-webster.com/dictionary/impose)

**Price Controls: a government regulation establishing a maximum price to be charged for specified goods and services, especially during periods of war or inflation.** (https://en.wikipedia.org/wiki/Price\_controls)

**Pharmaceutical Industry: Pharmaceutical industry, the discovery, development, and manufacture of drugs and medications (pharmaceuticals) by public and private organizations.** (https://www.britannica.com/technology/pharmaceutical-industry)

### Theory

**Disclosure Theory- Good**

**A. Interpretation: Debaters must, on the page on the NDCA wiki with the school they attend, disclose the taglines, full citations, and the first and last three words of any pieces of evidence read in their case which they have read in their case in a previous round at least thirty minutes before the round.**

**B. Violation: They have not posted cites.**

**C. Standards:**

**1. Research – disclosure increases research and gets rid of anti-educational arguments because debaters are forced to prepare cases knowing that people will have answers AND people get the opportunity to research answers to disclosed cases.**

Nails 13 - (Jacob [I am a policy debater at Georgia State University. I debated LD for 4 years for Starr's Mill High School (GA) and graduated in 2012.] "A Defense of Disclosure (Including Third-Party Disclosure)" [http://nsdupdate.com/2013/a-defense-of-disclosure-including-third-party-disclosure-by-jacob-nails/) GHS//GB](http://nsdupdate.com/2013/a-defense-of-disclosure-including-third-party-disclosure-by-jacob-nails/%29%20GHS//GB)

I fall squarely on the side of disclosure. I find that the largest advantage of widespread disclosure is the educational value it provides. First, disclosure streamlines research. Rather than every team and every lone wolf researching completely in the dark, the wiki provides a public body of knowledge that everyone can contribute to and build off of. Students can look through the different studies on the topic and choose the best ones on an informed basis without the prohibitively large burden of personally surveying all of the literature. The best arguments are identified and replicated, which is a natural result of an open marketplace of ideas. Quality of evidence increases across the board. In theory, the increased quality of information [this] could trade off with quantity. If debaters could just look to the wiki for evidence, it might remove the competitive incentive to do one’s own research. Empirically, however, the opposite has been true. In fact, a second advantage of disclosure is that it motivates research. Debaters cannot expect to make it a whole topic with the same stock AC – that is, unless they are continually updating and frontlining it. Likewise, debaters with access to their opponents’ cases can do more targeted and specific research. Students can go to a new level of depth, researching not just the pros and cons of the topic but the specific authors, arguments, and adovcacies employed by other debaters. The incentive to cut author-specific indicts is low if there’s little guarantee that the author will ever be cited in a round but high if one knows that specific schools are using that author in rounds. In this way, disclosure increases incentive to research by altering a student’s cost-benefit analysis so that the time spent researching is more valuable, i.e. more likely to produce useful evidence because it is more directed. In any case, if publicly accessible evidence jeopardized research, backfiles and briefs would have done LD in a long time ago. Lastly, and to my mind most significantly, disclosure weeds out anti-educational arguments. I have in mind the sort of theory spikes and underdeveloped analytics whose strategic value comes only from the fact that the time to think of and enunciate responses to them takes longer than the time spent making the arguments themselves. If [theory spikes] these arguments were made on a level playing field where each side had equal time to craft answers, they would seldom win rounds, which is a testimony to the real world applicability (or lack thereof) of such strategies. A model in which arguments have to withstand close scrutiny to win rounds creates incentive to find the best arguments on the topic rather than the shadiest. Having transitioned from LD to policy where disclosure is more universal, I can say that debates are more substantive, developed, and responsive when both sides know what they’re getting into prior to the round. The educational benefits of disclosure alone aren’t likely to convince the fairness-outweighs-education crowd, but I’ve learned over the course of many theory debates that most of that crowd has a very warped and confusing conception of fairness. Debaters who produce better research are more deserving of a win. Debaters who can make smart arguments and defend them from criticism should win out over debaters who hide behind obfuscation. That so many rounds these days are resolved on frivolous theory and dropped, single-sentence blips suggests that wins are not going to the “better debaters” in any meaningful sense of the term. The structure of LD in the status quo doesn’t incentivize better debating.

Research skills is a voter because it’s key to our ability to a) actually learn about the topic and become engaged in the real world and b) process large amounts of information, which is a necessary portable skill in the digital age.

2. Clash – Disclosure is the best method for increasing clash in debates because it allows debaters to substantively engage positions rather than relying on sketchy tricks to avoid the discussion. It also allows for more specific clash because debaters can see specific arguments disclosed instead of trying to link generic arguments in. That’s a voter because a) specific education also helps our ability to learn about the topic and engage in the real world and b) clash is key to advocacy skills since it forces us to defend positions, which we need to actually promote social change to fix screwed up things in the real world.

3. Argument quality –

a) Disclosure prevents the element of surprise. A world without disclosure rewards debaters for running arguments not because they are good, but because their opponents won't know how to respond. Disclosure forces debaters to commit to quality; under my interpretation, debaters would have to write cases knowing that their opponents will have the opportunity for thoughtful preparation.

b) Disclosure encourages increased research and cross-pollination—Argument quality is a voter because debate is a unique space in which we need to have in-depth education about these social issues.

Gary Alan Fine 01, [Professor of Sociology at Northwestern], “Gifted Tongues: High School Debate and Adolescent Culture”, Princeton University Press, 2001. RFK

Debate is justified as a learning tool, not merely as a means by which adolescents enjoy themselves. In a society concerned about the perceived failures of its educational institutions, high school debate is a voluntary activity in which some students--a small and highly select group--choose to engage in research, practice socially valued skills, and demonstrate these abilities in public settings. Anecdotal evidence suggests that students who participate in intermural debate do extremely well in their schoolwork and then (and as a consequence) are successful in college and in graduate or professional school, achieving occupational success. Since debate does not appeal to a random sample of the student body, causality is hard to establish, but the claim that debate is beneficial is surely plausible. Debate is one program through which an often shaky institution encourages adolescents to acquire culturally valued skills. While debate is not the only activity in which the adolescent attachment to competition is mixed with the acquisition of socially valued skills--Model UN, academic bowls, math teams, chess clubs, and mock trials also have these attributes--it provides an exemplary case in its organization, its longevity, and its intensity. High school debate potentially could produce curricular reform based on "teaching the conflicts"9: learning how to discuss contentious social issues can permit students to engage and confront moral ideals. Today many find America's school systems in disarray, attempting, often ineffectively, to solve seemingly insoluble social problems. If we cannot educate the masses effectively, some suggest that at least we should properly educate our "best and brightest." Gifted education is a concern for both educators and parents. High school debate teams are highly selective--sometimes self-selected, but often with the assistance of coaches, teachers, and principals who recruit their most energetic, brightest, and most articulate students. Debate helps to reproduce the class system. Most debaters--although not all--are high achievers. In general, debaters are young men and women from affluent homes in which education is valued and in which ideas are discussed. Many of these students have succeeded in school and have established, prior to their immersion in the world of debate, a record of achievement. High school debate magnifies these successes, providing an enriched atmosphere in which students expand their educational horizons. The competitiveness of debate motivates this achievement drive, particularly among those students who have already succeeded in academic competitions.

4. Inclusion – Disclosure is key to the inclusion of small schools – the current system just favors the “big” schools who bring more students who can scout more rounds.

Bietz 10, Mike (former President of the National Debate Coaches Association; debate coach at Harvard-Westlake School in Los Angeles.) “The Case for Public Case Disclosure.” May 2010.) GHS//GB

Since disclosure happens anyway, it ought to be open to all competitors regardless of the number of teammates, coaches or friends one has at any given tournament. **The current “system” is exclusionary and often makes tournaments hurtful situations. It benefits large teams who either 1) bring many kids to tournaments or 2) have many judges in the judging pool, both of which go hand-in-hand. Finally, open disclosure provides the academic check and peer-review of research that is common in all of academia.**

**D. Drop the debater –**

**1. It’s the same as dropping the argument since the argument is the entire case that wasn’t disclosed.**

**2. Voting for us sets a precedent in favor of a positive model of debate—wins and losses determine the direction of activity.**

**3. There’s no way to rectify the abuse — going and forcing them to disclose now won’t fix the lack of education we get from this round.**

**Disclosure Counter- Bad**

1. **You can never be sure that we violate, since there is no way he can say we haven’t posted unless he went on the internet, which one, merits disqualification because using the internet is forbidden according to this tournament’s rules and two, gives them access to unlimited arguments they can potentially read on us in the next speech. Also, using the internet is inherently bad because warrants and arguments should be developed in the round to avoid time skew.**
2. **We’ve been disconnected from the Internet so we literally could not post our cases, you shouldn’t vote us down for something that we can’t do. That’s like saying Kanye’s responsible for a bad rap album.**
3. **We meet because in between last round and this round we changed up our case with new arguments and cards so there was no way that we could have even disclosed a case we literally made less than 30 minutes ago.**
4. **We meet, because I don’t have a coach, we have a Speech teacher who volunteers to ride the bus with us to and from tournaments. This is a solvency deficit, because kids with more numerous and more active coaches will always have more prep than we do.**
5. **We meet, because they could have just asked us before the round to disclose, and we would have done it, we just don’t have access to the wiki but we do have access to them. Disclosure is an easy thing to ask someone for and they had to say the magic words before the round.**
6. **We meet. Their theory shells presume that everything we’re reading was updated 30 minutes before this round but that’s not true. We updated everything we’re reading 15 minutes before the round.**

**A) Counter interp – At tournaments where disclosure is not mandated explicitly in the rules, debaters can win the round without having disclosed their arguments**

**B) Violation – You can look at their off for this part, AND this tournament does not say anywhere that debaters need to disclose what they read.**

**C) Standards**

1. **Predictability, because we had no idea that we would have to disclose at this tournament when there is absolutely no rule that mandates or obliges us to do so. Forcing us to do something that we can’t anticipate is unfair because there’s no way for us to conduct prepare for something totally unpredictable whereas everything we are reading was predictable so it creates unfair research burdens.**
2. **Small school and disadvantaged debater’s participation- their interp literally makes the circuit more esoteric because it prevents small school debaters or those who don’t have as many resources on hand from participating. They require that debaters have regular access to the NDCA, which already has a membership fee that some schools either a) do not have or b) cannot afford to have, just like Milpitas High. If you vote on their interp, that means you perpetuate the perception that only the kids from top notch schools will ever get anywhere in this activity and you’ll exclude even more kids from doing PF than are already excluded.**
3. **Critical Thinking Skills- We increase critical thinking skills because we force thinking on the spot compared to debating a case which has already been disclosed which consequently makes it easier to debate. Furthermore, debaters can just get their coaches to prep out their opponent’s cases for them which ultimately means that they don’t have to do any thinking at all. This is the strongest internal link to education because the purpose of debate is the skills we gain from the round. We won’t remember some deep metaphysical justifications from the round but rather the skills we gained from debate.**

**D) Voters**

**It’s a voter for fairness, which precedes substance because unfair arguments arbitrarily skew your evaluation of the round towards the unfair debater. Voter for education as the only lasting impact of debate. Also, punishing the abusive debater with a loss deters future abuse. And give us the RVI because theory is a no risk issue for them while we are forced to answer it and theory without an RVI incentivizes debaters to read many theory shells in a round without any risk of dropping.**

**Internet Use- Bad**

**A. Interpretation: Debaters should not use or access the Internet in round to research.**

**B. Violation: They have used the Internet in round, which is conceded in cross. We can’t access Internet because we have it locked onto off.**

**C. Standards:**

1. **Research- Using Internet in round inherently damages research capabilities. Using Internet in round decreases research because people can just Google answers to non-stock arguments in round, giving them an advantage because people research outside of round but finding specified sources in round allows for better responses that we don’t have access to. On the other hand, requiring research causes people to use good ideas from each other and also be forced to prep and research for more arguments. That means it’s better for argument quality because people can clash more specifically instead of making bad, generic arguments.**
2. **Critical Thinking Skills- We increase critical thinking skills because we force on the spot debating instead of finding answers to argument during round. Debating a round in which there are no on the spot answers because they are found during round on the Internet sets a precedent to not think ahead, consequently making it easier for them to debate. This is the strongest internal link to education because the purpose of debate is the skills we gain from the round. We won’t remember some deep justifications from round, but rather the speaking skills and thinking abilities we gained from debate.**

**D. Voters**

1. **Fairness- Them using Internet decreases fairness as it sets a precedent to decrease research and increase round Internet use. Fairness precedes substance because unfair arguments arbitrarily skew your evaluation of the round towards the unfair debater.**
2. **Education- Decreasing critical thinking skills and finding information quickly in round decreases education. Vote for us because by voting for us, you set the precedent for other teams to learn about the topic ahead of time. Punishing abusive debaters with a loss deters future abuse, and remember that education is the only long term impact from debate.**
3. **RVI- We are forced to answer Internet abuse because it makes the round harder from us, but using Internet is no risk issue from them. There’s no way to rectify the abuse because turning of Internet now won’t fix the unfairness and lack of education from the round.**

# A/2: PRO (CON)

## Overviews

### Innovation v Affordability

1. **Wright of Cleveland State University writes that because new drugs reduce hospital stays and physician office visits, every dollar spent on innovation reduces healthcare spending $7.20.**

<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

1. **Even if they still win 100% of their offense, innovation still outweighs affordability for three reasons.**
	1. **Prerequisite- It doesn’t matter that these drugs become affordable if new drugs stop being developed altogether. Easton explains that as a result of price controls, companies would be forced to cut their research and development budgets by about 80%. You can’t buy drugs that don’t exist.**
	2. **Scope- Whereas they only impact to decreasing costs for 10% of drugs, we impact to straining Research and Development on 100% of the market.**
	3. **Long-term timeframe- Francis of the NBER writes that even if consumers did see a benefit from price controls, it would only be ST at best and would be completely outweighed in the LT by social welfare harms from losing innovation.**

**.If price controls pressure the U.S. industry into a more conventional process industry model, like that of the chemical industry, pharmaceutical R&D budgets would be slashed. To achieve the chemical industry’s rate of R&D spending, as would be required to achieve profitability competitive with the chemical industry, top pharmaceutical companies would have to reduce their R&D budgets by 80 percent — almost $50 billion in total. This reduction in spending would take a few years to realize, but would be completely evident by 2023 or earlier.**

1. file:///Users/jscmedley/Desktop/LT%20innovation%20OW%20ST%20Affordability.htm
2. Some critics of the drug companies assume that patent protection and the freedom to price drugs in the United States at market prices, along with an ability to exploit inefficiencies in the existing insurance system, actually encourages pharmaceutical firms to exploit consumers with high costs. However, numerous economic studies indicate that price controls, **by cutting the return that pharmaceutical companies receive on the sale of their drugs, also would reduce the number of new drugs being brought to the market. So, a short-run benefit for consumers could lead to a long-run negative impact on social welfare.** And, this damage wouldn't be fully felt for several decades because it takes so long to develop new drugs.

## A/2: High Prices

### A/2: Affordability

1. **Mitigate. Three reasons.**
	1. **Winegarden of Forbes writes that nearly 90 percent of all drugs dispensed in the US in 2016 were generics, which are inexpensive, so price controls wouldn’t impact most patients.**
	2. **Langreth of Bloomberg finds that most drug costs are either paid for by Medicare, Medicaid, or private insurers. This means that people aren’t directly bearing the costs they tell you about.**
	3. **Lakhadwalla for The New York Times writes that price controls at best, knock only 2% off our healthcare bill over the next decade.**
2. **Turn. Rose of MIT finds that countries which impose prices controls have only been able to affect brand name drugs and charge higher prices on generic drugs. By affirming, 90 percent of the market is in jeopardy.**
3. **Turn affordability.**
	1. **Hughes explains that for every dollar in consumer benefit realized from providing greater access to the current stock, future consumers would be harmed at a rate of three dollars in present value terms from reduced future innovation.**
	2. **Danzon of The University of Chicago writes that as pharmaceutical revenue falls, as under price controls, more companies merge as an attempt to salvage the remaining profits and escape financial panic. This is worse, as Ashenfelter of Fortune finds mergers kill competition and increase prices 80 percent.**

Wayne Winegarden (Forbes) "Price Controls Will Reduce Innovation and Health Outcomes" October 12, 2017 https://www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduce-innovation-and-health-outcomes/#495ad7f663a6

This logic does not change simply because the price controls are applied to pharmaceuticals, not doctors. If effective price caps were imposed on pharmaceuticals, then current price increases would moderate. The health care system’s underlying problems would only worsen, however.To start, the price controls would be irrelevant for most patients. Nearly 90 percent 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.It is also important to note that generic medicines are significantly cheaper in the U.S. compared to the other major industrialized countries. In fact, total pharmaceutical spending as a percentage of total health care spending is lower in the U.S. (12.2 percent) than the average for the 30 nations that comprise the Organization for Economic Cooperation and Development, or OECD, (16.9 percent). This is due to, in part, the prevalence of generic medicines that are more affordable here than in other OECD nations.

Langreth, Robert, 5-11-18, “Drug Prices”<https://www.bloomberg.com/quicktake/drug-prices> Bloomberg,

Unlike other nations, the U.S. doesn’t directly regulate medicine prices. In Europe, the second-largest pharmaceutical market after the U.S., governments negotiate directly with drugmakers to limit what their state-funded health systems pay. The U.K.’s National Health Service has refused to pay for some cancer drugs widely used in the U.S. on the grounds that they don’t constitute value for money. In the U.S., drug companies can more or less set whatever price the market will bear. For most outpatient drugs reimbursed through Medicaid, the public health program for the poor, drugmakers must provide the government rebates. But most medicine costs are paid for by Medicare, the government program for the elderly, or by private insurers. When prescription-drug benefits were added to Medicare under a 2003 law, the pharmaceutical industry successfully lobbied to prohibit the federal government from using its huge purchasing power to negotiate drug prices. Private payers typically rely on third-party pharmacy-benefit managers, such as Express Scripts, to negotiate discounts. Often they make exclusive deals with drugmakers, which limits the choice of drugs patients have. Patients directly pay about 17 percent of prescription medicine costs out of their own pockets. In a 2013 survey, one in five adults in the U.S. said they failed to complete a prescribed course of medicine because of cost. The figure was one in ten in Germany, Canada and Australia.

Nancy Rose. Professor of Applied Economics, MIT, "Regulation of the Pharmaceutical‐Biotechnology Industry" in \*Economic Regulation and Its Reform: What Have We Learned?\* University of Chicago Press, 2014. Available at: http://www.nber.org/chapters/c12572.pdf

Cross-national comparisons of drug prices vary significantly, depending on the time period, sample of drugs used, the price index methodology used—including unit for measuring price (grams, units, daily doses), consumption weights, and exchange rates. Most price comparisons have been biased by use of very small, nonrandom samples including only branded drugs, and have not adhered to standard index number methods (GAO 1992; GAO 1994). **The exclusive focus on branded drugs tends to bias comparisons in favor of countries with strict price regulation. Regulation and competition are to some degree substitutes: less regulated markets tend to have higher brand prices but larger generic market shares and lower priced generics. Overall, countries that use direct price controls do not consistently have lower prices than countries that use other indirect means to constrain prices** (Danzon and Chao 2000a, 2000b; Danzon and Furukawa 2003, 2006). However, comparisons are very sensitive to the sample of drugs, weights, exchange rate, and prices used.

<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.**

<https://www.nber.org/papers/w9229>

We find that providing greater access to the current stock of prescription drugs yields large benefits to existing consumers. However, realizing those benefits has a substantially greater cost in terms of lost consumer benefits from reductions in the flow of new drugs. Specifically, the model yields the result that for every dollar in consumer benefit realized from providing greater access to the current stock, future consumers would be harmed at a rate of three dollars in present value terms from reduced future innovation.

https://www.nber.org/reporter/fall06/danzon.html

In addition to product licensing, mergers and acquisitions (M&A) are common in the pharma-biotech industry. Large horizontal mergers were particularly frequent in the late 1980s and 1990s, while pharmaceutical acquisitions of biotech companies have become more common recently. Several of the largest firms are the result of successive large horizontal mergers, and this has contributed significantly to industry concentration. Such mergers are often rationalized on grounds of economies of scale and scope in R and D, marketing, and administration. In our analysis of M&A in the pharma-biotech industry, we tested various alternative hypotheses to explain both large and smaller mergers, and then examined the effects of mergers using propensity scores to control for merger endogeneity.(4) For larger firms, we find that mergers are a response to patent expirations and gaps in a company's product pipeline, which lead to excess capacity of the fixed marketing resources. For smaller firms, **mergers are primarily an exit strategy in response to financial trouble**, as indicated by a low Tobin's q, few marketed products, and low cash-sales ratios. Controlling for a firm's ex ante propensity to merge significantly affects the estimates of merger effects. Firms with relatively high propensity scores experienced slower growth in sales, employees, and R and D, regardless of whether they actually merged; this is consistent with mergers being a response to distress. For large firms, a merger did not significantly affect subsequent performance on average, whereas small firms that merged had slower R and D growth than similar firms that did not merge; this suggests that post-merger integration may divert cash from R and D. This conclusion, that merger is often a response to distress but is usually not an effective solution, is consistent with the subsequent slow-down in M&A in this industry, with the exception of selective, strategic acquisitions, as large firms acquire smaller firms with spe cifically well-matched capabilities or products. Thus, although the "survivor" evidence -- with increased market share of the top ten firms over time -- might suggest that large firms have advantages, recent stock market performance tells a very different story.

http://fortune.com/2016/05/17/high-drug-prices-mergers-pharma-competition/

**Economics teaches that under conditions of perfect competition, firms earn normal profits and “prices will be kept low by competitive pressures.” To achieve perfect competition, you need many firms to operate in the same business. Therefore, antitrust policy is supposed to ensure that competitive markets remain that way by limiting mergers that reduce market competition.** However, as even casual observation attests, the number and value of takeovers has soared over the years, with only a tiny minority of acquisitions drawing regulatory scrutiny.

