Resolved: The United States Federal Government should impose price controls on the pharmaceutical industry.

Our First Contention is driving down prices

Currently, American drug prices are artificially inflated to dangerous levels. Blumenthal of the Commonwealth Fund in 2018 furthers that federally enforced patent laws have created government-sanctioned monopolies by outlawing competition.

As a result, the National Center for Policy Analysis in 2017 finds that over the past few years, even the price of generic drugs has increased at unprecedented rates, with over a thousand increasing by up to 500%.

This trend shows no sign of stopping. Thaul of the Congressional Research Service in 2018 projects that prescription drug costs will increase by 6% every year for the next decade.

The solution is simple – to control the skyrocketing prices of pharmaceuticals, the US should adopt price controls. As Pettinger of Oxford in 2017 explains, price controls mean that firms aren't allowed to set prices above a certain level, leading to lower prices for consumers.

This is empirically proven, as the American Journal of Managed Care in 2015 finds that European countries that imposed price controls, such as Germany, Spain, and Italy saw the prices of pharmaceuticals decrease by up to 24%. Jena of the Hill in 2018 thus argues that the reason foreign pharmaceutical prices are far lower than American prices is because nearly all countries except the U.S. have policies to lower drug costs.

Lowering drug prices is key for increasing access.

When drug prices are high, many are faced with the choice of either forgoing their prescription or going into debt. McGrath of Forbes in 2016 confirms that 63% of Americans don't have enough savings to cover a $500 dollar emergency medical expense. As a result, Dart of the PJ Institute quantifies that within the last year alone, 45 million Americans did not fill their drug prescriptions due to overwhelming costs.

Even when Americans manage to purchase these drugs, the costs they incur push them deeper into poverty. Weissman of Slate Magazine confirms that in 2016, medical expenses drove 11.2 million Americans into poverty. Crucially, poverty hurts long-term health, which is why Columbia University '16 concludes that poverty is one of the leading cause of death in America.

Our second contention is value based pricing.

Currently USFG is testing and planning to implement a value based pricing process, a process that would make price controls lower for the drugs that are needed the most by consumers. A value based process differs from simple price cap as it does not place the same generic ceiling on all drugs, instead it places different constrictions on drugs based on societal benefits and alternative drugs already on the market.

The **Hogan Lovells Foundation** found that the shift towards a value based process has already begun. The **Deloitte Institution in 2012** found that nearly all policy makers and government payers have aligned with the move towards value based pricing. If that weren't enough, President Trump has outlined the policy in his new drug pricing plan. This

policy is far more likely to be implemented because instead of harming the pharma industry, it just redirects attention in far more beneficial direction.

Mitenna from Forbes in 2018 finds that the reason why support for this pricing model has been so high is because drug revenues for drug companies could potentially increase. This is because the government bonus for good outcomes could exceed the penalty for bad ones. He concludes that a value based pricing system may actually result in a win-win situation in which drug prices are on net lower, yet drug companies still garner enough profits to further innovation.

The **Independent in 2013** finds that currently big pharmaceutical companies have begun to focus on lifestyle drugs, like hair loss and erectile dysfunction, rather than growing concerns within today's society.

Critically, affirming switches this trend as the **PTB** reports that pharmaceutical companies can maximize their benefits by directing resources and research efforts towards areas likely to achieve higher price/ reward. Remember that the drugs that receive the most rewards are those that have the most impact on patients' lives.

As a result Ocana in 2013 finds that value based pricing would put pressure on pharma companies to develop innovative drugs that have a **visible** impact on patients lives. That's why **The Hill in 2018** finds that the value based prices are the **key** to biomedical innovation, a sector that has the opportunity to reduce hospital costs for everyone by 1.5 billion dollars.

Frontlines

F2/ Drug Shortages

1) De-Link: **Devi** of **The Lancet** in 2012 explains that the FDA ensures that patients maintain access to critical drugs, with a 2011 executive order requiring drug companies to report to a federal agency when supplies were threatened. In fact, **Roy** of **Forbes** in 2012 furthers that since the approval of the executive order, the FDA has prevented over 150 shortages in under a year. In fact, **Elvidge** of the **Biopharma Drive** explains in 2017 that the FDA created a new task force specifically to minimize the impact of drug shortages on patients and create long-term solutions to drug shortages.