Somewhat surprisingly, as **Princeton economist Orley Ashenfelter** noted, there has been little empirical evaluation of the effects of mergers on consumer prices. **A study of five mergers by Ashenfelter** and Federal Trade Commission economist Daniel Hosken **found that in four of the cases, there was evidence of an increase in some consumer prices.**

Scott Atlas [Senior Fellow at the Hoover Institute], "An Overlooked Key To Lower Drug Prices," Hoover Institute, April 4 2018. Available at:[https://www.hoover.org/research/overlooked-key-lower-drug-prices](https://facebook.us6.list-manage.com/track/click?u=7eae7f86cf29ae45535f6b117&id=1a2026eac3&e=dfb87b8c0a)

**In addressing legitimate public concern about drug prices, our politicians must avoid the temptation to impose top-heavy regulations. Price caps may seem intuitively attractive, yet** price caps always restrict supply of the product, and drugs are no different. Iain **Cockburn** of Boston University**showed that price regulation strongly delayed drug launches of 642 new drugs in 76 countries**. The University of Connecticut’s Thomas **Abbott showed that price controls significantly diminish early-stage research and development. In that study, cutting prices by 40 to 50 percent in the United States would lead to 30 to 60 percent fewer early-stage R&D projects**. And Rexford **Santerre** of the University of Connecticut **calculated that drug price controls would have led to 198 fewer new drugs being brought to the U.S. market from 1981 to 2000, at a societal cost of about $100 billion more than the estimated savings from those price controls.**

 Andrew Spiegel, The Hill, "The tragic toll of drug price controls | TheHill", 05/05/17,

Colon cancer is one of the biggest killers in the developing world. The disease claims more than 600,000 lives every year. Breakthrough treatments can contain this disease and dramatically extend life. However, **many colon cancer patients are currently denied access to these breakthrough treatments because of short-sighted government policies. In hopes of driving down drug costs, public authorities all over the world have installed price controls in the pharmaceutical market.** **This approach, though it generates some short-term savings, is ultimately counterproductive. Price controls significantly restrict patients' access to life-saving medications, condemning many to die from eminently treatable conditions.** One of the most popular forms of drug price controls is "reference pricing." Officials group drugs into therapeutic classes, based on how the drugs attack disease. They then set a single price for each class. In fact, several forms of reference pricing do not distinguish between innovative new medications and older generic alternatives. So, for instance, a new, breakthrough medication gets priced exactly the same as an older, less effective drug that's been off-patent for years. By doing this, reference pricing fails to value the innovative nature of the next generation of treatments and cures. The Canadian province of British Columbia has incorporated reference pricing into its public health system. So have Italy, Spain, and Germany. Less developed economies have resorted to even more nefarious means. By issuing so-called "compulsory licenses," they have broken patent protections on innovative medicines. Compulsory licenses were designed to be used only in the event of a public health disaster, but some countries are now using them to drum up discounts for drugs without any plausible connection to an emergency. In Indonesia, compulsory licensing is an industrial policy tool. If a new treatment isn't manufactured locally, anyone can petition the government to break the patent on that product. And, of course, several major economies have installed straight-up caps on drug prices. South Korea's public insurance system imposes some of the most stringent caps in the world, tightly controlling even generics. Newly introduced generics can't be sold for more than 60 percent of the price of the brand name upon which they're based. And that cap drops to 53 percent after a year. Likewise, India's National Pharmaceutical Price Authority aggressively controls product prices, dictating down the cost of diabetes drugs by 40 percent over the last year and cancer drugs by nearly 90 percent. And these controls are only going to get tighter. Just this February, the World Health Organization released a draft report criticizing industry pricing practices and sketching out a spreadsheet for governments to calculate a "fair price" for medicines. That's a barely disguised call for lower caps. The justification for these controls rests on a simple story: drug prices as a whole are spiraling skyward, preventing sick patients from affording needed medications. That's pure fiction. Drugs actually represent a relatively small slice of global medical spending. Just consider: over the next decade, spending on prescriptions will account for less than 10 percent of total healthcare spending growth in the OECD, the economic association encompassing the United States, Canada, and much of Europe. 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. **In America, which has a relatively free drug market, the average medicine is approved 90 days quicker than in Europe and about a year quicker than in Canada. This delay can be deadly, especially for colon cancer patients.** The drug industry has invented advanced drugs proven to beat back this disease, including specialty chemotherapy agents such as panitumumab and "angiogenesis inhibitors," which prevent colon cancer cells from growing by cutting off their blood supply. Obviously, these drugs can only help patients if regulators approve them. Too often, that approval is slow to come. **And such delays are now common across a wide variety of drug classes, leading to serious carnage: some 600,000 European deaths could be avoided each year if the continent's healthcare systems simply offered "timely and effective medical treatments," according to the European Union's own data.** This fatal foot-dragging, and the accompanying wave of price controls, must end. That's why my organization, the Global Colon Cancer Association, and over 70 other groups have sent a letter to President Trump and other government officials asking them to pressure foreign allies to expand access to lifesaving medicines. Everyone wants lower healthcare costs. But it's counterproductive to blame companies that create life saving therapies. Foreign leaders would better serve their citizens by expanding access to treatments that improve health and lower long-term costs.

at:[https://www.hoover.org/research/overlooked-key-lower-drug-prices](https://facebook.us6.list-manage.com/track/click?u=7eae7f86cf29ae45535f6b117&id=1a2026eac3&e=dfb87b8c0a)

**In addressing legitimate public concern about drug prices, our politicians must avoid the temptation to impose top-heavy regulations. Price caps may seem intuitively attractive, yet** price caps always restrict supply of the product, and drugs are no different. Iain **Cockburn** of Boston University**showed that price regulation strongly delayed drug launches of 642 new drugs in 76 countries**. The University of Connecticut’s Thomas **Abbott showed that price controls significantly diminish early-stage research and development. In that study, cutting prices by 40 to 50 percent in the United States would lead to 30 to 60 percent fewer early-stage R&D projects**. And Rexford **Santerre** of the University of Connecticut **calculated that drug price controls would have led to 198 fewer new drugs being brought to the U.S. market from 1981 to 2000, at a societal cost of about $100 billion more than the estimated savings from those price controls.**

### A/2: Accessibility

* + - 1. **Market entry barriers delay drug launch. Spiegel ofThe Hill writes that 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. At best, they’re not making drugs more accessible even if they become affordable, and at worst, they’re actually killing more people because by their own logic, any delay in launch is deadly for those who need timely treatment. That’s why Spiegel furthers that it takes 90 days longer to approve a drug in price-controlled Europe than in America, which he says causes 600,000 deaths a year. Atlas of the Hoover Institute writes that while price caps may seem intuitively attractive price regulation strongly delayed drug launches of 642 new drugs in 76 countries.**
			2. **Turn.**
			3. **Sullivan explains that Price controls incentivize pharmaceutical companies to leave the market for generic drugs in search of profit elsewhere, meaning that even less people have access to medicines. 2. Price controls would lead to shortages. Since prices go down, the quantity demanded goes up, but the supply curve shifts to the left because producers are unwilling to sell them at a cheaper price, leading to a fall in supply. So not only are they making future drugs less accessible, but they’re even making the drugs currently in the market inaccessible.**

Andrew Spiegel [Opinion Contributor, The Hill, “The tragic toll of drug price controls,” The Hill, May 5 2017. Available at: <https://thehill.com/blogs/punditsblog/healthcare/332145-the-tragic-toll-of-drug-price-controls>

Drugs actually represent a relatively small slice of global medical spending. Just consider: over the next decade, spending on prescriptions will account for less than 10 percent of total healthcare spending growth in the OECD, the economic association encompassing the United States, Canada, and much of Europe. 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.**

**In America**, **which has a** relatively **free drug market, the average medicine is approved 90 days quicker than in Europe** and about a year quicker than in Canada. **This delay can be deadly**, especially for colon cancer patients. The drug industry has invented advanced drugs proven to beat back this disease, including specialty chemotherapy agents such as panitumumab and “angiogenesis inhibitors,” which prevent colon cancer cells from growing by cutting off their blood supply. Obviously, these drugs can only help patients if regulators approve them. Too often, that approval is slow to come. And such delays are now common across a wide variety of drug classes, leading to serious carnage: some 600,000 European deaths could be avoided each year if the continent’s healthcare systems simply offered “timely and effective medical treatments,” according to the European Union’s own data.

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.”

### A/2: Price Gouging

1. **Price controls wouldn’t change anything that the pharmaceutical industry is doing. Lamattina of forbes[[1]](#footnote-1) 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.**
2. **No impact-Loria of business insider[[2]](#footnote-2) explains that only 1/10 drugs actually get the FDA approval, this is after all the billions of dollars spent testing**
3. **Turn- Loria continues[[3]](#footnote-3) that If prices decrease, so would the number of investors. As it right now according to Loria 16 from Business Insider, potential investors don't invest unless the drug is very likely to succeed.**
4. **Mitigate it even more- Loria 16[[4]](#footnote-4) continues that from the beginning of research to the clinical test run it can cost 2.6 billion dollars for a new drug. Inventors are not going to be incentivized to create new life-saving drugs if they can’t even get their money back.**

### A/2: Uninsured

1. **Turn: Drugs arent even being made- Easton of STATNews[[5]](#footnote-5) explains that Price controls reduce the incentive for companies to innovate, ultimately resulting in a longer-term problem where there are fewer drugs in the long-term. This is problematic as Cong of Rand[[6]](#footnote-6) explains that Introducing new pharmaceutical products is key to ensuring that the uninsured are able to afford pharmaceuticals. Howard of New York Times[[7]](#footnote-7) impacts in 2015 that a study on the European market has demonstrated that, by dashing innovation, price controls ultimately increase the price of drugs.**
2. **Robert Easton. “Price controls would stifle**
3. **Turn: drugs are more expensive- Danzon 07 of UChicago[[8]](#footnote-8) writes writes that as pharmaceutical revenue falls, as under price controls, more companies merge as an attempt to salvage the remaining profits and escape financial panic. That’s really bad because Ashenfelter of Princeton[[9]](#footnote-9) finds in 2016 that because they kill all market competition, 80% of mergers result in higher drug prices, meaning even less people are able to get access to medicines**
4. **Turn: price controls reduce life expectancy- Gutierrez of Michigan[[10]](#footnote-10) writes that as a result of increased prices of drugs in a world with price controls, the life expectancy of Americans would be expected to lose almost 6 months of life expectancy.**

### A/2: Protecting Consumers

1. **Rose 14 of MIT[[11]](#footnote-11) writes that Less regulated markets tend to have larger generic market share and lower priced generics**
2. **Turn- Pitts 17 National Review[[12]](#footnote-12): U.S Dept. of Commerce calculates price controls among OECD countries reduces 5-8 billion in potential pharmaceutical development investment every year. This loss deprives all individuals of life saving treatments.**
3. **Turn- Howard 15 of the Manhattan Institute[[13]](#footnote-13): Cutting prices by 40-50% will decrease R&D projects being taken by 30-60%. On net, a RAND Study on european price controls found pharmaceutical price controls hurt patients.**

### A/2: Racism

1. **Delink- Most drugs accessed by the public are inexpensive. Winegarden from Forbes[[14]](#footnote-14) corroborates in 2017 that 90% of drugs dispensed in 2016 were inexpensive generic medicine. At this point they lose out on any impact as any price control scheme would not apply to the majority of patients who are using inexpensive generics, not more expensive patented products.**
2. **Turn- Innovation is a prerequisite to affordability. Wright 13 of Cleveland State[[15]](#footnote-15) writes that because new drugs reduce hospital stays and physician office visits, every dollar spent on innovation reduces healthcare spending $7.20. However, innovation goes down in the affirmative world as Lamatinna of Forbes contends in 2018[[16]](#footnote-16) that setting price controls would reduce the incentive for pharmaceutical companies to innovate, resulting in fewer and less effective new drugs.**

### A/2: Low Income

1. **delink. Price controls would not affect the price of the majority of the U.S.’s drugs. Winegarden of Forbes[[17]](#footnote-17) quantifies in 2017 that 90 percent of drugs dispensed in the U.S. are inexpensive generics.**
2. **Turn. Tate from the Health Care Institute of New Jersey[[18]](#footnote-18) finds in 2002 that price controls would create drug shortages which limit drug access. He highlights how as a result of price controls that the government set on vaccines, there are only 4 current developers of vaccines compared to 20 from a few years ago**
3. **Turn. Sullivan of Forbes[[19]](#footnote-19) writes in 2018 that price controls incentivize pharmaceutical companies to leave the market for generic drugs in search of profit elsewhere. This means that the generic drugs many low-income individuals depend on actually decrease in their world.**

### A/2: Price Discrimination

1. **Two turns.**
	1. **Bhanji of Harvard writes that price discrimination occurs due to the high cost of research and development and that it is critical in order to maintain prices at an affordable rate. Lichtenberg writes price discrimination makes it less likely that high fixed costs would prevent manufacturers from pursuing socially desirable investment opportunities, and thus increases social welfare**
	2. **price discrimination is critical to supplying drugs for third world countries. Schweitzer of Health Affairs explains that developing countries pay 27 percent of the prices charged in industrialized countries. This is problematic as the Hill notes that a reduction in profits by American companies would directly impact 3rd world countries by making drugs unaffordable. Stanford terminalizes this by finding that a 4% increase in health aid leads to 360,000 less deaths, something that cant happen in the aff world**

Bhanji, Shaira “Price Discrimination in Pharmaceutical Companies: The Method to the ‘Madness’”, Harvard College Global Health Review, 2 April 2012, https://www.hcs.harvard.edu/hghr/online/price-discrimination-method/

**“One of the primary reasons for price discrimination is the astronomical cost of drug research and development.** The total average cost of developing a new drug is more than $1 billion over the course of 15 years of research and testing. **Many drugs fail in clinical trials and do not even make it to the market, resulting in sunk costs**. A recent study conducted by the Centre for Medicine Research (CMR) on 16 pharmaceutical companies that account for 60% of the world’s research and development spending estimates that Phase II trial success rates have fallen by 10 percentage points to just 18% from 2006 to 2009. Furthermore, only half of drugs make it through Phase III trials. All this is to say that drug development is a high-risk, high-reward game. When the game is won, the rewards have the potential to benefit many lives around the globe in addition to generating the profits that pharmaceutical companies may reap. **Price discrimination can be thought of as a way for pharmaceutical companies to hedge against this huge inherent risk by allowing them to take advantage of the entire market.** An August 2011 Health Affairs article affirms that the strategy promotes production of new and existing products by providing money for research and development in the future. Thus, some believe that the long-term benefits of continued innovation outweigh the short-term benefits of more standard pricing.”

Schweitzer, Stuart. “Prices of Pharmaceuticals in Poor Countries are Much Lower Than in Wealthy Countries”, Health Affairs, Aug. 2011, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0923

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

 <https://thehill.com/opinion/healthcare/369727-us-drug-prices-higher-than-in-the-rest-of-the-world-heres-why>

<https://med.stanford.edu/news/all-news/2014/04/health-care-aid-for-developing-countries-boosts-life-expectancy-study-finds.html>

## A/2: Medicine

### A/2: Black Market

1. **Delink-. Winengarden of Forbes writes in 2017 that most of the drugs and medicines that consumers use are generic medicines. Therefore, these price ceilings won’t apply to these cheap medicines and therefore won’t cause a shift to the black market. The Medical Review Institute of America reveals in 2015 that generics offer a cheaper alternative of the same quality. Moreover, by showing that generic drugs offer the same quality, people don’t need to turn to the black market if they can receive a similar drug at a quarter of the cost.**
2. **Non unique- Christopher Coyne of the Institute of Economic Affairs in 2015 finds that shortages caused by price controls push people to the black market as well. This means that my opponent have no solvency for their impacts.**
3. **Turn- Price controls would force shortages. Reisman 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 concludes that price controls would incentivize a shift to the black market as there would be enough drugs available in the general market**

 Winegarden, Wayne. “Price Controls Will Reduce Innovation and Health Outcomes.” Forbes, Forbes Magazine, 12 Oct. 2017, <www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduceinnovat ion-and-health-outcomes/#32f4201363a6.>

 **“To start, the price controls would be irrelevant for most patients. Nearly 90 percent 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. It is also important to note that generic medicines are significantly cheaper in the U.S. compared to the other major industrialized countries.** In fact, total pharmaceutical spending as a percentage of total health care spendingis lower in the U.S. (12.2 percent) than the average for the 30 nations that comprise the Organization for Economic Cooperation and Development, or OECD, (16.9 percent). This is due to, in part, the prevalence of generic medicines that are more affordable here than in other OECD nations.**”**

Mrioa. “Generic Versus Proprietary Medications.” Medical Review Institute of America LLC, 2 Apr. 2015, <http://www.mrioa.com/generic-versus-proprietarymedications/.>

**“A generic drug (generic drugs, short: generics) is a drug defined as “a drug product that is comparable to a brand/reference listed drug product in dosage form, strength, quality and performance characteristics, and intended use.**” It has also been defined as a term referring to any drug marketed under its chemical name without advertising. Although they may not be associated with a particular company, generic drugs are subject to the regulations of the governments of countries where they are dispensed. Generic drugs are labeled with the name of the manufacturer and the adopted name (nonproprietary name) of the drug. **A generic drug must contain the same active ingredients as the original formulation.** According to the U.S. Food and Drug

Administration (FDA), generic drugs are identical or within an acceptable bioequivalent range to the brand-name counterpart with respect to pharmacokinetic and pharmacodynamic properties. By extension, therefore, generics are considered (by the FDA) identical in dose, strength, route of administration, safety, efficacy, and intended use. The FDA’s use of the word “identical” is very much a legal interpretation, and is not literal. In most cases, generic products are available once the patent protections afforded to the original developer have expired. **When generic products become available, the market competition often leads to substantially lower prices for both the original brand name product and the generic forms.** The time it takes a generic drug to appear on the market varies. In most countries of the world, patents give 20 years of protection. However, many countries/regions, e.g. the European Union and the USA may grant up to 5 years of additional protection for drugs (“patent term restoration”).”

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.”

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.>

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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

### A/2: EpiPen

1. **Non-unique: The FDA[[20]](#footnote-20) 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[[21]](#footnote-21) 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.**

### A/2: 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[[22]](#footnote-22) 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[[23]](#footnote-23) 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[[24]](#footnote-24) 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.**

### A/2: Birth Control

1. **Turn- Price controls greatly decrease profits and revenue that companies gain. Sood from NCBI[[25]](#footnote-25) finds that this would lead them to cut research and innovation and find other measures to compensate for the lack of innovation. This is bad because historically this has spelled trouble when it comes to birth control. In 1984, after the 1980’s price control legislation came into effect, The NY times[[26]](#footnote-26) concludes that the Food and Drug Administration seized more than 330,000 counterfeit birth-control pills from national distributors. The aff just incentivizes the use and creation of these pills.**
2. **Delink- less innovation means that future research into birth control is affected. Most research is undertaken as a part of R&D projects. Ladwakalla from NY times[[27]](#footnote-27) argues that Research shows that price controls in the United States 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/2: Prices HIgh

Winengarden of Forbes reports in 2018[[28]](#footnote-28) that the FDA approved two new medications to treat Hepatitis C. These medicines were expensive, but they were also cures for a disease that was previously incurable. Of course, by curing the disease, more expensive surgeries can now be avoided. Price controls risk such benefits in the future.

### A/2: Hospital Costs

1. **The US Health Department[[29]](#footnote-29) explains that Hospitals are reimbursed at super high rates by medical care, with rates up to 106% of the price being reimbursed.**
2. **No link- Graban of HHN[[30]](#footnote-30) writes that out of all hospital costs, 30 to 50% of all costs can be describes as waste. Bentley of the Millbank Quarterly[[31]](#footnote-31) contextualizes this by finding that there are two main types of waste; productive inefficiencies, which create waste in the form of excess costs in producing a given output, and allocative inefficiencies, which produce the wrong output.**
3. **no link- Langwell of the HCFR[[32]](#footnote-32) 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[[33]](#footnote-33) 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[[34]](#footnote-34) 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.**

### A/2: Rural Hospitals

**Even if hospitals have to spend less money on medicines, this doesn’t necessarily mean that the patients are the ones who benefit.**

1. **Delink- Graban in 2011[[35]](#footnote-35) 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.**
2. **Turn- Brownlee from the Huffington Post[[36]](#footnote-36) in 2017 corroboratse that currently hospitals and pharmaceutical companies are driven by a growing desire for more and more profit.**
3. **This is actually happening right now. Beaton[[37]](#footnote-37) in 2015 concludes that in 2012, Bayer paid $110 million to settle allegations that some consumers experienced fatal blood clots when using the oral contraceptive Yasmin. In 2010, makers of diabetes drug Avandia agreed to pay $460 million to settle 10,000 lawsuits whose plaintiffs claimed the company hid its heart attack risks. In 2008, the manufacturer of the painkiller Vioxx paid out $4.85 billion to settle 50,000 claims that users suffered heart attacks and strokes.**

## A/2: Economy

### A/2: Competition

1. **NU. The current free market system that manages the pharmacy industry is competitive. The competition of drugs is already taking place. For example, generic drugs compete with name brand drugs through prices.**
2. **T. Because of the enormous lobbying power of big Pharma companies, price controls are ineffective against them. This only discourages competition because bog business is given a huge competitive advantage**

### A/2: Market Failure

1. **Alt. Caus. The high prices of drugs aren’t an example of market failure, they’re the result of the costly, time-consuming, and intensive process of manufacturing and researching drugs. Lamatinna of Forbes in 2018[[38]](#footnote-38) concludes that the upfront cost of making new pharmaceuticals is exceedingly high, and drug companies need to be able to recoup that capital.**
2. **Turn. Wright from Citizens Against Government Waste[[39]](#footnote-39) impacts in 2016 that price controls would make pharmaceuticals more expensive in the long-run by shifting costs and reducing the efficiency of innovation.**

### A/2: State Budget

* + - 1. **delink- Werner of the Washington Post[[40]](#footnote-40) explains that there are cuts to programs like medicare right now at the federal level. This isnt a voting issue as there already is solvency in the squo.**
			2. **Turn- Wright from Citizens Against Government Waste impacts in 2016[[41]](#footnote-41) that price controls distort the pharmaceutical market, ultimately resulting in higher medical costs elsewhere and no real reduction in spending. Ultimately, price controls increase pharmaceutical consumption in the short-term and increase prices in the long-term.**

### A/2: 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. **Lanjouw of Cambridge[[44]](#footnote-44) empirically finds that patent systems encourage the introduction of products to the market sooner, whereas price controls discourage the introduction of new products.**
4. **Price controls wouldn’t change anything that the pharmaceutical industry is doing. Lamattina of forbes[[45]](#footnote-45) 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.**

### A/2: Competition

1. **Companies will find loopholes: Fox of the Harvard Business review[[46]](#footnote-46) writes that Large pharmaceutical companies have filed false citizen petitions and have marketed the same drug under another name in order to prolong their monopoly.**
2. **Product Hopping: Jones of the NCBI[[47]](#footnote-47) 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.**
3. **Regardless, Fox[[48]](#footnote-48) 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.**

### A/2: Mergers

1. **Make them give you an example of a merger.**

## A/2: Politics

### A/2: Conservative Backlash

1. **Delink: There’s going to be no backlash because the issue is bipartisan. Hancock in 2017 from The New York Times[[49]](#footnote-49) Writes that powerful members of Congress from both parties have said that drug prices are too high.**
2. **Nothing will happen even if there is backlash, as Jopson in 2016 from The Financial Times[[50]](#footnote-50) finds that deadlock has been endemic in Congress for years now ever since the Republicans won, and both parties are facing internal divisions between moderates and hardliners.**

### A/2: Popular Support

* + - 1. **The exact opposite is true. A poll by Harvard Public Health[[51]](#footnote-51) quantifies that two-thirds of Americans said they did not believe that Medicare negotiating with drug companies to lower prices would lead to fewer medicines being developed. And a majority — 55 percent — believes that even outright price controls wouldn’t slow the flow of new drugs. Those are two specific examples, but the findings suggest that Americans reject a key counterargument the industry makes whenever the specter of government action on drug costs comes up: The current system, while imperfect, allows drug companies to create breakthrough lifesaving medications**

### A/2: Trump’s Plan

**Leonard of the Washington Examiner[[52]](#footnote-52) reports in 2018 that Trump's plan is creating political backlash as we speak. It also models foreign price controls that have been known to deny access to vital drugs for senior citizens and decrease innovation.**

### A/2: No Regulation Right Now

1. **Pharma already experiences a significant amount of regulation in the status quo. In fact, Francis from the National Bureau of Economic Research[[53]](#footnote-53) concludes that about only one in several thousand companies make it through the full development process of drug after gaining approval from the FDA.**

### A/2: Causing negotiations

1. **Government negotiations can’t even happen. Kertscher of Politico[[54]](#footnote-54) explains that the government currently can’t negotiate prices due to the current law which dictates that “in order to promote competition," the health and human services (HHS) secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and prescription drug plans”.**

**Even if you buy that negotiations can happen**

1. **Turn- Spiegel writes for The Hill in 2017[[55]](#footnote-55) that pharmaceutical firms have to undergo along, 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. At best, they’re not making drugs more accessible even if they become affordable, and at worst, they’re actually killing more people because by their own logic, any delay in launch is deadly for those who need timely treatment. That’s why Spiegel furthers that it takes 90 days longer to approve a drug in price-controlled Europe than in America, which he says causes 600,000 deaths a year.**

### A/2: Excess Government Spending

* + - 1. **Mitigate- Paul Howard of the Manhattan institute[[56]](#footnote-56) 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.**
			2. **Turn- Howard of the New York Times continues that countries that use price controls actually spend more on drugs than the US[[57]](#footnote-57)**
			3. **Turn. By reducing innovation and increasing consumption of pharmaceuticals, price controls would increase government spending in the long-run. Lamatinna of Forbes contends in 2018[[58]](#footnote-58) that setting price controls would reduce the incentive for pharmaceutical companies to innovate, resulting in fewer and less effective new drugs.**
			4. **Turn. Prada of BioMed Central[[59]](#footnote-59) writes in 2018 that making drugs artificially cheaper than they should be creates a moral hazard, where people consume more prescription drugs, ultimately increasing public expenditures.**
			5. **Wright from Citizens Against Government Waste impacts in 2016[[60]](#footnote-60) that price controls distort the pharmaceutical market, ultimately resulting in higher medical costs elsewhere and no real reduction in spending. Ultimately, price controls increase pharmaceutical consumption in the short-term and increase prices in the long-term.**

### A/2: 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[[61]](#footnote-61) 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[[62]](#footnote-62) 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.**

### A/2: General

1. **The issue is being solved right now in 4 ways**
	1. **Federal Legislation- Sotomayor of NBC[[63]](#footnote-63) 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[[64]](#footnote-64) 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[[65]](#footnote-65) 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[[66]](#footnote-66) 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[[67]](#footnote-67) 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.**

### A/2: Lobbying power

1. **The Hill[[68]](#footnote-68) explains that recent legislation at the federal level has weakened pharmaceutical companies by forcing them to reduce prices by billions on drug prices. They further that despite the high amounts of money that Pharmaceutical companies are putting into PR campaigns, they aren’t as successful as our opponents claim as both public perception is anti-big Pharma and their lobbying doesn’t have an impact on Trump’s policies.**
2. **CNBC[[69]](#footnote-69) notes the shift in Washington, finding that Washington has slowly become more anti big-business as a result of progressive voices in congress. They further that despite large political contributions, large pharmaceutical corporations have seen policies that they have pushed for be rejected at the federal level.**
3. **Affirming won’t do anything- Shepherd of Emory[[70]](#footnote-70) explains that drug manufacturers are not the key driving force in drug prices anymore, rather that insurance companies are now, it is insurance companies**
4. **Legislation. Bowmer for The Center for American Progress [[71]](#footnote-71)writes that there is legislation to ban members from lobbying permanently.**
5. **Executive power. Ferry of Wired News[[72]](#footnote-72) reports that Trump will facilitate negotiations with drug companies over prices and has refused their funding.**
6. **The affirmative is overstating the political power of pharmaceutical companies, and price controls would do little to limit pharmaceutical revenues anyways. Lamatinna of Forbes[[73]](#footnote-73) contends in 2018 that pharmaceutical companies aren’t actually bringing in outrageous profits – their political industries are more specific to their industry interests than to their levels of revenue. Pharmaceutical companies aren’t actually bringing in huge levels of profit compared to other industries: their political influence owes more to their persistence in lobbying, rather than high levels of revenue.**

## A/2: Healthcare

### A/2: Healthcare Costs

1. **No impact- Gleason of Forbes[[74]](#footnote-74) finds that spending on drugs is insignificant and that price controls are a misguided solution which attempt to correct an issue that doesn’t exist.**
2. **NU. Healthcare costs are addressed by insurance, let’s allow insurance to fulfil its purpose and help bear high medical costs**
3. **Turn- Danzon 07 of UChicago[[75]](#footnote-75) writes that as pharmaceutical revenue falls, as under price controls, more companies merge as an attempt to salvage the remaining profits and escape financial panic. That’s really bad because Ashenfelter of Princeton[[76]](#footnote-76) finds in 2016 that because they kill all market competition, 80% of mergers result in higher drug prices.**

### A/2: PBMs

1. **The status quo is one with PBM negotiations. This is key, because The Yale Global Health Partnership[[77]](#footnote-77) reports that spending is only increasing, and higher and higher prices are forcing people to choose between drugs and other necessities.**
2. **Prices are still really high, because they have perverse incentives. Azar ’18 of the US Dept of Health and Human Services[[78]](#footnote-78) finds that PBMs are paid based off of the number of rebates they negotiate. This is key, because This incentivizes them to actually retaliate against the manufacturers that cut prices. Essentially PBMs get their paycheck from the very companies they’re fighting**
3. **There is historical evidence for the PBM threat. Sheperd ’18 of the Emory School of Law[[79]](#footnote-79) finds that from 2012-2016, the PBM industry pushed drug companies to increase the prices, such that their profits increased by more than 100%**
4. **Turn- PBMS are actively trying to increase prices in the status quo. You vote for us, because we ensure that this does not get out of hand, affirming just gives PBMS the power they need to exploit prices even more.**

### A/2: Premiums

* + - 1. **Delink- Time Magazine in 2018[[80]](#footnote-80) 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[[81]](#footnote-81) 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.**
			3. **Turn-. The Foundation for Economic Education[[82]](#footnote-82) 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.**
			4. **No impact- kaick[[83]](#footnote-83) writes that premiums being high are a result of monopolization, not because of drug prices. Affirming the resolution doesn’t do anything.**

### A/2: Tradeoff

1. **Even if people pay more drug drugs, they’re still going less to hospitals. Lichtenberg of the Montreal economic institute[[84]](#footnote-84) explains that as a result of innovation and new drugs, people spend less on medical care. However this goes away in the aff world as Vernon of the Southern Economic Journal[[85]](#footnote-85) writes that as a result of less profits being made because of price controls, research and development would fall by 38%, meaning less drugs would be put out into the market**
2. **Non unique- Blumberg of CNBC[[86]](#footnote-86) explains that holistically, the united states pays more for healthcare than any other country worldwide due to high administrative costs. She furthers that these costs are at least twice as high as in other countries. She concludes that there are multiple factors that contribute to high medical costs and that drug prices aren’t the main cause.**

### A/2: Increasing Medical Coverage

* + - 1. **Turn- Nix of the Heritage foundation[[87]](#footnote-87) writes that price controls reduce quality of care, a trend that has been seen in the VA after they implemented price controls.**

Turn- even if Medicare/Medicaid increase, those programs are ineffective. Donlan of Barrons[[88]](#footnote-88) explains that comparatively, these programs spend up to 40% more on the same treatment that a private insurance would.

* + - 1. **Non-unique- Holahan of Health affairs[[89]](#footnote-89) writes that there are other factors that will contribute to the inevitable rise in the cost of Medicaid.**
			2. **Turn- Winegarden of the pacific research institute[[90]](#footnote-90) concludes that implementing price controls would only decrease the quality of care and accessibility to government sponsored healthcare**

# A/2: CON (PRO)

## Overviews

### Affordability vs Innovation

1. **Three reasons as to why voting for affordability always outweighs innovation.**
	1. **Prerequisite. We don’t need new drugs; we need to make the drugs we currently have cheaper, especially as Light of Rowan University finds that 90% of new drugs don’t provide any benefits over drugs we have now. It doesn’t matter how many new drugs are created if they remain unaffordable for million.**
	2. **Timeframe. Easton of STAT News[[91]](#footnote-91) reports that any research funding loss wouldn’t materialize until 2023. However, the minute you affirm, prices are lowered, immediately increasing affordability for millions.**
	3. **Clarity of impact. We don’t know exactly what type of and how many drugs or how many lives we would lose by affirming, but we do know that “x” amount of lives are being lost annually in the status quo from a lack of medication adherence because of high drug costs.**

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### Innovation

According to Canoy[[92]](#footnote-92), member of the Dutch Health Care Institute, if companies gain more than the benefit of the drug to society, we show that this creates two inefficiencies in innovation. First, companies invest too many resources in projects where they expect to be able to gain more than the drug is worth to society. Second, pharmaceutical companies invest too few resources in other valuable drug development projects. As a result, high drug prices lead to crowding out of valuable drug development projects. In these instances, enforcing lower prices does not harm innovation but improves it, because as a result of lowering those prices future investments will be geared towards projects that are more desirable for society.

## A/2: Accesibility

### A2: Drug Prices are Cheap

Mitigation - According to a study by Bloomberg[[93]](#footnote-93) that even after discounts, we pay more in the U.S. common medicines than almost every other country in the study.

 Turn - According to the commonwealth fund[[94]](#footnote-94) in 2014 35 million U.S. citizens did not get their prescriptions because they could not afford it, if they lowered the price then they would open up the market for poorer individuals

 Mitigation - C.E.Os.[[95]](#footnote-95) of pharmaceutical S and P companies make 71% more than other S and P C.E.Os.

 Mitigation - According to money magazine[[96]](#footnote-96) from may 2015 to may 2016 the average cost for medication increase 10% while overall inflation only increase 1%.

### A/2: Small Spending

1. **This isn’t a reason to negate. Even if they prove that drugs are a minimal factor in overall healthcare spending, people are still dying. The New York Times in 2017 found that 125,000 patients have died as they skipped medication due to high costs. We O/W on scope because saving lives is the most important impact in the round.**
2. **TURN - Prescription drug spending is high and increasing in the status quo. According to a study conducted by the Centers for Medicare and Medicaid Services in 2018[[97]](#footnote-97), spending growth is projected to be fastest for prescription drugs, averaging an increase of 6.3 percent by 2026. This study postdates all of their evidence, so you give their argument to us.**

### A/2: Insurance

1. **Delink - Chan from Boston University in 2016[[98]](#footnote-98)** found that as the cost of medication increases, health insurers look to shift the burden of expenses onto patients through higher deductibles or premiums. This is confirmed by the **Healthline Board in 2018[[99]](#footnote-99)** when they find that an increase in drug prices greatly outpace healthcare inflation costs, which have been comparatively low in the past few years. These price increases increase insurance premiums
2. **Delink -** This argument completely isolates low income individuals. **The Kaiser Family Foundation in 2017[[100]](#footnote-100)** found that 45% of uninsured adults said that they remained uninsured because the cost of coverage was too high. Many people do not have access to coverage through a job, and some people remain ineligible for financial assistance for coverage. These are the patients that matter, by affirming these patients gain the access to drugs that their insurance blatantly denies them.

## A/2: Innovation

### A/2: R&D General

Uniqueness

1. **Dickinson of the Scientist Explains [[101]](#footnote-101)** that right now R&D and investment is already dropping due to US policies. A majority of companies specializing in research already cite our current administration’s regulations on the pharmaceutical industry as the principal reason that innovation is dropping the status quo.
2. Companies want to innovate in both worlds
3. Innovation is failing now. **Forbes in 2014[[102]](#footnote-102)** finds that the pharmaceutical industry has been scaling back R&D investment for the last 5 years and continues to do so. They further that $12 billion has been undercut from investment.

Delink

1. **Sampat ’11 of Health Affairs[[103]](#footnote-103)** finds that in 2/3 of new, important drugs, it is the government funding the underlying research that goes into that drug. Public sector is solving, not the private. Continues to find that the National Institute of Health supports a majority most of the nation’s basic biomedical research
2. **Mazzucato ’13 of New Scientists[[104]](#footnote-104)** notes that the US National Institutes of Health spends around $30 billion every year on pharmaceutical and biotechnology research and is responsible for 75 per cent of the most innovative new drugs annually.
3. **Bernstein ’15 of the NY Times[[105]](#footnote-105)** furthers, that the private sector cannot be relied on for innovation, because the medicines they seek out are the ones that would be most profitable, which ARE NOT the drugs that have social benefits.
4. **De-link:** Empirically, high pricing has not been used for innovation. Rather, once companies develop a profitable drug, they stop funding research and just jack up prices. This way, they bring in huge revenues without shelling out billions to develop new products. **David Belk[[106]](#footnote-106)** further writes that as early as 1990, the pharmaceutical industry had made enough effective products to generate billions of dollars for years, and thus they stopped funding foundational research and just kept pushing what they already had. **Belk** concludes that almost no new important therapies have been created in over 15 years, while pharmaceutical profits have skyrocketed.

No Impact

1. **Most of these new drugs are not actual breakthroughs as they’re simply clones of existing drugs that are marketed as the new big thing**. **Light** [[107]](#footnote-107)cites studies showing that in the last 40 years, only about 11 to 15 percent of new drugs provided significant clinical improvement over existing ones, while the remaining 85 to 89 percent include what are called "me-too" drugs, clones of existing drugs, marketed as the latest breakthrough.

Turns

1. **Turn. Chaip of The World Health Organization** [[108]](#footnote-108)explains that even though Europe had strict price controls, there has been a threefold rise in R&D there in the last few decades.
2. **Link Turn:** Moderating profits will encourage more innovation in areas which typically lack interest, thus creating more efficient investment. **Richard Frank of Harvard Medical School[[109]](#footnote-109)** writes in 2017 that pharmaceutical companies tend to pursue R&D investments where market sizes and potential profits are greatest, in the hope of realizing large returns. However, because competitors are generally unaware of each others investments, this creates overinvestment in certain clinical areas. Affirming solves this because imposing price controls limits the profit on popular areas, making uncovered diseases more attractive.

### A/2: Funding

1. **Ginsburg of USC writes in 2018[[110]](#footnote-110)** that we’ve reached the point where the yield from additional resources going into R&D no longer justifies what society is paying in the form of higher prices to support this. The returns are never proportional to investment
2. **Mitigate on scope -** Sure companies have a lot of money, but they don’t tell you what this money is actually going toward. **Goldacre of The Guardian[[111]](#footnote-111)** reports that pharmaceuticals spend twice as much on advertising than R and D. Indeed, **University of New Jersey[[112]](#footnote-112)** writes that these companies devote a net of only 1.3% of sales to innovation. This has two implications**:**
	1. A loss of funding has literally zero impact on innovation.
	2. Their narrative about needing high prices to sustain investment incentive is broken if 99% of funds are wasted in the squo. That’s why **Vivian 16 of US News[[113]](#footnote-113)** reports that drug development actually only costs a tenth of what they say it does.
3. Even if you buy that they lose this profit, it still doesn’t matter. Realize pharmaceutical companies are so profitable that **Emanuel of UPenn[[114]](#footnote-114)** finds that even if profits were cut by 50%, there would still be plenty of incentive to assume the risks of drug development. In fact, you can actually
	1. That’s why you can **TURN** it. **Hopkins of the FGC[[115]](#footnote-115)** reminds us that none of their funding loss studies take into account government subsidies, but the **IMF[[116]](#footnote-116)** reports that price controls would automatically be accompanied by government subsidy revenue. Prefer subsidies over blank profits because while profits can and are spent on less useful things like advertising, with only 1.3% going to actual innovation research, 100% of subsidies have to go directly towards the core research. That’s why **Shang 18 of the MDPI[[117]](#footnote-117)** finds that every 1% increase in subsidies increases private R and D investment 58%.

### A/2: Profits

1. **Uniqueness overwhelms the link –** even if we do reduce profits by a lot (which we don’t), the incentive to innovate is still incredibly high. **Emanuel of the New York Times writes in 2015[[118]](#footnote-118)** that drug companies are making so much money – up to 20-30% profit – that even with half the profits, they’d continue innovating.
2. Mitigate. Companies have a lot of money, but they don’t tell you what this money is actually going toward. **Goldacre of The Guardian**[[119]](#footnote-119) reports that pharmaceuticals spend twice as much on advertising than R&D. Indeed**, University of New Jersey[[120]](#footnote-120)** writes that these companies devote a net of only 1.3% of sales to innovation. This has two implications:
	1. A loss of funding has literally zero impact on innovation.
	2. Their narrative about needing high prices to sustain investment incentive is broken if 99% of funds are wasted. That’s why **Vivian of US News[[121]](#footnote-121)** reports that drug development actually only costs a tenth drug company reports.
3. Three turns on profits.
	1. **The International Monetary Fund[[122]](#footnote-122)** reports that price controls would automatically be accompanied by government subsidy revenue. Prefer subsidies over blank profits because while profits can and are spent on less useful things like advertising, 100% of subsidies have to go directly towards the core research. Thus, Shang of the MDPI[[123]](#footnote-123) finds that every 1% increase in subsidies increases private R&D investment 58%.
	2. **Edmunds of The Houston Chronicle[[124]](#footnote-124)** explains that selling at lower prices increases sales volume, by making up for decreased profit per unit by creating bigger gross profits. For example, **Anderson of BBC[[125]](#footnote-125)** reports that in the UK, a country with strict price controls, profits for companies have still doubled.
	3. My opponents assume that the government would price drugs at absurdly low prices, but this simply ignores international precedent. Indeed, **Lo of Pharmaceutical Technology writes in 2017[[126]](#footnote-126)** that European countries which use price controls follow a ‘fair value’ method, by which public agencies price drugs by their clinical worth, considering the innovative characteristics of new therapies and their benefits. Thus, companies will still receive fair returns and be incentivized to create more innovative drugs.

### A/2: Global Health

1. Make them show you specific examples, lives it has saved, or policies- otherwise, there’s no probability that this truly occurs.

Non-Unique.

* 1. American foreign aid. **Kaiser of the KFF[[127]](#footnote-127)** explains that American government foreign aid efforts improve the health of people in countries while addressing diseases with almost 11 billion dollars in funding this year.
	2. Foreign price controls**. The Council of Economic Advisers [[128]](#footnote-128)** posits that foreign governments already force drug manufacturers to comply with pricing rules to gain market access and set drug prices lower- meaning distribution will be cheap either way.

Delink

1. **The Economist ’01[[129]](#footnote-129)** explains that companies historically have faced backlash whenever they try to increase prices in other places, and as a result end up dropping them.

2. Other countries have price controls, it won’t get out of hand

Turn

1. **Turn. MacDonald of The Western Journal of Medicine[[130]](#footnote-130)** gives three reasons as to why the pharma’s distribution is a bad thing.
	1. Companies test their products on the developing world which they see as free trial subjects.
	2. Drugs are refused when they will not reap corporate rewards, which takes away the possibility of cures in the area.
	3. Companies stop poorer countries from manufacturing the generic, much cheaper versions of essential medicines when they move into the area.
2. They never tell you that companies are operating at their max. limit in other nations, there’s no reason to believe that the first place they go to increase is those places. In fact, **Pear ’18 of the NYT[[131]](#footnote-131)** explains that right now, the first place that the US is looking to increase prices in is DEVELOPED NATIONS

### A/2: Innovation

1. Recognize that even if innovation occurs, if it is not affordable innovation, it has no impact on the general public. This is why **Bernstein of the New York Times[[132]](#footnote-132)** notes that the private sector cannot be relied on for innovation, because the medicines they seek out are the ones that would be most profitable, which are not the drugs that have social benefits.
2. **Delink. Sampat of Health Affairs**[[133]](#footnote-133) finds that in 2/3 of new, important drugs, it is the government funding the research that goes into that drug. **Mazzucato of New Scientists[[134]](#footnote-134)** notes that the US National Institutes of Health spends around $30 billion every year on pharmaceutical research and is responsible for 75% of the new, innovative drugs annually.
	1. The AFF doesn’t even make a dent in the majority of the productive innovation.
	2. There will never be an impact because government research always persists.
3. Pharmaceutical innovation is extremely unlikely. 2 reasons.
	1. Probability. **The Medicine Net [[135]](#footnote-135)** reports that the chance for a new drug to hit the market is 1 in 5000, due to regulations and research boundaries.
	2. Efficiency. **Paul of Nature Reviews [[136]](#footnote-136)**writes that there has been a decline of R&D productivity in the past two decades, which is why it takes 12 years to bring a medicine from the lab to shelf. **Leaf of Fortune[[137]](#footnote-137)** confirms that pharmaceutical companies only get one-tenth of their revenue from drugs released in the past 5 years- they aren’t effective.

### A/2: Superbugs

1. Status quo solves. **Hu of Business Insider [[138]](#footnote-138)** gives two reasons as to why the problem is being tackled.
	1. The FDA is already researching a model to stop multi-drug resistant infections.
	2. The CDC has a strategic plan and solution initiative to fight superbugs.
2. Delink. **Hu** [[139]](#footnote-139)continues that most pharmaceutical companies are pulling out from antiviral research against superbugs because of a lack of profit- there are literally 3 companies left researching, and only 12 antibiotics have been approved in the last 2 decades.

### A/2: Venture Capital

1. **Non-Unique:** When prices are higher, by my opponent’s logic investors would increase investment. However, drug prices are at an all-time high and the opposite is true. According to **Andrew Low of Fortune[[140]](#footnote-140)**, because the development process has become extremely tedious, the general trend over the last decade is that venture capitalism has decreased in the pharmaceutical industry.
2. **De-link:** The risk of having less profit doesn’t apply to venture capitalists. **Jacob Bell of Biopharma Dive in 2017[[141]](#footnote-141)** writes that when venture capitalist make investments, it is typically in the later stages of development. This means that they can assure that they are investing in drugs that are already set to turn a profit.

### A2 Large Pharma Innovation

1. Non-Unique: When prices are higher, by my opponent’s logic investors would increase investment. However, drug prices are at an all time high and the opposite is true. **John Lamattina of Forbes[[142]](#footnote-142)** in June of this year writes that because the industry is running out of the easiest innovations, investment in the industry are projected to go down by 4 percent over the next few years.

2. Mitigate: Research is actually only a small percentage of pharmaceutical expenses, so reductions in price controls will be offset by other areas of budgeting. Indeed, **David Belk[[143]](#footnote-143)** analyzes the 13 biggest pharmaceutical companies and finds that marketing cost 60% more than R&D, totaling $895 billion. Moreover, R&D budgets are made up of numerous costs other than actual research, such as more marketing, corporate takeovers, and repeated attempts to approve old drugs.

3. Mitigate: Even if companies lose profit, they will still receive critical funding from the US government. **Gilman of the New England Journal of Medicine writes in 2017[[144]](#footnote-144)** that the U.S. government substantially subsidizes basic research and the provision of health care for the pharmaceutical industry. Indeed, **Cleary of PNAS finds in 2018[[145]](#footnote-145)** that government funding contributed to every one of the 210 new drugs approved by the FDA from 2010-2016. Collectively, the government contributed over $100 billion.

### A/2: Rare Orphan Disease

DL. The Orphan Drug Act has made substantial progress to making breakthroughs in rare orphan diseases. The National Organization for Rare Disorders found that as of 2017, the FDA has approved 600 orphan drugs. These advancements are not related to the private sector but are rather coming from federal organization funding.

DL. The FDA decides what orphan drugs are approved and what rate they are licensed at. In fact, under Section 529 to the FD&C Act, the FDA awards priority review to rare orphan diseases. Under this program, a drug sponsor who receives priority approval may qualify to receive a priority review, expediting the licensing procedure and making it top priority. This means that the private sector has nothing to do with how these drugs get to the people

T. Because the investment that goes to these orphan diseases come from the Orphan Drug Act and not the private sector, reducing the cost of these drugs has no correlation with taking away investment. The reason that this is important is because we increase access to orphan drugs by capping the price at which they are sold, without touching the federal investment that is making the breakthroughs for these rare diseases. Voting for the PRO is a win-win situation.