2) A2: Increasing Healthcare Costs: Their argument's logic is that when people have to go to the doctor more often, their copays eventually add up and cost them more. That's wrong for two main reasons, the first of which is that copays for most insurance holders aren't even that much. **Debt.org** finds that they are only $15-25 per visit. Second, we would outweigh with our decreasing insurance premiums, which are thousands of dollars per person as compared to the $25 per visit. We save the people more, on net.

3) Copays are $15-20
https://www.debt.org/medical/health-insurance-premiums/
A typical copay for a routine visit to a doctor's office, in network, ranges from $15 to $25; for a specialist, $30-$50; for urgent care, $75-100; and for treatment in an emergency room, $200-$300. Copays for prescription drugs depend on the medication and whether it is a brand-name drug or a generic version.

Suzanne Elvidge, “FDA creates task force to combat drug shortages”, BioPharma Drive, July 13, 2018, https://www.biopharmadive.com/news/fda-creates-task-force-to-combat-drug-shortages/527734/, SP, October 19, 2018

New drug shortages in the U.S. have been steadily declining since a peak in 2011. **However, in 2017, The Food and Drug Administration tracked more new drug shortages than in either of the two previous years.** These disruptions followed issues at a Pfizer manufacturing plant in Kansas, and a damaging hurricane season wiping out facilities in Puerto Rico. While last year may be an aberration, the FDA announced its commitment in June to mitigating existing issues and preventing new ones from occurring.

Food and Drug Administration head Scott Gottlieb has formed a new task force to try to minimize the impact of drug shortages on patients and physicians. This will focus on creating long-term solutions to the "underlying structural concerns that give rise to these recurring challenges."
The task force, which will be led by Keagan Lenihan, the agency's associate commissioner for strategic initiatives, has been charged by Gottlieb to look into why some shortages remain an issue. The task force will include senior leaders from the FDA, the Centers for Medicare and Medicaid Services and the Department of Veterans Affairs. The next step will be to engage with the public, and hold a meeting with stakeholders.

As the rolling waves of generic drug shortages and recent escalations in generic drug prices should remind us, both of these assumptions are questionable. The market’s invisible hand works until it doesn’t, and then, as Adam Smith wrote in The Wealth of Nations, we are left with conditions of market failure when supply doesn’t meet demand. **In the generic drug industry, market failure occurs when a crowd of different companies that once competed to sell a drug like doxycycline ditch it to pursue more profitable drugs, leaving just one generic supplier—or a new gray-market monopoly able to raise prices just like brand-name manufacturers. This happens in part because generic companies are drawn toward the market exclusivity of newer drugs when they come off patent, in part because of bottlenecks in the supply of precursor chemicals, and in part because of shrinking margins in the production of older generic drugs. The stampede leaves the supply of many older but essential medicines in the hands of just a few suppliers, whose production lines are unprepared to deal with surges in demand, leading to shortages of key pharmaceutical agents needed for the treatment of cancer, pneumonia, and heart disease, as well as for basic anesthesia**. Prices eventually recede—but by then, usually, other drugs are seeing similar cost surges.

Avik Roy, ‘How Margaret Hamburg's FDA Causes Cancer Drug Shortages”, Forbes, June 15, 2012, https://www.forbes.com/sites/theapothecary/2012/06/15/how-margaret-hamburgs-fda-causes-cancer-drug-shortages/#5f780c164a03, SP, October 21, 2018

Preventing drug shortages is a top priority for the FDA. In the seven months since the President’s Executive Order, FDA has made important progress on drug shortages. Early notification by manufacturers has made a huge difference in our ability to prevent these shortages. **More than 150 shortages have been prevented since the Executive Order and the agency has prevented more than 50 shortages so far in 2012 due to early notification from manufacturers, which is voluntary.**