National Organization for Rare Disorders

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

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

FDA

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

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

### A/2: Vaccine Innovation

DL. Private sector development is not where vaccines are researched and developed. There are two main sources of vaccine research

Caceres in 2018 finds that the majority of vaccine research is done in universities like Harvard, UCLA, and the University of Washington.

A study by Hinman from Clinical Infectious Disease in 2004 found that 57% of immunizations do not come from the private sector. Make them uniquely prove why the private sector will start providing more immunizations when they are not doing it in the status quo, ILL TELL YOU WHY, IT IS BECAUSE THEY CAN’T…

NU. Tate from the Healthcare Institute of New Jersey in 2002 found that vaccine prices already have price regulations and have been stagnant since 1994. This has been an issue for over 20 years, voting for them on this reason literally does nothing.

T. Research on new vaccines is useless if people cannot afford them. According to the New York Times in 2014, 1/3 of doctors considered giving up immunizations because they were so expensive and patients could not afford them. Dumping more research into vaccines would be useless as consumers are unable to financially access them in the status quo.

Caceres

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

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

Hinman

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

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

Tate

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

Consider the recent flu vaccine shortage. The largest purchaser of the vaccine is the federal Vaccines for Children Program. The program buys up nearly 70 percent of all childhood vaccines at government-set prices and then distributes them to states according to a federally-set formula. The end result is that vaccines have been distributed to states where there is no epidemic often leaving a shortage where it is needed. **Because the government controls the price, the vaccine makers are discouraged from producing more than what the government orders. Vaccine prices have remained stagnant since 1994. Thanks to these price controls, there now are only four developers of childhood vaccines. That’s down from 20 companies just a few years ago.** Even the U.S. Department of Health and Human Services recognizes the consequences to medical innovation if the federal government should choose to impose price controls. In a recent study the Department stated, **“There are potentially serious consequences to medical innovation with the implementation of government controls that are inevitably arbitrary and out of touch with the diversity of patients needs and consequences.**

New York Times

Rosenthal, Elisabeth. “The Price of Prevention: Vaccine Costs Are Soaring.” The New York Times, 2 July 2014. NYTimes.com, https://www.nytimes.com/2014/07/03/health/Vaccine-Costs-Soaring-Paying- Till-It-Hurts.html.

**To deal with the rising prices, some doctors, who say they lose money on every vaccination, reserve their shots for longstanding patients. A survey of family-practice doctors, who along with pediatricians are among the lowest-earning physicians, found that about one-third were considering giving up immunizations because of the expense. Another survey found that 40 percent do not offer at least some required childhood immunizations.** That is why Breanna Farris, a San Antonio mother, had to call 10 pediatricians in April before she found Dr. Irvin to vaccinate her son, Traven, who is entering kindergarten this fall. The family’s usual doctors do not offer vaccinations, and referred Ms. Farris to local pharmacies (which do not vaccinate children) or the city health clinic (which would not take Traven’s insurance).

## A/2: Economy

### A/2: Jobs

1. **Non unique. Two reasons.**
	1. **Current losses. Paavlova of The Hospital Review [[146]](#footnote-146) explains that the healthcare sector has increased the jobs it is cutting by 124 percent per year- all jobs will be cut.**
	2. **Automation. Medioros of The RD Magazine [[147]](#footnote-147)writes that automation adoption in the pharmaceutical industry is at its highest peak ever. In fact, Wilkins of The Engineer [[148]](#footnote-148)finds that robots will handle one third of pharmaceutical operations by the end of the year.**
2. **Make them give you a terminal impact to unemployment- workers can just switch to other industries.**

### A/2: Investment

1. **Cross apply mitigation on profits.**
2. **Investment increase in status quo unlikely. Root of The Independent[[149]](#footnote-149) writes that pharmaceuticals have been volatile and tend to lag the market- people don’t invest as they look for value in the economy, not defensive growth areas.**
3. **Turn. More exposure means more investment; examples empirically prove.**
	1. **Investors don’t leave. Thomson of The APBI [[150]](#footnote-150) writes that even with strict price controls, the pharmaceutical industry in the UK saw a 10 percent increase in investments relating to R&D. Miller of BMJ Journals [[151]](#footnote-151) corroborates that amidst Canadian price controls, venture capital in Canada doubled.**
	2. **More accessibility means more sales. Beattie of Investopedia [[152]](#footnote-152)writes that when Viagra surged into consumer’s bedrooms, its stock saw a sudden rise.**

### A/2: Shortages

1. **This is extremely illogical- just because prices go down, consumer need does not increase. For example, a discount on Tylenol does not mean you go and buy 6- you still buy only as many as necessary.**
2. **If the medicines are bought out that means that the people who needed them.**
3. **Price controls have empirically happened in other countries and shortages have never occurred. Make them prove to you that the companies will not keep up with demand.**
4. **Just because innovation may be stifled doesn’t mean basic drugs are stopped in production.**
5. **A/2 examples: (US) and food(Venezuela) example-**
	1. **Oil was in the 1970s**
	2. **This is imported and not necessarily produced.**
	3. **This is a limited resource rather than pills which are produced at a much faster rate in the modern day**

### A/2: Big Pharma

1. **Historically untrue- Europe has passed price controls without loopholes and America has passed things like Medicare and the Affordable Care Act without hurting the policies.**
2. **Make them give specific policies or its unclear.**
3. **Delink. Big Pharma is getting weaker. Three warrants.**
	1. **Public backlash. Jones of The Hill[[153]](#footnote-153) writes that Big Pharma’s polling numbers remain low as no amount of money can change the fact that drug makers have set high prices. Jones thus concludes that despite lobbying and financial power, drug makers are still losing and have been singled out by both parties.**
	2. **Legislation. Bowmer for The Center for American Progress [[154]](#footnote-154)writes that there is legislation to ban members from lobbying permanently.**
	3. **Executive power. Ferry of Wired News [[155]](#footnote-155) reports that Trump will facilitate negotiations with drug companies over prices and has refused their funding.**

### A2: Competition

**1. You’re going to prefer us when it comes to increasing competition anyway.** **Nocerca ’17 of Bloomberg[[156]](#footnote-156) finds that the main way companies prevent competition, is by using their patent monopolies to crowd out generic drugs. Since we solve for that patent crowding out, you affirm.**

**2. Amin ’18 of CNBC[[157]](#footnote-157) furthers that companies extend their patents through ‘evergreening’ where they add on a new patent claiming that a drug does something new, thus extending is exclusivity period. Negotiations solve because part of negotiations is that US agencies get to analyze how beneficial a drug is compared to previous iterations.**

## A/2: Miscellaneous

### A2: Bioterrorism

Non-Unique. There are so many alternate causes of bioterror happening. According to the U.S. International Trade Commission in 2007[[158]](#footnote-158), countries like India and China are also major pharmaceutical giants. By my opponent’s, logic they could trigger these same impacts, worldwide. At best we should prioritize happiness right now for American people.

### A2: PBMs

**There is historical evidence for the PBM threat. Sheperd ’18[[159]](#footnote-159) of the Emory School of Law finds that from 2012-2016, the PBM industry pushed drug companies to increase the prices, such that their profits increased by more than 100%**

### A2: Failed Product Compensation

1. **NU. This argument is making the assumption that every drug that is ever developed is going to be successful. Unless they can prove to you that voting CON means that every drug they develop without price controls will be a success then they lose uniqueness**
2. **T. Drug companies are exploiting consumers to compensate themselves. This is inherently immoral because the New York Times[[160]](#footnote-160) finds in 2017 that a result of skipping medication due to high costs has resulted in a 10% increase in hospitalization. If you agree with the idea that we should overcharge and kill patients that need lifesaving medication just to compensate a drug company then by all means, negate the resolution. We reject these inherently corrupt and blatantly immoral standards at which consumers must be exploited for the mistakes of companies.**

### A2: Generics

* + - 1. Just because generics make up 90% of the market does not mean we ignore the minority of the population. The point of the resolution is to debate in favor of the 10% of the population that does not use generics. Our opponents are basically telling you that 1/10 of American patients do not matter and we disagree

# Indicts

### I/2: Easton

The author is biased due to owning multiple pharmaceutical firms.

Leads multiple pharma firms

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

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

### I/2: South Africa

**Nothing can be taken from South Africa. Bangalee and Fatima Suleman of the University of KwaZulu-Natal[[161]](#footnote-161) 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.”**

### I/2: Europe

1. **Lakdawalla of Health Affairs[[162]](#footnote-162) 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[[163]](#footnote-163) 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.**

### I/2: Canada

* + - 1. **The Fraser Institute[[164]](#footnote-164) quantifies in 2015 that Canada loses 5 billion dollars annually by not switching to a free market system.**

### I/2: India

* + - 1. **Lo[[165]](#footnote-165) 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[[166]](#footnote-166) 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.**

### I/2: Britain

**Britain’s policies take way to long losing lives in the process. According to Lo[[167]](#footnote-167) 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.**

1. 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-1)
2. Loria 16 of Business Insider Loria, Kevin. “Why Exciting Ideas for Cures Almost Never Make It to Patients.” Business Insider, Business Insider, 3 Mar. 2016, [www.businessinsider.com/why-its-so-hard-to-get-drugs-approved-2016-3](http://www.businessinsider.com/why-its-so-hard-to-get-drugs-approved-2016-3).

There are [different ways of calculating how likely the Food and Drug Administration](http://www.nature.com/nbt/journal/v32/n1/full/nbt.2786.html) (FDA) is to approve a new drug, but one thing is for sure: Getting a medication from the early "this looks like it could be interesting" stage into clinical trials is a difficult process — and one that, more often than not, ends in failure. Many drugs, especially in early stages, seem like they could have the potential to revolutionize medicine, offering new ways to fight some of our deadliest, most difficult-to-treat diseases. **Yet only about** [**one in 10 drugs**](http://www.nature.com/nbt/journal/v32/n1/full/nbt.2786.html) **that make it all the way to clinical trials (a long and arduous journey in itself) turns out to be safe and effective enough to get FDA approval**. Some argue that the [regulatory process and bureaucratic red tape stifle life-saving innovation and prevent cures](https://www.nejm.org/doi/full/10.1056/NEJMp1400868) from reaching patients that need them. Novel types of drugs and medical tests are particularly difficult to get past regulatory screening. Others say that the FDA is too lenient, and that if anything, [legislation](https://www.congress.gov/bill/114th-congress/house-bill/6) [under consideration right now](https://www.healthnewsreview.org/2015/08/21st-century-cures-act-a-huge-step-backward-for-fda-standards/) could make it even easier to sell dangerous drugs and [medical devices](http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=5799). Stalling innovation is arguably worth it, if it keeps patients safe from potentially harmful interventions. But is the issue really one of too much or not enough scrutiny? There are areas where regulatory processes could be tweaked to promote innovation. But the real hurdle might be just that inventing and developing something truly new is both incredibly hard and incredibly expensive. Many ideas peter out because of a lack of resources, not because of a lack of promise or a regulatory stumbling block. And that's a tougher problem to address. When there are no approved cures The main question regulators face is how to balance the need to keep patients safe from dangerous drugs while also — when necessary — taking risks to advance medicine. It's hard to say that sick people should take an experimental drug that could have devastating side effects before we even know if it will work. Yet there's a good argument for trying those experimental, unproven treatments if a disease will most likely (or sometimes even certainly) end in death, even after any approved treatments are used. Some cancer doctors in particular argue that we need to be more aggressive in these cases. "The rate-limiting step in eradicating cancer today is not the science but the regulatory environment we work in," top [cancer expert Dr. Vincent T. DeVita Jr. argues](https://www.nytimes.com/2015/12/01/science/review-science-and-politics-collide-in-the-death-of-cancer.html) in his new book, "[The Death of Cancer](https://www.amazon.com/The-Death-Cancer-Pioneering-Winnable/dp/0374135606?tag=bisafetynet2-20)." He writes that he thinks "we have the tools to eradicate cancer" but that the bureaucracy hasn't caught up with the science. DeVita, a former director of the National Cancer Institute, thinks we could cure an additional 100,000 cancer patients a year if doctors were allowed to experiment with more unorthodox ways of trying to stop the disease. [↑](#footnote-ref-2)
3. **Loria 16 Business Insider** Kevin Loria, 3-3-2016, "Why exciting ideas for cures almost never make it to patients," Business Insider, https://www.businessinsider.com/why-its-so-hard-to-get-drugs-approved-2016-3

Most potential new drugs don't actually turn out to be viable, explains Dr. Michael Kurilla, director of the Office of Biodefense Research Resources and Translational Research at the NIH's National Institute of Allergy and Infectious Diseases. That means pharmaceutical companies are only willing to invest in research that is far enough along that it seems likely to have a payoff. **Even organizations like the NIH that are willing to invest in early stage research want to know how that research will pass regulatory hurdles, and the regulatory barriers for radical proposals are difficult to overcome**. "What we've found working with investigators that have very unique modes and types of inventions is that the biggest obstacle is regulatory," Kurilla says. It's hard to show that a new type of medicine, like the one Rider designed to treat many diseases, is safe. Other examples include potential treatments like specially tailored probiotics, which would provide a patient with "good" health-promoting bacteria to treat a wide variety of conditions. Getting the FDA to even approve a trial of these types of drugs is "incredibly difficult," infectious disease physician [Dr. Shira Doron recently told STAT](https://www.statnews.com/2016/01/21/probiotics-shaky-science/), even more so than normal. It took five years for Doron to get approval to test one such drug, and the FDA still hasn't approved any medical use for probiotics. [↑](#footnote-ref-3)
4. Loria 16 Business Insider Kevin Loria, 3-3-2016, "Why exciting ideas for cures almost never make it to patients," Business Insider, https://www.businessinsider.com/why-its-so-hard-to-get-drugs-approved-2016-3

**Not only is it hard to make novel, safe medications, it can cost** [**more than $2.6 billion**](https://www.nejm.org/doi/full/10.1056/NEJMc1504317) **to shepherd an invention from a promising early study to the end of the clinical trial process**. A lot of those really innovative ideas come from universities and small labs that try something truly different from already existing drugs. Their early results might suggest the possibility of a cure, but getting a drug company to invest billions into unproven and even "out-there" ideas is a very different proposition. Many ideas fail because they should; many potential drugs don't live up to their initial promise. That's why rigorous testing and clinical trials are necessary. But we want a system that encourages new ideas and — when necessary — risk-taking to cure patients who don't have any other option. In some ways, we're getting better at that, at least in making some experimental drugs available to patients with fatal diseases. [↑](#footnote-ref-4)
5. Robert Easton. “Price controls would stifle innovation in the pharmaceutical industry”, STAT News, 22 Jan 2018, https://www.statnews.com/2018/01/22/price- controls-pharmaceutical-industry/

**“If price controls pressure the U.S. industry into a more conventional process industry model, like that of the chemical industry, pharmaceutical R&D budgets would be slashed.** To achieve the chemical industry’s rate of R&D spending, as would be required to achieve profitability competitive with the chemical industry, top **pharmaceutical companies would have to reduce their R&D budgets by 80 percent — almost $50 billion in total. This reduction in spending would take a few years to realize, but would be completely evident by 2023 or earlier.** An important corollary is that, if profitability and value creation opportunities for new drugs declined, the appetite of the venture community for risky, long-term biopharmaceutical investments would shrink exponentially. Price controls on drugs would have the surprising effect of accelerating the flow of investment into high technology, where timelines to market are shorter, less regulated, and less risky. The venture capital community is flush with cash and anxious to invest where high returns can be achieved — ideally within a much shorter time than is typically possible in the realm of drug R&D. **As a society, if we force pharma into a chemical industry model, where there is no biotech equivalent and no venture investing, we will be trading better and sooner effective drugs for better and sooner virtual reality devices and self-driving cars**.**”**  [↑](#footnote-ref-5)
6. Cong, Ze. "Value of Pharmaceutical Innovation." (2009). Rand Corporation. https://www.rand.org/content/dam/rand/pubs/rgs\_dissertations/2009/RAND\_R GSD242.pdf

“By employing econometrics models with data from various data sources, **we do find statistically significant access effects of new drugs, in terms of increasing number of drugs prescribed.** Those effects are heterogeneous among different new drug subgroups. More specifically, we find that more creative drugs (e.g., NCEs) tend to have larger, more significant access effects, whereas less creative drugs (e.g., generic drugs, nonNCEs) contribute smaller or even negative access effects. **Non-NCE brand-name drugs significantly increase the number of uninsured prescriptions**, whereas no significant effect is found for insured prescriptions. **These findings confirm the hypothesis that new drugs can impact population health not only with change in clinical effectiveness on existing treatments, but also with change in the quantity of prescriptions written and/or people treated**” [↑](#footnote-ref-6)
7. Paul Howard. “To Lower Drug Prices, Innovate, Don’t Regulate”, The New York Times, Sep 23 2015, https://www.nytimes.com/roomfordebate/2015/09/23/should-the-governmentimpose-drug-price-controls/to-lower-drug-prices-innovate-dont-regulate

“Price control advocates argue that curtailing profits in the pharmaceutical industry would save the country money without reducing innovation. There is, however, no such thing as a free lunch. Bureaucratic price manipulation would only hurt the sickest patients. **Streamlining drug approvals would get more drugs on market, increasing competition and lowering prices.** 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 [↑](#footnote-ref-7)
8. ####  Danzon

https://www.nber.org/reporter/fall06/danzon.html

In addition to product licensing, mergers and acquisitions (M&A) are common in the pharma-biotech industry. Large horizontal mergers were particularly frequent in the late 1980s and 1990s, while pharmaceutical acquisitions of biotech companies have become more common recently. Several of the largest firms are the result of successive large horizontal mergers, and this has contributed significantly to industry concentration. Such mergers are often rationalized on grounds of economies of scale and scope in R and D, marketing, and administration. In our analysis of M&A in the pharma-biotech industry, we tested various alternative hypotheses to explain both large and smaller mergers, and then examined the effects of mergers using propensity scores to control for merger endogeneity.(4) For larger firms, we find that mergers are a response to patent expirations and gaps in a company's product pipeline, which lead to excess capacity of the fixed marketing resources. For smaller firms, **mergers are primarily an exit strategy in response to financial trouble**, as indicated by a low Tobin's q, few marketed products, and low cash-sales ratios. Controlling for a firm's ex ante propensity to merge significantly affects the estimates of merger effects. Firms with relatively high propensity scores experienced slower growth in sales, employees, and R and D, regardless of whether they actually merged; this is consistent with mergers being a response to distress. For large firms, a merger did not significantly affect subsequent performance on average, whereas small firms that merged had slower R and D growth than similar firms that did not merge; this suggests that post-merger integration may divert cash from R and D. This conclusion, that merger is often a response to distress but is usually not an effective solution, is consistent with the subsequent slow-down in M&A in this industry, with the exception of selective, strategic acquisitions, as large firms acquire smaller firms with spe cifically well-matched capabilities or products. Thus, although the "survivor" evidence -- with increased market share of the top ten firms over time -- might suggest that large firms have advantages, recent stock market performance tells a very different story. [↑](#footnote-ref-8)
9. http://fortune.com/2016/05/17/high-drug-prices-mergers-pharma-competition/

**Economics teaches that under conditions of perfect competition, firms earn normal profits and “prices will be kept low by competitive pressures.” To achieve perfect competition, you need many firms to operate in the same business. Therefore, antitrust policy is supposed to ensure that competitive markets remain that way by limiting mergers that reduce market competition.** However, as even casual observation attests, the number and value of takeovers has soared over the years, with only a tiny minority of acquisitions drawing regulatory scrutiny.

Somewhat surprisingly, as **Princeton economist Orley Ashenfelter** noted, there has been little empirical evaluation of the effects of mergers on consumer prices. **A study of five mergers by Ashenfelter** and Federal Trade Commission economist Daniel Hosken **found that in four of the cases, there was evidence of an increase in some consumer prices.** [↑](#footnote-ref-9)
10. ####  Price controls lower life expectancy

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804349/

We begin by analyzing the effect of new regulations in the United States. **Introducing price controls — or, more generally, lowering manufacturer prices by 22% while leaving consumer copayments unchanged — would affect the pace of innovation**, as well as health care spending. The net value of a price controls strategy derives from its impact on longevity, and on spending. [Figure 2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804349/figure/F2/)illustrates the impact of introducing US price controls on the longevity of 55–59 year-old cohorts. The figure shows that the introduction of price controls would reduce life expectancy by two-tenths of a year for 55–59 year-old Americans alive in 2010, and by one-tenth for 55–59 year-old Europeans alive in the same year. **The longevity effects are larger for the older cohorts, because the effects of price controls on innovation accumulate over time**. In our model, for instance, changes in revenues do not affect rates of innovation for at least 10 years. Therefore, the 2010 cohort is not exposed to its innovation effects for that initial period of time. In contrast, the later cohorts are exposed to heavier doses. **By 2060, 55–59 year-old Americans lose almost 0.6 years of life expectancy due to US price control implementation**, while 55–59 year-old Europeans lose around half a year. [↑](#footnote-ref-10)
11. Nancy Rose [Professor of Applied Economics, MIT], “Regulation of the Pharmaceutical-Biotechnology Industry” in Economic Regulation and Its Reform: What Have We Learned? University of Chicago Press, 2014. Available at: http://www.nber.org/chapters/c12572.pdf

Cross-national comparisons of drug prices vary significantly, depending on the time period, sample of drugs used, the price index methodology used—including unit for measuring price (grams, units, daily doses), consumption weights, and exchange rates. Most price comparisons have been biased by use of very small, nonrandom samples including only branded drugs, and have not adhered to standard index number methods (GAO 1992; GAO 1994). The exclusive focus on branded drugs tends to bias comparisons in favor of countries with strict price regulation. Regulation and competition are to some degree substitutes: **less regulated markets tend to have higher brand prices but larger generic market shares and lower priced generics. Overall, countries that use direct price controls do not consistently have lower prices than countries that use other indirect means to constrain prices** (Danzon and Chao 2000a, 2000b; Danzon and Furukawa 2003, 2006). However, comparisons are very sensitive to the sample of drugs, weights, exchange rate, and prices used. [↑](#footnote-ref-11)
12. Peter J. Pitts, 5-19-2017, National Review, "The False Promise of Drug-Price Controls",10-22-2018, https://www.nationalreview.com/2017/05/drug-price-controls-bad-idea/

Companies are willing to make such a risky investment because a breakthrough product can generate a huge payoff. But price controls squeeze that payoff. They prevent drug firms from charging prices commensurate with those massive development costs. For some companies, the payoff is no longer worth the risk, and they’re forced to scale back on new research. The **U.S. Department of Commerce calculates that price controls among countries in the OECD**, a major economic organization comprising much of Europe, **drives away $5 billion to $8 billion in potential pharmaceutical development investment every year. That prevents the creation of three to four new drugs annually. This loss** of development dollars doesn’t just hurt citizens in controlled markets; it **deprives all of us of new, life-saving treatments**. This is the terrible toll of drug-price controls. Foreign authorities need to wake up to the harm they’re causing. [↑](#footnote-ref-12)
13. 1. price controls in Europe found pharmaceutical price controls hurt patients.Paul Howard. “To Lower Drug Prices, Innovate, Don’t Regulate”, The New York Times, Sep 23 2015, www.manhattan-institute.org/html/lower-drug-prices-innovate-don%E2%80%99t-regulate-8229.html

“Price control advocates argue that curtailing profits in the pharmaceutical industry would save the country money without reducing innovation. There is, however, no such Pro Arguments with Con Responses Nov/Dec 2018 Champion Briefs 64 thing as a free lunch. Bureaucratic price manipulation would only hurt the sickest patients. Streamlining drug approvals would get more drugs on market, increasing competition and lowering prices. 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.” [↑](#footnote-ref-13)
14. Winegarden 2017

<https://www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduce-innovation-and-health-outcomes/#4a9da37063a6>

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-14)
15. ####  Wright

<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-15)
16. John Lamattina. “About Those Soaring Pharma Profits”, Forbes, 23 Jan 2018, https://www.forbes.com/sites/johnlamattina/2018/01/23/about-those-soaringpharma-profits/#299331d53f9d

**“If price controls pressure the U.S. industry into a more conventional process industry model, like that of the chemical industry, pharmaceutical R&D budgets would be slashed. To achieve the chemical industry’s rate of R&D spending, as would be required to achieve profitability competitive with the chemical industry, top pharmaceutical companies would have to reduce their R&D budgets by 80 percent — almost $50 billion in total.** This reduction in spending would take a few years to realize, but would be completely evident by 2023 or earlier. An important corollary is that, if profitability and value creation opportunities for new drugs declined, the appetite of the venture community for risky, long-term biopharmaceutical investments would shrink exponentially. Price controls on drugs would have the surprising effect of accelerating the flow of investment into high technology, where timelines to market are shorter, less regulated, and less risky. The venture capital community is flush with cash and anxious to invest where high returns can be achieved — ideally within a much shorter time than is typically possible in the realm of drug R&D. **As a society, if we force pharma into a chemical industry model, where there is no biotech equivalent and no venture investing, we will be trading better and sooner effective drugs for better and sooner virtual reality devices and self-driving cars.”** [↑](#footnote-ref-16)
17. Winegarden, Wayne. “Price Controls Will Reduce Innovation and Health Outcomes”, Forbes, 12 Oct 2017, https://www.forbes.com/sites/econostats/2017/10/12/price-controls-willreduce-innovation-and-health-outcomes/#64083a1863a6

**“To start, the price controls would be irrelevant for most patients. Nearly 90 percent 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. It is also important to note that **generic medicines are significantly cheaper in the U.S. compared to the other major industrialized countries**. In fact, total pharmaceutical spending as a percentage of total health care spending is lower in the U.S. (12.2 percent) than the average for the 30 nations that comprise the Organization for Economic Cooperation and Development, or OECD, (16.9 percent). This is due to, in part, the prevalence of generic medicines that are more affordable here than in other OECD nations.”

 [↑](#footnote-ref-17)
18. Tate, Edward. “Government Price Controls On Prescription Drugs May be More Than Patients Bargain For”, HealthCare Institute of New Jersey, 7 Oct 2002, http://hinj.org/government-price-controls-on-prescription-drugs-may-be-morethan-patients-bargain-for/

Another even more important consideration is that **price controls stifle innovation and can lead to supply shortages in both the quality and quantity of medications**. Consider the recent flu vaccine shortage**. The largest purchaser of the vaccine is the federal Vaccines for Children Program. The program buys up nearly 70 percent of all childhood vaccines at government-set prices and then distributes them to states according to a federally-set formula. The end result is that vaccines have been distributed to states where there is no epidemic often leaving a shortage where it is needed. Because the government controls the price, the vaccine makers are discouraged from producing more than what the government orders**. **Vaccine prices have remained stagnant since 1994. Thanks to these price controls, there now are only four developers of childhood vaccines. That’s down from 20 companies just a few years ago.”** [↑](#footnote-ref-18)
19. Sullivan, Thomas. “Increasing Generic Drug Shortages Linked to Government Price Controls”, Policy & Medicine, 6 May 2018, http://hinj.org/government-pricecontrols-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-19)
20. 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-20)
21. https://www.athenahealth.com/insight/prescriptions-jump-epipen-alternatives [↑](#footnote-ref-21)
22. 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-22)
23. 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-23)
24. 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-24)
25. Sood from NCBI

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3829766/>

In addition, such regulations might reduce the pace of innovation, by limiting pharmaceutical revenues and the profitability of investing in research and development ([Acemoglu and Linn, 2003](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3829766/#R1)). [↑](#footnote-ref-25)
26. NY Times

<https://www.nytimes.com/1984/11/16/nyregion/pills-for-birth-control-seized-as-counterfeit.html>

**The Food and Drug Administration has seized more than 330,000 counterfeit birth-control pills from two distributors on Long Island as part of a nationwide effort to remove the pills from the market.** Donald McLaren, a spokesman for the F.D.A., said last night that the pills were part of a shipment from Panama that arrived at Kennedy International Airport [↑](#footnote-ref-26)
27. Ladwakalla

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

Drug price controls would stifle the introduction of valuable new drugs, because innovators will spend less pursuing new drugs if they expect to earn fewer rewards from discovering them. Our research finds that, if the U.S. government were to begin negotiating drug prices the way other governments do, drug prices would fall by about 20 percent [↑](#footnote-ref-27)
28. https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm551407.htm [↑](#footnote-ref-28)
29. ####  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-29)
30. Graban, Mark. Cut Costs by Reducing Redundant or Inefficient Activity. 9 Aug. 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. The word "waste," or muda in Japanese, is one of the most commonly used terms in Lean management, which is based on the Toyota Production System. According to Toyota, there are eight types of waste, each of which can be translated directly into health care: [↑](#footnote-ref-30)
31. Bentley, Tanya G. K., et al. “Waste in the U.S. Health Care System: A Conceptual Framework.” The Milbank Quarterly, vol. 86, no. 4, Dec. 2008, pp. 629–59. PubMed Central, doi:10.1111/j.1468-0009.2008.00537.x.

**In order to help reduce waste in the U.S. health care system, we first must understand the sources of the problem.** While many studies have examined different types of aste, there has been, to date, no comprehensive conceptual framework to guide researchers and policymakers in categorizing and developing specific strategies to address different types of waste. We propose such a framework in this article. This framework builds on the traditional understanding of waste as a measure of inefficiency. **Conceptually, economists distinguish between two types of inefficiencies: productive inefficiencies, which create waste in the form of excess costs in producing a given output, and allocative inefficiencies, which produce the wrong output. Waste in production is the difference between the cost of producing the item or service under the current system and the cost of producing it efficiently. Waste in misallocated outputs is the difference between the cost of the item or service and its actual value.** While these types of inefficiencies differ in theory, they overlap significantly in reality. For example, additional imaging tests of low value to the patient could be considered a productive inefficiency, because the output (a diagnosis, in this case) could have been made with fewer tests and at lower cost. [↑](#footnote-ref-31)
32. 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-32)
33. 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-33)
34. **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-34)
35. Graban 2011

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

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36. 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-36)
37. Beaton 2015

<https://www.huffingtonpost.com/caroline-beaton/holding-big-pharma-accoun_b_8280952.html>

These cases aren’t anomalies. In 2012, Bayer paid $110 million to settle allegations that some consumers experienced fatal blood clots when using the oral contraceptive [Yasmin](http://www.bloomberg.com/news/articles/2012-04-13/bayer-said-to-pay-110-million-in-yaz-birth-control-cases). In 2010, makers of diabetes drug [Avandia](http://www.bloomberg.com/news/articles/2010-07-13/glaxosmithkline-is-said-to-pay-460-million-to-settle-avandia-damage-suits) agreed to pay $460 million to settle 10,000 lawsuits whose plaintiffs claimed the company hid its heart attack risks. In 2008, the manufacturer of the painkiller [Vioxx](http://www.nytimes.com/2007/11/09/business/09merck.html) paid out $4.85 billion to settle 50,000 claims that users suffered heart attacks and stroke [↑](#footnote-ref-37)
38. [↑](#footnote-ref-38)
39. 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-39)
40. Werner, Erica. “House GOP Plan Would Cut Medicare, Medicaid to Balance Budget.” The Washington Post, WP Company, 19 June 2018, <www.washingtonpost.com/news/business/wp/2018/06/19/house-gop-plan- would-cut-medicare-social-security-to-balance- budget/?noredirect=on&utm\_term=.7a1c 1bea5971.>

**“The House Republican budget**, titled “A Brighter American Future,” **would remake Medicare by giving seniors the option of enrolling in private plans that compete with traditional Medicare, a system of competition designed to keep costs down but dismissed by critics as an effort to privatize the program. Along with other changes, the budget proposes to squeeze $537 billion out of Medicare over the next decade. The budget would transform Medicaid, the federal-state health-care program for the poor, by limiting per capita payments or allowing states to turn it into a block-grant program — the same approach House Republicans took in their legislation that passed last year to repeal the Affordable Care Act** (the repeal effort died in the Senate, but the GOP budget assumes that the repeal takes place). It also proposes adding work requirements for certain adults enrolled in Medicaid. Changes to Medicaid and other health programs would account for $1.5 trillion in savings.**”**  [↑](#footnote-ref-40)
41. 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-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. Lanjouw, Jean O. Patents, price controls and access to new drugs: how policy affects global market entry. No. w11321. Cambridge (MA): National Bureau of Economic Research, 2005. http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.610.965&rep=rep1& type=pdf

“The first two columns of Table 7 present the main results for estimates when additional variables are included in the random effects specification. The first adds a country’s R&D share and its level of tariff protection (which together lead to a sizable drop in the number of observations due to missing data). **We again find that having a long process patent regime significantly encourages rapid drug launch.** A new finding is that countries with a high technical capacity as measured by R&D expenditure are far less likely to see new pharmaceuticals in the market quickly. Starting from no R&D and then increasing R&D to the mean level of one-half of one percent of GDP drops the probability of rapid launch by an estimated 13.6 percentage points. **This negative effect of local capacity, however, is significantly offset if a country offers the strongest level of patent protection**. Although the effect of a higher R&D share remains negative even when interacted with strong patent protection, its marginal effect is diminished by a third (joint marginal effect = -0.19, p-value = 0.01, versus -0.28). As in the simpler specification, **extensive price control has a significant negative effect on the probability of rapid launch**. Moderate regulation of prices is also found to have a negative effect now that the specification allows for its interaction with GDP per capita.” [↑](#footnote-ref-44)
45. 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-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



“Citizen petitions” offer drug companies another way to delay generics from being approved. These ask the Food and Drug Administration to delay action on a pending generic drug application. By law, the FDA is required to prioritize these petitions. However, the citizens filing concerns are not individuals, they’re corporations. **The FDA recently said branded drug manufacturers submitted 92% of all citizen petitions. Many of these petitions are filed near the date of patent expiration, effectively limiting potential competition for another 150 days.** “Authorized generics” are another tactic to limit competition**.** These aren’t really generic products at all; they are the same product sold under a generic name by the company that sells the branded drug. Why? **By law, the first generic company to market a drug gets an exclusivity period of 180 days. During this time, no other companies can market a generic product.** But the company with the expiring patent is not barred from launching an “authorized generic.” **By selling a drug they’re already making under a different name, pharmaceutical firms are effectively extending their monopoly for another six months.”**  [↑](#footnote-ref-46)
47. 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-47)
48. 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-48)
49. Hancock, Jay, 9-23-2017, “Everyone Wants To Reduce Drug Prices so Why Can’t We Do It?” <https://www.nytimes.com/2017/09/23/sunday-review/prescription-drugs-prices.html>  New York Times.

Of all the promises President Trump made for the early part of his term, controlling stinging drug prices might have seemed the easiest to achieve. An angry public overwhelmingly wants change in an easily vilified industry. The pharmaceutical industry’s recent publicity nightmare included 1,000 percent price increases and a smirking chief executive who said, “I liken myself to the robber barons.” Even **powerful members of Congress from both parties have said that drug prices are too high**.But any momentum to curtail prescription drug costs — a problem that a large number of Americans now believe government should solve — has been lost amid rancorous debates over replacing Obamacare and stalled amid roadblocks erected via lobbying and industry cash. [↑](#footnote-ref-49)
50. Barney Jopson, 2016, The Financial Times “U.S. Election Winner Faces Deadlock on Capitol Hill” <https://www.ft.com/content/ada7f512-a1e6-11e6-aa83-bcb58d1d2193>

**Deadlock has been endemic in the US Congress since Republicans seized the House of Representatives** in 2010, ending the full Democratic control that President Barack Obama enjoyed for two years. **In the six years since, the “do-nothing Congress” tag has stuck as the frustrations of businesses and others who want to see some lawmaking pile up.** Whether the next president is Donald Trump or Hillary Clinton, breaking the logjam on Capitol Hill is the only way the commander-in-chief will get close to fulfilling pledges made on the campaign trail. The best chance of a legislative surge would come from an electoral sweep that gave one party control of the White House, Senate and House. Yet the chances of that are remote. The battle for the Senate, currently under Republican control, is too close to call. But polls suggest the presidency is most likely to go to Mrs Clinton while Republicans keep hold of the House. That is not an encouraging prospect for the already frustrated. It would make the former secretary of state the first newly-elected Democratic president since the second world war to be sworn in knowing his or her party does not call all the shots on Capitol Hill. **Complicating matters further, both Republicans and Democrats are likely to face damaging internal battles between moderates and hardliners who have been emboldened by the populist tumult of the 2016 campaign.** [↑](#footnote-ref-50)
51. [↑](#footnote-ref-51)
52. Kimberly Leonard , Washington Examiner , "Pharma lobby blasts Trump's 'socialized' drug pricing plan", October 25, 2018, https://www.washingtonexaminer.com/policy/healthcare/pharma-lobby-blasts-trumps-socialized-drug-pricing-plan

The country's largest pharmaceutical lobbying group said Thursday that **President Trump's plan to control drug spending would jeopardize access for seniors and patients with disabilities, likening the proposal to socialized healthcare systems in Europe**. "The administration is imposing foreign price controls from countries with socialized healthcare systems that deny their citizens access and discourage innovation," said Stephen Ubl, president and CEO of the Pharmaceutical Research and Manufacturers of America, or PhRMA. "These proposals are to the detriment of American patients." Countries such as the United Kingdom, Germany, France, and Canada have healthcare systems in which the government pays for most healthcare services and also sets prices, including on prescription drugs. The U.S. pays for drugs by allowing private health insurers to negotiate, but not the federal government. Certain programs, such as Medicaid and the Veterans Administration, get lower prices for drugs. [↑](#footnote-ref-52)
53. David R. Francis, The National Bureau of Economic Research, "The Effect of Price Controls on Pharmaceutical Research", http://www.nber.org/digest/may05/w11114.html

For the pharmaceutical industry, one economic problem is that only 3 out of every 10 of their products generate after-tax returns (measured in present value terms) in excess of average, after-tax R and D costs. The scientific process is heavily regulated, and involves significant technical risk. **Only one in several thousand compounds investigated ever makes it through the full development process to gain approval of the Food and Drug Administration.** The vast majority of R and D projects fail for reasons related to safety, efficacy, or commercial viability, the authors note. **For compounds that do gain FDA approval and are taken to market, the entire process from discovery to launch takes on average about 15 years.** Further, it's estimated that the pre-tax cost of a new drug runs around $802 million. The after-tax cost of an average drug is about $480 million, assuming the company has sufficient revenues to take advantage of the tax benefits or can somehow sell the tax benefits to another firm. The average net revenues for a new drug amount to about $525 million in present value. Thus at the time of a product launch, the drug company can foresee a potential average profit or economic value for their pharmaceutical R and D of about $45 million. With this economic scene as background, a company must make a financial decision about whether to take an R and D project into clinical development. This step is called the Phase 1 Go/No-Go decision. **Only one out of five projects that are given the "Go" signal into clinical development actually reach the market as a product. Factoring in this uncertainty, the authors write, is essential to understanding the behavior of the industry. This uncertainty factor may explain what critics say is a tendency of the pharmaceutical industry to focus on only minor innovations (me-too products) because of their greater probability of success, at the expense of conducting more revolutionary research that carries a higher risk of failure but also may yield greater health improvements** [↑](#footnote-ref-53)
54. <https://www.politifact.com/wisconsin/statements/2017/jan/17/tammy-baldwin/tammy-baldwin-federal-government-prohibited-negoti/>

The current law says that "in order to promote competition," the health and human services (HHS) secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and prescription drug plans." [↑](#footnote-ref-54)
55. ####  Spiegel

Andrew Spiegel [Opinion Contributor, The Hill, “The tragic toll of drug price controls,” The Hill, May 5 2017. Available at: <https://thehill.com/blogs/punditsblog/healthcare/332145-the-tragic-toll-of-drug-price-controls>

Drugs actually represent a relatively small slice of global medical spending. Just consider: over the next decade, spending on prescriptions will account for less than 10 percent of total healthcare spending growth in the OECD, the economic association encompassing the United States, Canada, and much of Europe. 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.** **In America**, **which has a** relatively **free drug market, the average medicine is approved 90 days quicker than in Europe** and about a year quicker than in Canada. **This delay can be deadly**, especially for colon cancer patients. The drug industry has invented advanced drugs proven to beat back this disease, including specialty chemotherapy agents such as panitumumab and “angiogenesis inhibitors,” which prevent colon cancer cells from growing by cutting off their blood supply. Obviously, these drugs can only help patients if regulators approve them. Too often, that approval is slow to come. And such delays are now common across a wide variety of drug classes, leading to serious carnage: some 600,000 European deaths could be avoided each year if the continent’s healthcare systems simply offered “timely and effective medical treatments,” according to the European Union’s own data. [↑](#footnote-ref-55)
56. **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-56)
57. Paul Howard. “To Lower Drug Prices, Innovate, Don’t Regulate”, The New York Times, Sep 23 2015, www.manhattan-institute.org/html/lower-drug-prices-innovate-don%E2%80%99t-regulate-8229.html

“Price control advocates argue that curtailing profits in the pharmaceutical industry would save the country money without reducing innovation. There is, however, no such Pro Arguments with Con Responses Nov/Dec 2018 Champion Briefs 64 thing as a free lunch. Bureaucratic price manipulation would only hurt the sickest patients. Streamlining drug approvals would get more drugs on market, increasing competition and lowering prices. 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.”** [↑](#footnote-ref-57)
58. John Lamattina. “About Those Soaring Pharma Profits”, Forbes, 23 Jan 2018, https://www.forbes.com/sites/johnlamattina/2018/01/23/about-those-soaringpharma-profits/#299331d53f9d

**“If price controls pressure the U.S. industry into a more conventional process industry model, like that of the chemical industry, pharmaceutical R&D budgets would be slashed. To achieve the chemical industry’s rate of R&D spending, as would be required to achieve profitability competitive with the chemical industry, top pharmaceutical companies would have to reduce their R&D budgets by 80 percent — almost $50 billion in total.** This reduction in spending would take a few years to realize, but would be completely evident by 2023 or earlier. An important corollary is that, if profitability and value creation opportunities for new drugs declined, the appetite of the venture community for risky, long-term biopharmaceutical investments would shrink exponentially. Price controls on drugs would have the surprising effect of accelerating the flow of investment into high technology, where timelines to market are shorter, less regulated, and less risky. The venture capital community is flush with cash and anxious to invest where high returns can be achieved — ideally within a much shorter time than is typically possible in the realm of drug R&D. **As a society, if we force pharma into a chemical industry model, where there is no biotech equivalent and no venture investing, we will be trading better and sooner effective drugs for better and sooner virtual reality devices and self-driving cars.”** [↑](#footnote-ref-58)
59. Sergio Prada, BioMed Central, “"Higher pharmaceutical public expenditure after direct price control: improved access or induced demand? The Colombian case”, 2 March 2018, https://resourceallocation.biomedcentral.com/articles/10.1186/s12962-018-0092-0

“Background High pharmaceutical expenditure is one of the main concerns for policymakers worldwide. In Colombia, a middle-income country, outpatient prescription represents over 10% of total health expenditure in the mandatory benefits package (POS), and close to 90% in the complementary government fund (No POS). In order to control expenditure, since 2011, the Ministry of Health introduced price caps on inpatient drugs reimbursements by active ingredient. By 2013, more than 400 different products, covering 80% of public pharmaceutical expenditure were controlled. This paper investigates the effects of the Colombian policy efforts to control expenditure by controlling prices. Methods Using SISMED data, the official database for prices and quantities sold in the domestic market, we estimate a Laspeyres price index for 90 relevant markets in the period 2011–2015, and, then, we estimate real pharmaceutical expenditure. Results **Results show that, after direct price controls were enacted, price inflation decreased almost − 43%, but real pharmaceutical expenditure almost doubled due mainly to an increase in units sold. Such disproportionate increase in units sold maybe attributable to better access to drugs due to lower prices, and/or to an increase in marketing efforts by the pharmaceutical industry to maintain profits.”** [↑](#footnote-ref-59)
60. 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-60)
61. 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-61)
62. 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-62)
63. 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-63)
64. <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-64)
65. 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-65)
66. 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-66)
67. 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-67)
68. <https://thehill.com/opinion/healthcare/376699-big-pharmas-lobbyist-are-losing-despite-their-pass-the-buck-campaigns>

As policymakers and the administration focus on high drug prices, the brand drugmaker lobby has responded by unleashing millions of dollars in an attempt to shift blame. They’ve blamed price gouging scandals on a “broken system” and claim to want to reform. They bankroll more than 1,400 lobbyists along with many “patient groups” and so-called “experts” to carry these messages to the media outlets and politicians on whom they lavish millions in advertising dollars and campaign contributions. **However, their polling numbers remain as low as before their advertising blitz began as Americans have overwhelmingly negative views of drugmakers** and the pricing schemes of “Pharma Bro" Martin Shkreli and others who increased drug prices simply because they found that they could. The response from the drugmaker lobby has been to rollout slick public relations slogans like “Share the Savings” and “Let's Talk About Cost” that use fancy infographics in an attempt to move the conversation away from those setting the price of the drug (drug companies) to everyone else who uses or pays for their products, like employers, hospitals, pharmacy benefit managers, insurers, and others. **This isn’t surprising and certainly not unpredictable, but ignores the basic challenge facing drug companies: no amount of money can change the fact that Republicans and Democrats know the problem is high drug prices and that drugmakers alone set those prices.** So despite all this overwhelming lobbying and financial firepower, the question remains: Why are drugmakers losing? **In the recent budget bill, drugmakers were singled out by both parties to pay billions more in discounts** to help seniors in the Medicare prescription drug benefit “donut hole.” This comes as **states across the country are taking a harder look at drugmaker pricing schemes and passing legislation in California and Nevada that faced significant pushback from drug companie**s (and their surrogates). Like the emperor who wore no clothes, drugmakers have confused politician’s fear of speaking out against them with support for their pricing practices. It appears that most politicians will tolerate, but not believe in the drug lobby's messages or goals. Drug manufacturers have a number of options to alter public perception of their pricing strategies. They can assert that their products are a great value at any price but there is definitely a level where that argument fails. They can also compete on price and refrain from automatic pricing increases that obviously impact healthcare affordability. Instead, they peddle distracting narratives and government mandates that undermine federal programs and result in huge industry profit windfalls. One recent example would be to prevent brand discounts and rebates from being used to lower premiums for seniors. According to the White House’s budget proposal, this mandate alone would cost the government about more than $42 billion and lead to higher premiums for Medicare beneficiaries.This is yet another distraction from the real problem of excessive drug pricing. If the drugmakers were truly concerned about affordability, the drug companies would simply reduce their prices. That would have a direct impact on the cost of health care to every American consumer. Simply put, drugmakers have failed to give policymakers the one thing they need: real solutions that reduce costs. They’ve offered no solutions that score savings — in fact, they all raise costs. Their relentless, ongoing PR blitz is simply an effort to pass the buck and direct attention away from their pricing strategies. **The drug lobby has underestimated the one politician, with whom their money and power doesn’t carry much weight: President Trump. It was only last year that he said drugmakers were “getting away with murder.” If the record is any indicator, he still thinks Big Pharma is one of the creatures lurking in the swamp he intends to drain**. [↑](#footnote-ref-68)
69. https://www.cnbc.com/2016/10/28/a-warning-for-big-pharma-lobbying-wont-work-anymore-commentary.html

Let's be blunt. **Corporate America is in delusional denial about how much the ground in Washington has shifted against it.** **The rise of Senators Bernie Sanders and Elizabeth Warren, both inside the halls of Congress and throughout the country, is more than just** a passing fad. Just ask Wells Fargo CEO John Stumpf... oops, I mean former CEO John Stumpf, who stepped down in part thanks to Senator Warren's grilling during recent Senate hearings.

Here's a warning and a wake up call to big business: If you try to use the same old lobbying and crony networks to get your way, it won't work. Not anymore. **And here's a special warning call just for Big Pharma: You need to change your public relations and marketing strategies now, or die. The good news is, unlike so many other industries, the drug companies have a very effective way out of this mess.**

But first let's set the stage a little more clearly**. The most immediate example of this new anti-big business reality in Washington comes from the just-announced AT&T/Time Warner merger deal**. Since it was first announced last week, Senator Sanders has gone from simply criticizing the deal online to now emphatically vowing to kill the deal.

Donald Trump also quickly said his administration wouldn't allow the deal. **These are serious threats that seem close to a death blow when you consider how the feds successfully ended the merger agreement between Time Warner Cable and CNBC-parent Comcast... and that was a year before Sanders and Trump rose to such national political prominence.**

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But again, pushing for more over the counter drugs would require the drug companies to realize their massive lobbyist army has outlived its usefulness. **Even the best connected lobbyists aren't yielding such great results in this climate. Just ask Pfizer, who must have felt shocked when its top lobbyist Sally Sussman couldn't save its coveted merger with Allergan even though Sussman has close ties to President Obama and she and her father were top campaign donation bundlers for his 2008 campaign. Gratitude often has a short shelf life, and nowhere is it shorter than in Washington**.

**The most likely result is that PhRMA and the drug companies are going to spend the next year or two years learning this lesson the hard way and much of that $300 million will go down the drain the second Senator Warren, Senator Sanders, and a Republican or two cry foul at the latest drug price hike. They key mistake is Big Pharma still thinks it needs to try to play by the old lobbying game and just a little bit more hard work and a lot more money will fix everythin**g. Instead, the industry's best chances involve taking the nearest exit off the Beltway jam. [↑](#footnote-ref-69)
70. <https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=1609&context=healthmatrix>

These and other innovative tools have saved Americans billions of dollars each year.44 **However, they have also dramatically changed the landscape of the pharmaceutical market by lessening drug companies’ influence over prices**. In the 1970s, most prescription drugs were prescribed by doctors that were largely insensitive to price, methodically filled by pharmacists, and paid for by consumers or, less frequently, by third-party payors that had little influence over the drug chosen or the price paid.45 As a consequence, drug manufacturers had enormous control over price**. In contrast, the market for prescription drugs in 2016 is one in which the PBMs and drug plans have harnessed the buying clout of millions of consumers to negotiate discounted prescription drug prices.**46 PBMs and drug plans now largely determine what consumers pay for drugs, which pharmacies they use, and which drugs they take.**47 As a result, PBMs and drug plans have replaced drug manufacturers in the driver’s seat when it comes to determining prices.**  [↑](#footnote-ref-70)
71. **Bowmer**, Rick. “Fighting Special Interest Lobbyist Power Over Public Policy.” **Center for American Progress**, 27 Sept. **2017**, https://www.americanprogress.org/issues/democracy/reports/2017/09/27/439 675/fighting-special-interest-lobbyist-power-public-policy/.

**Some proposals would even ban members from lobbying permanently.** Extending the ban on lobbying would give lawmakers one less reason to elevate special interest concerns over the concerns of their constituents. Implementing effective policies to fight the corrupting influence of special interest lobbyists depends on an accurate and effective system of lobbyist registration. Unfortunately, the current definition is all too easily evaded and has resulted in many people engaged in lobbying activities deregistering or failing to register in the first place. Fortunately**, bills have been introduced** in both the House and Senate **that would institute a commonsense definition of lobbying that applies to anyone who makes more than one lobbying contact on behalf of a client over a two-year period.** In addition to enabling enforcement of the proposals above, expanding lobbying disclosure would also allow the public to better understand who is spending money to try to influence government—as well as how much money is being spent—so that representatives are held accountable. [↑](#footnote-ref-71)
72. **Ferry**, David. “The New War on (Overpriced) Pharmaceuticals.” **Wired**, Conde Nast, 8 Nov. **2017**, www.wired.com/story/fighting-high-drug-prices/.

President Donald **Trump has said that the pharmaceutical industry is “getting away with murder” and that he wants to let Medicare negotiate with drug companies over the prices we pay—**something that was forbidden in 2003, part of a compromise with the politically potent industry to get the Medicare drug expansion plan passed. (Since 1998, Big Pharma has spent more on lobbying than any other industry.) [↑](#footnote-ref-72)
73. John Lamattina. “About Those Soaring Pharma Profits”, Forbes, 23 Jan 2018, https://www.forbes.com/sites/johnlamattina/2018/01/23/about-those-soaringpharma-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 Healthcare Support Services (14.4%).”**  [↑](#footnote-ref-73)
74. Gleason, 2017, Gleason Patrick Gleason is vice president of state affairs at Americans for Tax Reform, and a senior fellow at the Beacon Center of Tennesse, <https://www.forbes.com/sites/patrickgleason/2017/02/21/states-consider-imposing-drug-price-controls/#4fedc887639b> States Consider Imposing Drug Price Controls

For starters, the justification for price controls on prescription drugs is based in myth. The claim that U.S. drug spending is growing out of control is simply not true. **Spending on prescription drugs as a share of all health care spending in the U.S. is the same as it was 60 years ago.** As the Manhattan Institute pointed out in a 2015 report, spending in the U.S. on drugs accounts for about 10% of total health care spending. In fact, drugs account for a lower percentage of total health care spending in the U.S. than in Europe, where drug price controls have been on the books for decades. Upon further investigation, it **becomes clear pharmaceutical price controls – like those now being debated in eight state capitals – are misguided solutions in search of a problem, and are a red herring when it comes to the effort to bend the overall health care cost curve.** [↑](#footnote-ref-74)
75. ####  Danzon

https://www.nber.org/reporter/fall06/danzon.html

In addition to product licensing, mergers and acquisitions (M&A) are common in the pharma-biotech industry. Large horizontal mergers were particularly frequent in the late 1980s and 1990s, while pharmaceutical acquisitions of biotech companies have become more common recently. Several of the largest firms are the result of successive large horizontal mergers, and this has contributed significantly to industry concentration. Such mergers are often rationalized on grounds of economies of scale and scope in R and D, marketing, and administration. In our analysis of M&A in the pharma-biotech industry, we tested various alternative hypotheses to explain both large and smaller mergers, and then examined the effects of mergers using propensity scores to control for merger endogeneity.(4) For larger firms, we find that mergers are a response to patent expirations and gaps in a company's product pipeline, which lead to excess capacity of the fixed marketing resources. For smaller firms, **mergers are primarily an exit strategy in response to financial trouble**, as indicated by a low Tobin's q, few marketed products, and low cash-sales ratios. Controlling for a firm's ex ante propensity to merge significantly affects the estimates of merger effects. Firms with relatively high propensity scores experienced slower growth in sales, employees, and R and D, regardless of whether they actually merged; this is consistent with mergers being a response to distress. For large firms, a merger did not significantly affect subsequent performance on average, whereas small firms that merged had slower R and D growth than similar firms that did not merge; this suggests that post-merger integration may divert cash from R and D. This conclusion, that merger is often a response to distress but is usually not an effective solution, is consistent with the subsequent slow-down in M&A in this industry, with the exception of selective, strategic acquisitions, as large firms acquire smaller firms with spe cifically well-matched capabilities or products. Thus, although the "survivor" evidence -- with increased market share of the top ten firms over time -- might suggest that large firms have advantages, recent stock market performance tells a very different story. [↑](#footnote-ref-75)
76. http://fortune.com/2016/05/17/high-drug-prices-mergers-pharma-competition/

**Economics teaches that under conditions of perfect competition, firms earn normal profits and “prices will be kept low by competitive pressures.” To achieve perfect competition, you need many firms to operate in the same business. Therefore, antitrust policy is supposed to ensure that competitive markets remain that way by limiting mergers that reduce market competition.** However, as even casual observation attests, the number and value of takeovers has soared over the years, with only a tiny minority of acquisitions drawing regulatory scrutiny.

Somewhat surprisingly, as **Princeton economist Orley Ashenfelter** noted, there has been little empirical evaluation of the effects of mergers on consumer prices. **A study of five mergers by Ashenfelter** and Federal Trade Commission economist Daniel Hosken **found that in four of the cases, there was evidence of an increase in some consumer prices.** [↑](#footnote-ref-76)
77. <https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf>

Yale- The high cost of prescription drugs in the United States is unsustainable. **Spending on prescription drugs is increasing at a faster rate than any other component of health care spending**, and a growing number of Americans report difficulty affording their medications. **High drug prices are forcing some patients to skip doses of critical medicines, and others to choose between their health and necessities like food and rent. Meanwhile, the pharmaceutical industry continues to launch new drugs at exorbitant prices, increase prices of many old drugs without justification, and reap record profits.** [↑](#footnote-ref-77)
78. http://www.medicaleconomics.com/money/are-pbms-blame-high-drug-prices

As part of his written testimony, Azar said that since PBMs are paid based on the number of rebates they negotiate, the possibility exists for them to retaliate against manufacturers who cut prices by dropping them from formularies or placing them on a higher tier.

“We may need to move toward a system without rebates, where PBMs and drug companies just negotiate fixed-price contracts,” he said. “Such a system’s incentives, detached from artificial list prices, would likely serve patients far better, as would a system where PBMs receive no compensation from the very pharma companies they’re supposed to be negotiating against.” [↑](#footnote-ref-78)
79. https://morningconsult.com/opinions/perverse-incentives-created-pbm-rebate-arrangements/

As market concentration in the PBM industry has increased — according to Food and Drug Administration Commissioner Scott Gottlieb, the top three PBMs control more than two-thirds of the [market](https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm) — PBMs have been able to demand larger and larger rebates from manufacturers. From 2012 to 2016, total rebates [increased](https://www.drugchannels.net/2017/06/new-data-show-gross-to-net-rebate.html) from $59 billion to $127 billion.

PBMs pass on some of these rebates to their drug plan clients, who can then use them to lower premiums for all covered individuals (though [recent analysis](https://www.drugchannels.net/2018/01/employers-are-getting-more-rebates-than.html) questions whether they do).  However, oftentimes the amount of the rebate that PBMs keep is either not negotiated or undisclosed, and evidence shows that PBMs keep a sizable share for themselves (see, for example, [here](https://www.drugchannels.net/2016/01/solving-mystery-of-employer-pbm-rebate.html) and [here](https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/)). [↑](#footnote-ref-79)
80. 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-80)
81. 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-81)
82. 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-82)
83. 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-83)
84. Lichtenberg, Frank R. “The Benefits of Pharmaceutical Innovation: Health, Longevity, and Savings.” *Montreal Economic Institute*, Montreal Economic Institute, June 2016, www.iedm.org/files/cahier0216\_en.pdf.

Although the costs of new pharmaceuticals are often the subject of critical media coverage, they are rarely juxtaposed with the benefi ts that these new drugs bring. Between 1995 and 2012, life expectancy at birth in Canada increased by more than three years and curative care hospital discharges per 100,000 population (a measure of hospital utilization) decreased by 25%. While these improvements naturally have multiple sources, a substantial and growing number of studies have demonstrated that pharmaceutical innovation is responsible for a large part of such long-term improvements in health and longevity. **Furthermore, although new drugs can appear expensive when considered in isolation, pharmaceutical innovation leads to cost savings elsewhere in the system through the reduced use of health services like hospitals and nursing homes.** Studies have also shown that pricing drugs appropriately is important in sustaining a robust rate of pharmaceutical innovation. [↑](#footnote-ref-84)
85. 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-85)
86. Blumberg, Yoni. “Here's the Real Reason Health Care Costs so Much More in the US.” *CNBC*, CNBC, 3 Sept. 2018, www.cnbc.com/2018/03/22/the-real-reason- medical-care-costs-so-much-more-in-the-us.html.

**The U.S. is famous for over-spending on health care. The nation spent 17.8 percent of its GDP on health care in 2016. Meanwhile, the average spending of 11 high-income countries assessed in a new report published in the Journal of the American Medical Association — Canada, Germany, Australia, the U.K,. Japan, Sweden, France, the Netherlands, Switzerland, Denmark and the U.S. — was only 11.5 percent**. Per capita, the U.S. spent $9,403. That's nearly double what the others spent. This finding offers a new explanation as to why America's spending is so excessive. According to the researchers at the Harvard Chan School, what sets the U.S. apart may be inflated prices across the board. **In the U.S., they point out, drugs are more expensive. Doctors get paid more. Hospital services and diagnostic tests cost more. And a lot more money goes to planning, regulating and managing medical services at the administrative level.**  [↑](#footnote-ref-86)
87. Nix, Kathryn. “Government Price Controls for Health Care: A Deficit-Reduction Strategy to Avoid.” The Heritage Foundation, 30 Nov. 2011, /health-care- reform/report/government-price-controls-health-care-deficit-reduction- strategy-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-87)
88. Donlan, Thomas G. A Funding Mess in the Medicaid Program. 19 Mar. 2016, http://www.barrons.com/articles/a-funding-mess-in-the-medicaid-program- 1458363194.

**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-88)
89. Holahan, John, et al. “Explaining The Recent Growth In Medicaid Spending.” Health Affairs, vol. 12, no. 3, Jan. 1993, pp. 177–93. healthaffairs.org (Atypon), doi:10.1377/hlthaff.12.3.177.

**Exhibit 5 displays increases in prices nationally for Medicaid-covered services. Average annual price growth for inpatient hospital services and nursing homes was slower than for most other services in the 1988-1992 period. However, price increases for these two sectors contributed the most to Medicaid expenditure increases.** This share reflects the overall predominance of these services in Medicaid spending, rather than particularly high price increases. **Payments to hospitals and nursing homes accounted for more than half of total Medicaid expenditures in 1992. Prescription drug prices had the highest rate of growth and alone accounted for 2.7 percent (or $1.7 billion) of Medicaid spending growth despite being a relatively small item in Medicaid budgets.** The important conclusion here is that rapid escalation in health care prices is largely outside of Medicaid's control, assuming the program seeks to maintain access. **Clearly, Medicaid spending will continue to increase along with overall health cost increases.**  [↑](#footnote-ref-89)
90. Winegarden, Wayne. Pacific Research Institute | The Price Control Hammer Will Break the Health Care System. 17 Oct. 2017, https://www.pacificresearch.org/the- price-control-hammer-will-break-the-health-care-system/.

To start, price controls are irrelevant for most patients. Nearly 90 percent of all drugs dispensed are generic medicines. Not only are generics significantly cheaper in the U.S., the prevalence of cheap generics helps explain why total pharmaceutical spending as a percentage of total health care spending is lower in the U.S. (12.2 percent) compared to the average OECD country (16.9 percent). **Price controls will harm patients who benefit from patented medicines, however. To see why, imagine the consequences if the government capped the salary of doctors at the U.S. median income level. Surely many doctors would cease practicing, causing a doctor shortage to arise. Over time, this doctor shortage would worsen as more young people would be discouraged from entering the field. Ultimately, the quality of health care would decline, and total costs would increase as untreated minor afflictions would become more expensive ailments.**  [↑](#footnote-ref-90)
91. Robert J. Easton, 1-22-2018, "Price controls would stifle innovation in the pharmaceutical industry," STAT, <https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/> [↑](#footnote-ref-91)
92. Marcel Canoy and Jan Tichem 2018 The authors work for the Netherlands Authority for Consumers & Markets. Canoy is also member of the Advisory Commission Basic Package (ACP) of the Dutch Health Care Institute. https://editorialexpress.com/cgi-bin/conference/download.cgi?db\_name=EARIE45&paper\_id=550

However, if companies gain more than the benefit of the drug to society, we show that this creates two inefficiencies in innovation. First, companies invest too many resources in projects where they expect to be able to gain more than the drug is worth to society. Second, pharmaceutical companies invest too few resources in other valuable drug development projects. As a result, high drug prices lead to crowding out of valuable drug development projects. In these instances, enforcing lower prices does not harm innovation but improves it, because as a result of lowering those prices future investments will be geared towards projects that are more desirable for society. [↑](#footnote-ref-92)
93. Fielding 16 of US news and world report fielding, Jonathan. “We Can Make Medicine Affordable.” U.S. News & World Report, U.S. News & World Report, 5 Oct. 2016, [www.usnews.com/opinion/articles/2016-10-05/the-us-can-make-prescription-drugs-more-affordable](http://www.usnews.com/opinion/articles/2016-10-05/the-us-can-make-prescription-drugs-more-affordable).

Whenever I am outside, I carry two EpiPens. If a bee stings me, the pens could save my life. I was recently stung, but not by a bee. **The sting came from Mylan pharmaceuticals when it raised the retail price of a two pack of EpiPens from about $100 to more than $600 dollars over nine years. According to** [**Money**](http://time.com/money/4481786/how-much-epipen-costs-to-make/) **magazine, each EpiPen costs about $30 to produce.** I am lucky because my health insurance pays most of the cost of my EpiPens. But millions of Americans, both young and old, cannot benefit from this drug or others when the initial price or rapid price increase make them unaffordable. Even those with insurance coverage who do not use costly drugs still pay for them through rising premiums and co-pays. List prices for all medicines are subject to various discounts and rebates often negotiated by insurance companies and pharmacy benefit managers, and the actual cost can be lower**. But a study by** [**Bloomberg**](http://www.bloomberg.com/graphics/2015-drug-prices/) **found that even after discounts, we pay more in the U.S. for common medicines like Crestor (high cholesterol), Lantus (insulin), Advair (asthma), Januvia (diabetes), Humira (rheumatoid arthritis) and Herceptin (breast cancer) than in most other countries in the study, including Australia, Canada, Japan, Saudi Arabia, China, Brazil, India, Russia, Morocco and several European countries.** The role of intermediaries like insurance companies and pharmacy benefit managers in our health care system makes it very difficult for doctors and patients to know the true price of medicine. [↑](#footnote-ref-93)
94. Prescription justice 17 Prescription Justice, 2-6-2017, "45 Million Americans Forego Medications Due to Costs, New Analysis Shows – 9 Times the Rate of the UK," <https://prescriptionjustice.org/press_release/45-million-americans-forego-medications-due-to-costs-new-analysis-shows-9-times-the-rate-of-the-uk/>

But it is not hard to know the public health implications. In 2014, **35 million Americans did not fill a doctor's prescription because they could not afford it, according to a study released by** [**The Commonwealth Fund**](http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2015/jan/1800_collins_biennial_survey_brief.pdf). In addition, the [Centers for Disease Control](http://www.cdc.gov/nchs/data/databriefs/db184.htm) and Prevention reports that Americans use a variety of other strategies to trim medication costs, including reducing the dosage to make a supply last longer, buying medicines from foreign countries and substituting alternative therapies. [WebMD reports](http://www.webmd.com/healthy-aging/features/letter-and-spirit-of-drug-import-laws) that medicines sold in Canada can cost 55 percent less than an identical medicine in the U.S. According to the [American Heart Association](http://www.heart.org/HEARTORG/Conditions/More/ConsumerHealthCare/Medication-Adherence---Taking-Your-Meds-as-Directed_UCM_453329_Article.jsp#.V9gTuU1TE5t), failure to take a prescribed medicine or reducing the amount costs $300 billion in extra medical expenses and contributes to 125,000 deaths a year. As a standalone category, nonadherence would be a leading [cause of death](http://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm) in the U.S., ahead of Alzheimer's, diabetes, influenza, pneumonia and kidney disease. [↑](#footnote-ref-94)
95. **Krantz 16 of USA today** Matt Krantz,, 8-26-2016, "Drug prices are high. So are the CEOs' pay.," USA TODAY, <https://www.usatoday.com/story/money/markets/2016/08/26/drug-money-pharma-ceos-paid-71-more/89369152/>

CEOs of publicly traded pharmaceutical companies have clear incentives and a fiduciary responsibility to raise prices to maximize shareholder profits. And these CEOs are richly rewarded for their success. [**USA Today**](http://www.usatoday.com/story/money/markets/2016/08/26/drug-money-pharma-ceos-paid-71-more/89369152/) **reports that in 2015, CEOs of pharmaceutical companies in the S&P 500 earned on average 71 percent more than the average for S&P 500 CEO.** Consolidation in the pharmaceutical industry also boosts prices. Mergers and acquisitions may make sense from a business perspective, but reduced competition means higher prices for brand name and generic medicines. So much for the problem; what about solutions? The good news is that there are common sense fixes to make widely used prescription drugs more affordable. [↑](#footnote-ref-95)
96. **Brady 16 of WP** Brady Dennis, 1-11-2016, "Prescription drug prices jumped more than 10 percent in 2015, analysis finds," Washington Post, <https://www.washingtonpost.com/news/to-your-health/wp/2016/01/11/prescription-drug-prices-jumped-more-than-10-percent-in-2015/?utm_term=.28b53dfc7d49>

Second, Congress should authorize the U.S. Food and Drug Administration, the agency that must approve new prescription drugs for the market, to consider a drug's value and price in addition to its safety and efficacy in that process. Shouldn't the price of a new drug reflect how its safety and efficacy compare to drugs already on the market? How does the requested price compare with existing products with similar indications for use? And shouldn't there be federal guidelines on prescription drug price increases? Is it fair that pharmaceutical companies, who have been granted a monopoly for many of their drugs in the form of a patent, are allowed to raise prices as much and as often as they want? We should not be surprised that the price of many prescription drugs is increasing at several times the rate of most other goods and services**.** [**Money**](http://time.com/money/4406167/prescription-drug-prices-increase-why/) **magazine reports from May 2015 to May 2016, medicine prices increased 10 percent. Overall inflation was just 1 percent**. Finally, the FDA should aggressively implement the biosimilars provisions of the Affordable Health Care Act. Biosimilars are lower-cost, interchangeable versions of biologic drugs. The law was designed to bring biosimilars to market sooner, creating competition for medicines like Humira, Remicade, Embrel and the cancer drugs Herceptin and Avastin. Biosimilar medicines are widely used in Europe. To date only three biosimilar medicines have been approved by the FDA, two in the last three months. These changes will be controversial. Pharmaceutical companies will strongly oppose them, arguing that they need high profits to continue to invest and innovate. But without these changes, the high price of prescription medicines will only worsen this crisis for patients and make our health care system less and less affordable. [↑](#footnote-ref-96)
97. ####  Centers for Medicare and Medicaid Services

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

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

 [↑](#footnote-ref-97)
98. ####  Chan

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

**Drugs feel more expensive when health insurers cover less of a drug. And as healthcare costs rise, health insurers look to shift the burden of expenses onto its patients through higher deductibles or premiums.** Deductibles refer to the amount you have to pay before coverage kicks in. And since 2010, average deductibles have increased over 67%. As more Americans enroll in High-Deductible Health Plans (HDHP), so does the feeling of cost. Under an HDHP, EpiPen, which may have been previously covered by a health insurer for a $50 co-pay, now costs $600 until the deductible is met. Premiums or the monthly payments one makes to be covered are rising too, and have increased by about 27%. **What’s ultimately driving this feeling of “cost” boils down to rising healthcare costs and insurers counteracting those costs by covering less of it.**  [↑](#footnote-ref-98)
99. ####  Healthline Board

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

**Drug price increases also greatly outpace healthcare inflation costs, which have been comparatively low in the past few years. These price increases affect insurance premiums and out of pocket expenses,** but it’s hard to say exactly how much**.** However, Jonathan Gruber, a professor of economics at the Massachusetts Institute of Technology and president of the American Society of Health Economists, says the overall direction is clear. **“Higher drug prices translate to higher health insurance costs for all of us,” he says**. He notes the convoluted system of rebates and discounts between pharmaceutical companies, pharmacy benefit managers, and insurance companies makes things even more murky. “Obviously, if they raise the price, that’s going to pass through to some extent to consumers. Whether PBMs are helping or hurting is still unclear, it all depends on how these rebates play through,” says Gruber. “We just don’t know yet. When they raise the price, how much of that is actually making its way to consumers?” [↑](#footnote-ref-99)
100. ####  Kaiser Family Foundation

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

**Even under the ACA, many uninsured people cite the high cost of insurance as the main reason they lack coverage. In 2016, 45% of uninsured adults said that they remained uninsured because the cost of coverage was too high. Many people do not have access to coverage through a job, and some people, particularly poor adults in states that did not expand Medicaid, remain ineligible for financial assistance for coverage.** Some people who are eligible for financial assistance under the ACA may not know they can get help, and undocumented immigrants are ineligible for Medicaid or Marketplace coverage. **Most uninsured people are in low-income families and have at least one worker in the family.** Reflecting the more limited availability of public coverage in some states, adults are more likely to be uninsured than children. People of color are at higher risk of being uninsured than non-Hispanic Whites. [↑](#footnote-ref-100)
101. Various Mechanisms, 4-4-1994, "Fear Of `De Facto' Price Controls Forcing Cuts In Biotech Innovation, Officials Say," Scientist Magazine®, https://www.the-scientist.com/news/fear-of-de-facto-price-controls-forcing-cuts-in-biotech-innovation-officials-say-59351 [↑](#footnote-ref-101)
102. John LaMattina is an expert in the pharma industry and a writer for Forbes. “Pharma R&D Cuts Hurting U.S. Competitive Standing” Forbes. 1/3/14, http://www.forbes.com/sites/johnlamattina/2014/01/03/pharma-rd-cuts-hurting-u-s-competitive-standing/>)

**A recent article in the New England Journal of Medicine (NEJM) should send warning signals to all interested in the state of the biopharmaceutical R&D in the U.S.** The article, “Asia’s Ascent – Global Trends in Biomedical R&D Expenditures”, analyzes global biomedical R&D spending for the period between 2007 and 2012. While the article focuses on the relative rise in spending by Japan, China and India, **the eye-opening data for me are the numbers from the U.S. The authors point out that the U.S. share of this global spend has fallen from 51.2% in 2007 to 45.4% in 2012**.Europe’s investment was essentially unchanged and Asia’s increased from 18.1% to 23.8%. Further digging into the numbers revealed the following. **“The decline of $12.0 billion in the inflation-adjusted U.S. expenditures from 2007 to 2012 was therefore driven by a $12.9 billion reduction in industry’s investment in R&D**. The U.S. share of global industry R&D expenditures decreased from 50.4% in 2007 to 42.3% in 2012.”The authors later say that “The decline is remarkable because the United States has provided a majority of the funding from biomedical R&D globally for the past two decades – a share that some previous analyses suggested was as high as 70 – 80%. Moreover, the decline was driven almost entirely by reduced investment by industry, not the public sector, between 2007 and 2012.”Much of the news from **the pharmaceutical industry over the past five years has been about scaling back R&D.** [↑](#footnote-ref-102)
103. Sampat- No Author, xx-xx-xxxx, "What Are The Respective Roles Of The Public And Private Sectors In Pharmaceutical Innovation?," No Publication, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0917> [↑](#footnote-ref-103)
104. Mariana Mazzucato, 8-1-2013, "State of innovation: Busting the private-sector myth," New Scientist, <https://www.newscientist.com/article/mg21929310-200-state-of-innovation-busting-the-private-sector-myth/>

The examples don’t just come from the military arena, either. **The US National Institutes of Health spends around $30 billion every year on pharmaceutical and biotechnology research and is responsible for 75 per cent of the most innovative new drugs annually.** Even the algorithm behind Google benefited from US National Science Foundation (NSF) funding. [↑](#footnote-ref-104)
105. No Author, 6-29-2016, "Drug Price Controls Are Vital in a Market That's Not Free," No Publication, <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-are-vital-in-a-market-thats-not-free>

The producers argue that this will stifle their incentive to innovate. But the evidence is increasingly clear that we cannot count on the private sector to make necessary medicines affordable. In fact, given the incentive structure, neither can we count on private drug companies to develop the drugs we most need versus the ones that will be most profitable. In health economics, maximizing social benefits is often at odds with private benefits. [↑](#footnote-ref-105)
106. **Belk, 18** – (David, “The Pharmaceutical Industry,” True Cost of Healthcare, 2018, http://truecostofhealthcare.org/the\_pharmaceutical\_industry/, CD - JO)

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

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

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

So, we in the US continue to overpay for brand name prescription medications, but **the pharmaceutical industry has given us almost no new important therapies in more than 15 years.** A somewhat unexpected result of this is that, total pharmaceutical revenue has been nearly flat since 2010. [↑](#footnote-ref-106)
107. **Stanford**

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

Contrary to public opinion, the research productivity of U.S. pharmaceutical companies has fallen behind European competition, says Donald Light, visiting professor in human biology and international health policy at Stanford. Light's latest study on the topic, which will be published in Health Affairs, also shows that new drugs often lack clinical advantage over existing ones. "While it's widely believed that most new drugs are discovered and developed in the United States and that American researchers have far outstripped their European competitors, on a level playing field of dollar for dollar, European researchers actually have been more innovative since 1982," Light said. By analyzing clinical studies and papers on pharmaceutical discoveries, Light found that European companies discovered more drugs than U.S. companies from 1982 to 2003, overall and in proportion to funding. **Light also cites studies showing that in the last 40 years, only about 11 to 15 percent of new drugs provided significant clinical improvement over existing ones, while the remaining 85 to 89 percent include what are called "me-too" drugs, clones of existing drugs, marketed as the latest breakthrough.**  [↑](#footnote-ref-107)
108. **http://www.euro.who.int/en/media-centre/sections/press-releases/2013/07/pharmaceutical-innovation-must-align-with-patient-needs,-says-new-report**

“Despite an **over three-fold rise in spending on pharmaceutical research and development in Europe since 1990**, there is an increasing mismatch between people’s real needs and pharmaceutical innovation. We must ensure that industry develops safe, effective, affordable and appropriate medicines to meet future health needs,” says Nina Sautenkova, Manager of Health Technologies and Pharmaceuticals at WHO/Europe. [↑](#footnote-ref-108)
109. **More resources going into innovation yield fewer important breakthroughs**

**Frank, 17** – (Richard, “Pharmaceutical Industry Profits And Research And Development,” Health Affairs, 13 November 2017, https://www.healthaffairs.org/do/10.1377/hblog20171113.880918/full/, CD - JO)

The manufacturers’ argument has validity in that expectations of lower revenues will lead to less investment in research and development (R&D). But we question the premise that more innovation is always a good thing. A central tenet of economics is the law of diminishing returns. In this case, **additional resources going into innovation inevitably yield fewer important breakthroughs.** At some point, perhaps already reached, the yield from additional resources going into R&D no longer justifies what society is paying in the form of higher prices to support this.

In the case of differentiated competition, **prescription drug manufacturers will tend to pursue R&D investments where the size of markets and the potential price-cost margins are greatest.** Because pharmaceutical manufacturers are uncertain about the investments that their rivals are making and long lead times are generally required to bring a new product to market, there are incentives for rival companies to all chase big markets, for example dementia or prevalent cancers, **in the hope of realizing large returns.**

**The result of this type of “arms race” is “overinvestment” in certain clinical areas and lower rates of return on investment than hoped for. This state of affairs can continue indefinitely**, eluding normal market self-correction mechanisms, due to prescription drug insurance that has become more common and more generous (see below) and to public-sector drug programs that are often passive purchasers.

Reviews of the literature on the impact of market size differences on innovation suggest two broad conclusions. First, increases in market size and potential profits have a strong positive impact on innovative activity, whether it is measured by clinical trial activity, R&D spending, or number of new drugs launched. The second conclusion is less unanimous but represents the weight of the evidence: innovation increases less than proportionately with market size.

These latter two results are consistent with a conception of the pharmaceutical market that exhibits differentiated competition and a tendency to overinvest in a limited number of clinical areas. It is important to note that the evidence on this point remains limited and more work is needed. Nevertheless the mix of research findings, alongside the institutional changes in the prescription drug markets, raises fresh questions about the trade-off between high prices and profits on the one hand and innovation on the other. [↑](#footnote-ref-109)
110. <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2017/11/17/pharmaceutical-industry-profits-and-research-and-development/>

The manufacturers’ argument has validity in that expectations of lower revenues will lead to less investment in research and development (R&D). But we question the premise that more innovation is always a good thing. **A central tenet of economics is the law of diminishing returns. In this case, additional resources going into innovation inevitably yield fewer important breakthroughs. At some point, perhaps already reached, the yield from additional resources going into R&D no longer justifies what society is paying in the form of higher prices to support this.** [↑](#footnote-ref-110)
111. ####  Goldacre

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

In 2002, the 10 **US drug companies** on the Fortune 500 list had combined international sales of $217bn (£106.6bn). They **spent only 14% of that money on research and development, but 31% on marketing and administration**. They are very careful not to let anyone see how much goes on marketing and on administration. Whenever you hear the drug companies explaining why they have to charge so much for their products - perhaps as they are denying their lifesaving Aids drugs to the 20 million HIV-positive people in Africa - the plea is that they need money to develop new drugs. That’s not true if they spend twice as much on marketing as on research and development. This unhappy collision of facts makes them look very evil indeed. They also charge this money in slightly evil ways. Drugs have 10 years ”on patent.” Loratadine is an effective antihistamine drug that does not cause drowsiness. Before the patent ran out, the price of this drug, by Schering-Plough, was raised 13 times in the US in just five years, increasing by over 50%. This is not a price rise in keeping with inflation. This is evil. [↑](#footnote-ref-111)
112. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1261198/#!po=37.5000

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

#### Vivian

 [↑](#footnote-ref-112)
113. Ho, Vivian. [Reporter for US News]. “The Harm of High Drug Prices”. US News, 2016. <https://www.usnews.com/opinion/policy-dose/articles/2016-12-12/the-harm-of-highdrug-prices-to-americans-a-continuing-saga>

Under criticism, the drug industry repeats the same arguments: 1) high cost of research and development; 2) benefit justifies price; 3) market forces; and 4) regulating prices stifles innovation. But all four arguments lack validity. **The cost of research and development is only 10 percent of the $1-2.6 billion figure that is claimed in industry-supported studies**. More than 50 percent of important discoveries are made in independent academic centers, funded by taxpayers, and 85 percent of basic research is conducted in academic centers. The drug industry spends 1.3 percent of its budget on basic research, but 20-40 percent on advertisements and related activities. Some studies show no relationship between drug benefits and price. Drug companies enjoy monopoly-like conditions that discourage competition based on price. Finally, innovation is driven by independent investigators who will continue to conduct research even if drug prices fall. [↑](#footnote-ref-113)
114. Emanuel, Ezekiel. [Oncologist and vice provost at the University of Pennsylvania]. “The Solution to Drug Prices”. New York Times, 2015. https://www.nytimes.com/2015/09/09/opinion/thesolution- to-drug-prices.html

Almost all developed countries — including those run by very conservative governments — have an effective solution for drug prices, which is why these countries often pay less than half of what people in the United States pay for drugs. For instance, Australia’s more than 60-year-old Pharmaceutical Benefits Scheme has been the single purchaser of drugs for the country, making drugs available at fixed prices that are now listed online. If the United States were to consider such an approach, drug companies would immediately raise two objections: the high risks associated with drug development and, related, the high cost of research and development. But both of these arguments are fatuous. It is true that a vast majority of drugs fail. On average, only one in every 5,000 compounds that drug companies discover and put through preclinical testing becomes an approved drug. Of the drugs started in clinical trials on humans, only 10 percent secure F.D.A. approval. Regardless of the risks, **many drug companies are making huge profits**. Gilead, maker of Sovaldi, has profits of around 50 percent. Biogen, Amgen and other biotech firms have profits of around 30 percent. Merck and Pfizer are seeing profits of 18 percent or more. **Even if profits were cut by a** third or a **half, there would be sufficient incentive to assume the risks of drug development.** [↑](#footnote-ref-114)
115. ####  Hopkins

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

I will present two case studies that deal with the effect of government regulation on innovation. Both opinions were that government regulation would have a significant negative effect on innovation. In the short run firms would have sustainable growth, but in the long run there would be no incentive to innovate and there would be a loss to the pharmaceutical market of new drugs. These views are consistent with economic views of how regulation effects innovation, but the pharmaceutical market may be an exception due to the unusual subsidization of the research and development. **In both case studies the amount of subsidization done by the government was not taken into account.** [↑](#footnote-ref-115)
116. ####  IMF

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

A price subsidy reduces the consumer price of a good or service below what it would be in the absence of the subsidy (consumer subsidy) or increases the price received by a producer above its market level (producer subsidy). In practice, **consumer subsidies are always implemented with price controls**, resulting in shortages of the subsidized item. Producer subsidies, on the other hand, are often administered through producer support prices. When support prices are set too high, there is an oversupply of the subsidized item. 37. Explicit price subsidies are recorded in the government budget as expenditures, although not necessarily under the category “subsidies.”15 Explicit subsidies can take many forms. In the case of a consumer subsidy, a public agency can make direct payments to producers to compensate them for charging lower prices for their output. Alternatively, the government can directly provide goods and services free of charge or at below-market prices through a public distribution system. [↑](#footnote-ref-116)
117. ####  Shang

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

As Table 7 illustrates, **a 1% increase in government subsidies leads to a** 33.1% and **58.7% increase in private R&D investment** . Therefore, H1 and H4 are further supported. It is worth noting that the coefficient of Sub on ROA in SOEs (β1 = 0.245, t = 1.846) is greater than that in POEs (β1 = 0.128, t = 0.988). This means that the impact of government subsidies on firm performance in SOEs is stronger than in private enterprises. [↑](#footnote-ref-117)
118. Ezekiel J. Emanuel, 9-9-2015, "Opinion", No Publication, https://www.nytimes.com/2015/09/09/opinion/the-solution-to-drug-prices.html?fbclid=IwAR1zwLd3jlbpEQnot\_\_qmf1649jR80MzKaU-kv1AMLstIzVtlBV2Js11Htg
Regardless of the risks, many drug companies are making huge profits. Gilead, maker of Sovaldi, has profits of around 50 percent. Biogen, Amgen and other biotech firms have profits of around 30 percent. Merck and Pfizer are seeing profits of 18 percent or more. Even if profits were cut by a third or a half, there would be sufficient incentive to assume the risks of drug development. What should be done? The United States government has created myriad special pricing arrangements that pervert incentives. For instance, Medicaid generally gets the lowest prices in the market. This discourages drug companies from experimenting with other payers on lower price arrangements, knowing that they will most likely have to give the same deal to Medicaid. Similarly, through the Orphan Drug Act of 1983 the United States created many incentives for developing drugs for orphan diseases — those with fewer than 200,000 patients nationwide. Through special tax credits and better deals on marketing exclusivity, the federal government is encouraging the companies to benefit thousands instead of millions. The result has been the development of more than 400 drugs and biologics. While it is important to find effective treatments for rare diseases, it is more important to target serious, common diseases such as stroke and antibiotic-resistant infections. Also, as outrageous as they are, prices are not the real issue. Value is. What really frustrates people are expensive drugs that do not provide a cure. For instance, Opdivo adds an average of 3.2 months of life to lung cancer patients and costs $150,000 per year for treatment. [↑](#footnote-ref-118)
119. ####  Goldacre

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 [↑](#footnote-ref-120)
121. Ho, Vivian. [Reporter for US News]. “The Harm of High Drug Prices”. US News, 2016. <https://www.usnews.com/opinion/policy-dose/articles/2016-12-12/the-harm-of-highdrug-prices-to-americans-a-continuing-saga>

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

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Stripping out the one-off $10bn (£6.2bn) the company made from spinning off its animal health business [↑](#footnote-ref-123)
124. **https://smallbusiness.chron.com/cutting-prices-good-marketing-strategy-61446.html**

**Selling at a lower price often increases your sales volume,** hopefully **making up for your decreased profit per unit by returning bigger gross profits.** Raising your price might increase your profit margins, but often results in a decrease in sales volumes. In a best-case scenario, a price increase creates enough perceived value among consumers that you realize both increased profit margins and sales volumes. Test different prices in several geographic areas to learn the elasticity of the demand for your product and help you find the optimal selling price. [↑](#footnote-ref-124)
125. leaves a margin of 24%, still pretty spectacular by any standard. **In the UK, for example, there was widespread anger when the industry regulator predicted** energy **companies' profit margins would grow from 4% to 8% this year.** [↑](#footnote-ref-125)
126. **In European countries, drugs are priced at what a public agency deems its fair value; critical drugs won’t be overpriced**

**Lo, 17** – (Chris, “Challenging the link between pharma innovation and US drug pricing,” Pharmaceutical Technology, 12 May 2017, https://www.pharmaceutical-technology.com/features/featurechallenging-the-link-between-pharma-innovation-and-us-drug-pricing-5813154/, CD - JO)

In many cases, **European countries follow** more of **a ‘fair value’ method, by which public agencies judge the clinical worth of a drug** and insist that its price matches its perceived value. This means that **national authorities are responsible for evaluating the innovative characteristics of new therapies and translating their benefits over current standards of care into their price calculations.** [↑](#footnote-ref-126)
127. \.S. government (**U.S.) global health efforts** aim to **help improve the health of people in low- and middle-income countries** while also contributing to broader U.S. global development goals, foreign policy priorities, and national security concerns. The U.S. has been engaged in international health activities for more than a century and today is the largest funder and implementer of global health programs worldwide. Many different U.S. government departments and agencies, congressional committees, and funding streams are involved in these efforts. Through both bilateral programs and multilateral engagement, the U.S. supports activities that address a range of global health challenges (including but not limited to HIV, malaria, family planning and reproductive health, and maternal and child health) in more than 70 countries. Total **U.S. global health funding was $10.8 billion in FY 2018**, up from $5.3 billion in FY 2006; the current Administration, however, has proposed significantly reducing global health funding for FY 2019. [↑](#footnote-ref-127)
128. This is because most **foreign governments, which are the primary buyers in their respective pharmaceutical markets, force drug manufacturers to comply with pricing rules to gain market access. Through this leverage, foreign governments are able to set drug prices below those that prevail in the United States** and erode the returns to innovation manufacturers might otherwise see from selling in their markets. Among members of the Organization for Economic Co-operation and Development (OECD), CEA estimates that Americans pay more than 70 percent of patented biopharmaceutical profits, despite the fact that the United States accounts for only 34 percent of OECD GDP at Purchasing Power Parity (PPP). [↑](#footnote-ref-128)
129. Apr 19th, xx-xx-xxxx, "The price of Africa's cheap drugs," Economist, https://www.economist.com/unknown/2001/04/19/the-price-of-africas-cheap-drugs [↑](#footnote-ref-129)
130. **First, drug companies are increasingly testing their new products** on people who will never benefit from them. Evidence exists that **companies see the developing world as a “virgin territory” with millions of potential trial subjects.** For example, CenterWatch, a clinical trials listing service, recently published an article called “Latin American fever,” in which it said that the continent “may offer a unique opportunity to reach much larger numbers of study subjects.”3 In 1994, Eli Lilly enrolled just 590 trial patients across Africa, the Middle East, and central and eastern Europe. This year, the company expects to enroll 7,309 subjects.4 It is cheaper to conduct trials in poor countries, which often have fewer regulatory controls, so the industry stands to benefit. But the trial subjects rarely do. Trials in poor countries are associated with local improvements in health care only while the trials are ongoing. **The improvements are rarely sustained after the trials end and the companies have withdrawn their treatments and patient monitoring.**5 Many drugs tested in the developing world are designed to treat conditions that largely affect industrialized, not developing, nations. And although in theory new treatments may be available to all who might benefit after being tested in poor countries, their inflated prices usually put them out of the reach of the study population. **The second way in which the poor lose out is that drug companies can refuse to market products that would save lives in the tropics but do not reap corporate rewards.** An illustration is the story of the drug eflornithine, which was originally developed—but found to be ineffective—as an anticancer agent. The drug is effective against African sleeping sickness,6 which claims thousands of lives annually in sub-Saharan Africa. It is the only known treatment for the resistant form of the disease, which has a prevalence of up to 20% in parts of Uganda.7 Hoechst Marion Roussel**, the company that developed it, stopped its production** in 1999, citing commercial failure. This decision **left thousands dying of a curable illness without treatment.** Would the US government stand by and allow a drug company to refuse to market a safe treatment for a disease that killed thousands of US citizens every year? We doubt it. And there is a distasteful twist in the story. Bristol-Myers Squibb and Gillette have just introduced Vaniqa, a facial cream containing eflornithine HCl, the “first and only prescription cream proven to slow the growth of unwanted facial hair in women” (www.vaniqa.com). The drug may indeed reach Africa, but only because its cosmetic properties make it profitable. **A third way in which the pharmaceutical industry stands to profit at the expense of others is in its attempts to prevent poor countries from manufacturing generic versions of essential medicines.**8 The industry fiercely guards its patents, and it has been aided by the World Trade Organization's agreements on intellectual property rights, which include the right to exclusively market a patented drug for at least 20 years. [↑](#footnote-ref-130)
131. Robert Pear, 5-9-2018, "To Lower Drug Costs at Home, Trump Wants Higher Prices Abroad," No Publication, https://www.nytimes.com/2018/05/09/us/politics/trump-prescription-drug-prices.html [↑](#footnote-ref-131)
132. No Author, 6-29-2016, "Drug Price Controls Are Vital in a Market That's Not Free," No Publication, <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-are-vital-in-a-market-thats-not-free>

The producers argue that this will stifle their incentive to innovate. But the evidence is increasingly clear that we cannot count on the private sector to make necessary medicines affordable. In fact, given the incentive structure, neither can we count on private drug companies to develop the drugs we most need versus the ones that will be most profitable. In health economics, maximizing social benefits is often at odds with private benefits. [↑](#footnote-ref-132)
133. Sampat- No Author, xx-xx-xxxx, "What Are The Respective Roles Of The Public And Private Sectors In Pharmaceutical Innovation?," No Publication, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0917> [↑](#footnote-ref-133)
134. Mariana Mazzucato, 8-1-2013, "State of innovation: Busting the private-sector myth," New Scientist, <https://www.newscientist.com/article/mg21929310-200-state-of-innovation-busting-the-private-sector-myth/>

The examples don’t just come from the military arena, either. **The US National Institutes of Health spends around $30 billion every year on pharmaceutical and biotechnology research and is responsible for 75 per cent of the most innovative new drugs annually.** Even the algorithm behind Google benefited from US National Science Foundation (NSF) funding. [↑](#footnote-ref-134)
135. In the United States**, it takes an average of 12 years for an experimental drug to travel from the laboratory to your medicine cabinet**. That is, if it makes it. Only 5 in 5,000 drugs that enter preclinical testing progress to human testing. One of these 5 drugs that are tested in people is approved. **The chance for a new drug to actually make it to market is thus only 1 in 5,000. Not** very good odds. The process of drug approval is controlled in most countries by a governmental regulatory agency. In the U.S., the Food and Drug Administration (FDA) governs this process. The FDA requires the following sequence of events before approving a drug [↑](#footnote-ref-135)
136. Here, using a large database that contains information on R&D projects for more than 28,000 compounds investigated since 1990, we examine the **decline of R&D productivity in pharmaceuticals in the past two decades** and its determinants. We show that this decline is associated with **an increasing concentration of R&D investments in areas in which the risk of failure is high**, which correspond to unmet therapeutic needs and unexploited biological mechanisms. We also investigate the potential variations in productivity with regard to the regional location of companies and find that although companies based in the United States and Europe differ in the composition of their R&D portfolios, there is no evidence of any productivity gap [↑](#footnote-ref-136)
137. On average, the 30 large and small pharmaceutical and biotech companies IDEA **Pharma examined got just 11% of their 2017 revenue from drugs developed within the past five years**, says Mike Rea, the firm’s CEO and one of the most insightful people I’ve met—no exaggeration—when it comes to pinpointing innovation choke points in the drug industry. Take out Gilead and Biogen from the mix and the group average drops to 8.1%. Nineteen of these 30 **companies, meanwhile, got less than 7% of sales in the last calendar year from “new” products, says Rea**. Please read his LinkedIn essay on this for more context (and you might want to follow him on Twitter, too). [↑](#footnote-ref-137)
138. To encourage the costly development of new antibacterial drugs, **FDA Commissioner** Scott Gottlieb has mentioned the possibility **of a reimbursement model for antibiotics that met certain criteria, primarily their ability to target dangerous, multi-drug resistant infections.** **Both the CDC and the National Institute of Allergy and Infectious Diseases have developed strategic plans and solutions initiatives to fight antimicrobial resistance.** [↑](#footnote-ref-138)
139. Just two years after Novartis announced it would embrace the challenge of searching for cures for life-threatening infections known as superbugs, **the drugmaker said last week it would exit antibacterial and antiviral research. Novartis' retreat follows a growing trend of big pharmaceutical companies** — including AstraZeneca, Sanofi, and Allergan — that **are exiting from this type of research because of a lack of profit. That leaves Merck, Roche, GlaxoSmithKline, and Pfizer** as the remaining pharmaceutical companies with active antibiotic programs, according to Nature Biotechnology. Only 12 antibiotics have been approved since 2000. [↑](#footnote-ref-139)
140. Andrew W. Lo, 1-21-2014, "Wall Street's next bet: Cures for rare diseases," Fortune, http://fortune.com/2014/01/21/wall-streets-next-bet-cures-for-rare-diseases/, accessed 10-22-2018 Josh B.

An orphan disease mega-fund is not only a potentially attractive investment; it’s also a potential lifesaver. **The drug development process has become expensive, lengthy, and risky — and not just for orphan diseases. The biotech and pharmaceutical sectors have performed miserably over the past decade, which has caused venture capital flows to wane.** At the same time, government funding — another important source of funding for biomedical research — has been declining. In other words, this is an area desperate for funding, and a mega-fund would bring much-needed resources to drug discovery. The fund also has appeal to philanthropists and patient advocacy groups because they can put their dollars to work in a new way — by providing financial guarantees to mega-fund securities. The impact of such guarantees is to reduce the risk of the mega-fund, greatly expanding their appeal to a broader audience of potential investors, giving philanthropists just what want: impact. Finance doesn’t have to be a zero-sum game. With sufficient scale and proper financial engineering, you can actually do well by doing good. [↑](#footnote-ref-140)
141. Jacob Bell, 9-26-2017, "What does venture capital look for when investing in biopharma?," BioPharma Dive, https://www.biopharmadive.com/news/what-does-venture-capital-look-for-when-investing-in-biopharma/505885/, accessed 10-22-2018 Josh B.

**Venture capital is frequently a vital resource for fledgling drugmakers, but not all investments are made the same. A drug's therapeutic target, stage in development and potential to yield returns shape whether its manufacturer is worth backing — or whether money would be better spent elsewhere**. At least, that's according to a few prominent life science investors. During a Tuesday panel discussion at the BioPharm America conference in Boston, Todd Foley of MPM Capital Inc., Kevin Johnson of Medicxi and Nilesh Kumar of Novo Ventures explained what catches the eyes of biopharma-focused VCs. Particularly attractive are medicines ahead of the curve, aimed at diseases likely to move into the spotlight over the next few years. "We do react to trends and emerging trends and try to build what we think the pharma companies are going to want to buy," Foley said. The biopharma sector literally has a wealth of VC funding at its fingertips. Biotechs, for instance, received the second most venture funding of any industry in the first half of 2016 despite [overall declines in deal value and volume](https://www.biopharmadive.com/news/pwc-biotech-deal-values-and-volume-drop/428425/) across a number of industries, including the life sciences. Those investments come from companies like MPM, which has provided capital to 23andMe Inc., Radius Health Inc. and Valeritas Inc. MPM specializes in financing early-stage life sciences businesses, usually conducting pay rounds in the $40 million to $60 million range, according to Foley. Identifying promising preclinical assets, therefore, is key to MPM's strategy. "As early-stage investors, we're willing to take significant biology risk and early development risk," Foley said. While not every drug selected will be a winner, those that hit can offer huge returns because "you start to see the value is quite high after proof of concept," he said. Therapeutic areas come into play as well. Treatments for neurodegenerative diseases are on MPM's radar. So are immuno-oncology drugs — as is the case across many life science VC funds. Behind each target, investors are considering how the candidate fulfills patient needs, according to Medicxi's Johnson. **"The general rule we think works is if you put the patient at the center of it, you won't go far off. Even though the world may not know it needs a particular modality for a particular condition, if you can see how that's really going to make an impact," then a VC can reason out whether a therapy is worth investing in, he said**. With the backing of Novartis AG and Alphabet Inc., Medicxi in June [launched a $300 million fund](https://www.biopharmadive.com/news/novartis-verily-venture-medicxi-european-biotech/445084/) aimed at European biotechs in late-stage drug development. At the time, Medicxi said it would be funding companies that craft treatments for unmet medical needs, but didn't specify much further. Yet, according to Johnson, at the top of the investor wish list are products that are forward-thinking rather than currently fashionable. "You do sort of have to have the idea of what's going to be a must-have in five years or beyond. The chances are it's not what's hot now — and I think people want to be in a hot area because it feels like where complex and interesting dealmaking are," he said. **In any case, investments are more likely to pour in when a company's drug is supported by strong data, particularly evidence demonstrating its effectiveness both in animals and in the clinic.** "People come up to us with some great animal data. The problem is attrition rates in those things and translatability to man is huge, they're a very difficult thing to go into. And once you've got something [that can make that leap], it's a huge validation that this stands a chance of working," Johnson said. [↑](#footnote-ref-141)
142. ####  Large Pharma decreasing investment

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

But what about Big Pharma’s internal investment in R&D? Traditionally, this has been relatively high, running at approximately 15% of top line revenues. Will this level of spend – higher than any other industry – be sustainable? A new analysis, “[World Preview 2018, Outlook to 2024”](http://info.evaluategroup.com/rs/607-YGS-364/images/WP2018.pdf) newly issued by *EvaluatePharma* provides guidance on this. Interestingly, *EvaluatePharma* is predicting accelerating sales for the pharmaceutical industry with annual compound growth of 6% between now and 2024. “The launch of novel therapies, including gene and cell therapies, as well as increased access to medicines globally should help fuel progress in the market. Total prescription sales are expected to be $1.2 trillion in 2024.” But, these higher sales are not expected to translate into higher R&D investments. “R&D spend is forecast to grow at a CAGR of 3.1% to 2024 lower than the CAGR of 3.6% between 2010 and 2017 signaling that companies will be improving R&D efficiencies or less revenue will be directed towards replenishing pipelines.” While disappointing, it is important to put these numbers into perspective. According to *EvaluatePharma*, in 2017 the top 20 pharmaceutical companies invested 20.9% of top line revenues into R&D - a very impressive number. This amounted to $97.2 billion in 2017. For comparison purposes, the NIH budget is $37 billion. In 2024, *EvaluatePharma* is projecting that the top 20 companies will be spending $116.4 billion on R&D, 16.9% of sales – still a very high percentage when compared to other industries. The 2024 leaders will be Roche at $11.7B, Johnson & Johnson at $10.0B and Novartis at $9B. These changes are probably not enough to allay Stott’s concerns. However, it is clear that the pharmaceutical industry is going to continue to invest in R&D at a pretty healthy rate for the foreseeable future. For all of our sakes, it is imperative that their efforts are successful. [↑](#footnote-ref-142)
143. **Virtually no innovation is happening now**

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

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

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

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

So, we in the US continue to overpay for brand name prescription medications, but **the pharmaceutical industry has given us almost no new important therapies in more than 15 years.** A somewhat unexpected result of this is that, total pharmaceutical revenue has been nearly flat since 2010. [↑](#footnote-ref-143)
144. **US government substantially subsidizes drug R&D**

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

This innovation has occurred within the context of an implicit social contract. **The U.S. government substantially subsidizes basic research and the provision of health care**, and it waives its ability to negotiate directly with manufacturers about prices. In return, the biomedical industry is allowed to attempt to recoup its R&D investments during a limited post-approval period defined by the Drug Price Competition and Patent Term Restoration Act of 1984 (often called the Hatch–Waxman Act), with the expectation that drug prices will be set at a point that ensures a reasonable level of population access. [↑](#footnote-ref-144)
145. **NIH funding is associated all 210 drugs approved from 2010-2016**

**Cleary, 18** – (Galkina, “Contribution of NIH funding to new drug approvals 2010–2016,” Proceedings of the National Academy of Sciences of the United States of America, 12 February 2018, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5878010/, CD - JO)

This report shows that **NIH funding contributed to published research associated with every one of the 210 new drugs approved by the Food and Drug Administration from 2010–2016. Collectively, this research involved** >200,000 years of grant funding totaling **more than $100 billion.** The analysis shows that >90% of this funding represents basic research related to the biological targets for drug action rather than the drugs themselves. The role of NIH funding thus complements industry research and development, which focuses predominantly on applied research. This work underscores the breath and significance of public investment in the development of new therapeutics and the risk that reduced research funding would slow the pipeline for treating morbid disease. [↑](#footnote-ref-145)
146. https://www.beckershospitalreview.com/human-capital-and-risk/job-cuts-in-healthcare-pharma-industries-soar-in-2017-3-things-to-know.html

While job cuts across all U.S. industries decreased by 22 percent in 2017, both **pharmaceutical and healthcare sectors saw a stark increase in job cuts** in 2017, according to a recent report published by Challenger, Gray & Christmas, an outplacement and career transitioning firm. Here are three things to know. 1. **The healthcare sector announced 38,145 job cuts so far this year, which is a 123.9 percent increase** from the 17,030 dismissals announced through the same period a year prior. [↑](#footnote-ref-146)
147. **https://www.rdmag.com/article/2017/07/growing-role-automation-pharmaceutical-industry**

Despite being an old concept, **automation and the extent of its adoption is at its highest peak in the industry.** Therefore, pharmaceutical organizations need a better understanding of its benefits and ensure they have a stringent automation strategy in place to guarantee they partner with the best technology provider that can deliver business efficiency without compromising security. [↑](#footnote-ref-147)
148. [**https://www.theengineer.co.uk/automating-pharmaceuticals/**](https://www.theengineer.co.uk/automating-pharmaceuticals/)

A recent study by the Association for Packaging and Processing technologies (PMMI) has predicted that **robots will handle 34 per cent of primary pharmaceutical** packaging **operations in North America by 2018.** An increase in the use of robots is particularly significant in dispensing, sorting, kit assembly and light machine-tending. The advantages include greater speed and accuracy, more flexibility and more reliability. [↑](#footnote-ref-148)
149. https://www.independent.co.uk/news/business/investment-should-you-invest-in-pharmaceutical-companies-1090074.html

Jeremy Batstone of NatWest Stockbrokers has a different focus." **Pharmaceuticals have been very volatile and the sector has tended to lag the market**," he says. "**People are looking more for value as the economy has improved, away from more defensive growth areas like pharmaceuticals."** Mark Mathias, head of investment funds at Rea Brothers Investment Management, agrees the sector's long-term growth potential is undisputed. Mathias, whose firm runs two specialist pharmaceutical funds, says: "There is the trend to ageing populations in the OECD countries, with the highest proportion of lifetime healthcare expenditure coming in the last two years of life, underpinned by the significant increase in healthcare research expenditure. At the same time, the OECD governments are trying to rein in the cost of government-subsidised healthcare and the way you do that is to spend more on drugs to keep people out of hospital." [↑](#footnote-ref-149)
150. Data published today by the ABPI shows that **the pharmaceutical industry continues to invest significantly in UK research** and development despite the future uncertainty of Brexit – working closely with healthcare professionals and organisations to improve patient care. The data published on Disclosure UK – the pharmaceutical industry’s database of payments and benefits in kind made to UK healthcare professionals (HCPs) and organisations (HCOs) – shows **industry spent £370.9 million on partnerships relating to research and development¹ activities in the UK during 2017. This is a 9.7% increase on 2016** (£338.1 million). Spending on research and development activities accounts for three quarters of the total spending disclosed on the database for working in partnership with leading UK health experts and organisations to improve patient care. [↑](#footnote-ref-150)
151. <https://innovations.bmj.com/content/2/3/111>

In the past decades, North American and European countries actively sought to increase the size of their venture capital markets.6–10 **The levels of venture capital available to Canadian life sciences companies have more than doubled** from 2001 to 2010.11 In Europe, the UK enjoyed in 2009 the second largest venture capital market, accounting for 21% of all investments. In the same year, 20% of the UK £677 million of venture capital was invested in the health sector.4 [↑](#footnote-ref-151)
152. **When Viagra surged into consumers' bedrooms, Pfizer's stock enjoyed a sudden rise** - satisfying investors and consumers alike. Although Pfizer was far from an unknown company at the time, most of us did not hold stock. There are many reasons why an investor may not feel comfortable investing in pharmaceutical companies, but if you do want to get in on the next little blue pill there is still the obstacle of how to evaluate the industry. This article will explore some of the issues involved in pharmaceutical investing. [↑](#footnote-ref-152)
153. **Jones**, John. “Big Pharma's Lobbyists Are Losing despite Their 'Pass the Buck' Campaigns.” **TheHill**, 5 Mar. **2018**, thehill.com/opinion/healthcare/376699-big-pharmas-lobbyist-are-losing-despite-their-pass-the-buck-campaigns.

However, **their polling numbers remain as low as before their advertising blitz began as Americans have overwhelmingly negative views of drugmakers** and the pricing schemes of “Pharma Bro" Martin Shkreli and others who increased drug prices simply because they found that they could. The response from the drugmaker lobby has been to rollout slick public relations slogans like “Share the Savings” and “Let's Talk About Cost” that use fancy infographics in an attempt to move the conversation away from those setting the price of the drug (drug companies) to everyone else who uses or pays for their products, like employers, hospitals, pharmacy benefit managers, insurers, and others. This isn’t surprising and certainly not unpredictable, but ignores the basic challenge facing drug companies: **no amount of money can change the fact that Republicans and Democrats know the problem is high drug prices and that drugmakers alone set those prices**. So **despite** all this overwhelming **lobbying and financial firepower, the question remains: Why are drugmakers losing? In the recent budget bill, drugmakers were singled out by both parties to pay billions more in discounts to help seniors** in the Medicare prescription drug benefit “donut hole [↑](#footnote-ref-153)
154. **Bowmer**, Rick. “Fighting Special Interest Lobbyist Power Over Public Policy.” **Center for American Progress**, 27 Sept. **2017**, https://www.americanprogress.org/issues/democracy/reports/2017/09/27/439 675/fighting-special-interest-lobbyist-power-public-policy/.

**Some proposals would even ban members from lobbying permanently.** Extending the ban on lobbying would give lawmakers one less reason to elevate special interest concerns over the concerns of their constituents. Implementing effective policies to fight the corrupting influence of special interest lobbyists depends on an accurate and effective system of lobbyist registration. Unfortunately, the current definition is all too easily evaded and has resulted in many people engaged in lobbying activities deregistering or failing to register in the first place. Fortunately**, bills have been introduced** in both the House and Senate **that would institute a commonsense definition of lobbying that applies to anyone who makes more than one lobbying contact on behalf of a client over a two-year period.** In addition to enabling enforcement of the proposals above, expanding lobbying disclosure would also allow the public to better understand who is spending money to try to influence government—as well as how much money is being spent—so that representatives are held accountable. [↑](#footnote-ref-154)
155. **Ferry**, David. “The New War on (Overpriced) Pharmaceuticals.” **Wired**, Conde Nast, 8 Nov. **2017**, www.wired.com/story/fighting-high-drug-prices/.

President Donald **Trump has said that the pharmaceutical industry is “getting away with murder” and that he wants to let Medicare negotiate with drug companies over the prices we pay—**something that was forbidden in 2003, part of a compromise with the politically potent industry to get the Medicare drug expansion plan passed. (Since 1998, Big Pharma has spent more on lobbying than any other industry.) [↑](#footnote-ref-155)
156. Joe Nocera, 10-23-2017, "Here's how drug companies game the patent system," chicagotribune, <https://www.chicagotribune.com/news/opinion/commentary/ct-perspec-drugs-health-care-pharm-1024-20171023-story.html> [↑](#footnote-ref-156)
157. **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-157)
158. William, U.S. International Trade Commission, 2007 “The Emergence of India’s Pharmaceutical Industry and Implications for the U.S. Generic Drug Market”, [http://www.usitc.gov/publications/332/ working\_papers/EC200705A.pdf](http://www.usitc.gov/publications/332/%20working_papers/EC200705A.pdf))

**There are approximately 34 foreign drug companies engaged in the Indian pharmaceutical market and among them are 15 of the world’s 20 largest pharmaceutical companies.** According to FICCI, although MNCs have not launched new products **they have invested in new production facilities and R&D centers and many are engaged in contract manufacturing, clinical trials, and other forms of outsourcing.**25 In 2005-06, MNCs invested more than $172 million in India’s pharmaceutical industry and FDI has grown by a compound annual growth rate (CAGR ) of 62 percent during 2002-06.26 However, many industry experts believe that the return of the world’s leading pharmaceutical companies will gradually erode India’s cost advantages. According to the Organization of Pharmaceutical Producers of India, multinational drug companies currently command 24 percent of the domestic Indian market, through their share could rise to 40 percent by 2010.27GSK-India, a 51 percent subsidiary of GSK Plc (UK), is the largest foreign company in India’s pharmaceutical market, its fourth largest pharmaceutical company, and leading prescription drug supplier**. GSK-India operates two Indian manufacturing plants and controls approximately 5.9 percent of the domestic Indian market.** GSK-India is among India’s leading suppliers of anti-infective, anti inflammatory, analgesic, gastroenterological, anti-allergic, and dermatological drugs**. GSK-India announced plans to extend its product line by launching several antibiotic, cancer, and cardiovascular products in India in the near term.** Likewise, MNCs dominate India’s OTC (over the counter) drug market, with Pfizer accounting for 5.1 percent of the market, Sanofi-Aventis for 5.0 percent, and Johnson & Johnson for 4.8 percent. These companies offer analgesics, cough and cold preparations, indigestion medicines, skin care products, and vitamins and minerals. Other foreign multinationals active in India’s pharmaceutical market include: Bristol-Myers Squibb, Eli Lilly, Boehringer, Bayer, Chiton Corp, Abbott, AstraZeneca, Janssen, and Roche. Recently, Teva Pharma (Israel), the world’s leading generic drug manufacturing company, acquired a bulk drug manufacturing and intermediate facility in the State of Uttar Pradesh, announced plans to add two more units, and more than triple the value of its exports from India by the end of 2007. Teva also opened an R&D facility in India and announced plans to register between 10 and 15 bulk drugs per year in the United States from its Indian facilities. Mergers, acquisitions, and other alliances: The last 3 years have seen a significant rise in the number of consolidations, mergers & acquisitions, and other types of alliances and tie-ins in the Indian pharmaceutical industry. **Most of the acquisitions involve Indian companies searching for ways to penetrate overseas markets and widen their global footprint, diversify and enhance their product portfolios, offer their customers a ‘nearshore-offshore’ option, improve their custom manufacturing, packing, and R&D capabilities, acquire existing brands, and gain access to the highly regulated markets of Western Europe and the United States. Indian companies without significant R&D capabilities for drug discovery are also purchasing Western drug discovery companies. In 2005-06, 18 Indian companies spent approximately $1.6 billion to acquire generic drug manufacturing firms in Europe, North America, and Mexico.29 These companies included Ranbaxy, Dr. Reddy’s Labs, Nicholas Piramal, Sun Pharmaceutical, and Jubilant Organosys** (table 5).30 Although eleven of these transactions were for medium-and-small sized companies valued between $5 million and $30 million, several have been significant acquisitions valued in excess of $500 million. To date, Dr. Reddy’s purchase of Betapharm Arzneimittel of Germany for $572 million is the industry’s largest overseas acquisition. [↑](#footnote-ref-158)
159. Pbm Rebate, 7-19-2018, "The Perverse Incentives Created by PBM Rebate Arrangements," Morning Consult, <https://morningconsult.com/opinions/perverse-incentives-created-pbm-rebate-arrangements/> [↑](#footnote-ref-159)
160. ####  New York Times

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

The numbers are staggering. “Studies have consistently shown that **20 percent to 30 percent of medication prescriptions are never filled**, and that approximately 50 percent of medications for chronic disease are not taken as prescribed,” according to a review in Annals of Internal Medicine. People who do take prescription medications — whether it’s for a simple infection or a life-threatening condition — typically take only about half the prescribed doses. This **lack of adherence**, the Annals authors wrote, **is estimated to cause approximately 125,000 deaths and at least 10 percent of hospitalizations**, and to cost the American health care system between $100 billion and $289 billion a year. Former Surgeon General C. Everett Koop put it bluntly: “Drugs don’t work in patients who don’t take them.” This partly explains why new drugs that perform spectacularly well in studies, when patients are monitored to be sure they follow doctors’ orders, fail to measure up once the drug hits the commercial market. [↑](#footnote-ref-160)
161. 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-161)
162. 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-162)
163. 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-163)
164. 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-164)
165. 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-165)
166. 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-166)
167. 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-167)