Sharmi Devi, “Maryland already sets hospitals’ prices. Now it wants to cap their spending.”, The Lancet, March 17, 2012, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60414-0/fulltext, SP, October 19, 2018

The FDA is at the forefront of an increasingly complex battle to ensure the USA retains access to critical drugs. President Barack Obama issued an executive order **in October, 2011, requiring drug companies to report to the federal agency when critical supplies were threatened. Meanwhile, new legislation that would make it mandatory for companies to notify the FDA of a wider range of supply problems and give it extra powers languishes in Congress. Last month, the FDA stepped in to resolve shortages of two cancer drugs that threatened thousands of patients**—methotrexate, used to combat lymphoblastic leukaemia, and doxorubicin, sold under the trade name Doxil, used to treat ovarian cancer, Kaposi's sarcoma related to HIV/AIDS, and multiple myeloma.

F2/ Doctors leave

1. Profits
2. Doctors leaving Regardless
    a. According to Paul of NBC, doctors are leaving because of two key reasons. Schooling for doctors is both extensive and expensive, doctors stay in education often till their late 20s and garner hundreds of thousands of dollars of debt.
    b. Second, Long Job hours and better alternatives. Horrid hours, and STEM jobs are far more appealing to the new generation.
    c. N/U As a conclusion a A recent report from the Association of American Medical Colleges projected a shortage of 121,300 physicians and 104,900 doctors by 2030.

F2/ Sell other countries

1. The United States is biggest market by wide margin. Swanson 15’ found the U.S., total pharmaceutical sales in 2013: $339.7 billion compared to just 94 billion for Japan. No company is going to give up that much profit

Cheryl Swanson, 5-12-2015, "5 Largest Markets for Pharmaceuticals," Motley Fool, https://www.fool.com/investing/general/2015/05/12/5-largest-markets-for-pharmaceuticals.aspx

No. 1: U.S., total pharmaceutical sales in 2013: $339.7 billion
The annual amount spent per-person on prescription drugs in the U.S. averages $1,000 -- more than twice as much as in countries like Canada, Germany, and Australia.
While the Affordable Care Act contains measures to control healthcare costs, it turns out that Americans not only spend more per drug, we also take more drugs. Disease rates are higher because of lifestyle risks such as obesity, physical inactivity, and excessive alcohol use, according to the Centers for Disease Control and Prevention. Accordingly, rates of heart disease, COPD, and diabetes are higher in the U.S. than in most developed countries.
Branded drugs take by far the biggest bite out of the healthcare drug budget, but a recent WSJarticle pointed out that the price of a variety of generics -- whether from coincidence or collusion -- has also been sky-rocketing. It's estimated that half of all small-molecule generics sold through retailers have become more expensive in the past 12 months. In some cases, price hikes exceeded 1,000%, and some even topped 17,000%.

No. 2: Japan, total pharmaceutical sales in 2013: $94 billion
Driven by the needs of a rapidly aging population, the world's third-largest economy is the world's second-largest drug market. Highly efficient drug reviews facilitate the rapid entry of new products into Japan, as seen by the country's rapid approval of Opdivo from Bristol-Myers Squibb, prior to its approval in the U.S.
Unfortunately, Japan's drug market has been declining rapidly as the economy struggles with stagnation, made worse by the triple disaster (earthquake, tsunami, nuclear leak) of 2011. The good news for Japan is that innovation in large-scale drug development is picking up.
Traditionally, Japanese drug companies keep research in-house, but that has been changing recently. Takeda Pharmaceutical, Japan's largest pharmaceutical company, is set to increase its global footprint with the announcement of incoming CEO Christopher Weber, a former GlaxoSmithKline executive. Weber will become Takeda's CEO in June, which will make him the company's first foreign CEO. Appointing a foreigner to Takeda's top job is an indication in itself that Takeda is looking to international markets.

F2/ VBP Unlikely

1) Its in trump's plan
2) Bipartisan Support
3) Pharma Companies support
    a) Corroborates: they know live-saving drug market is more profitable than lifestyle market

F2/ VBP Causes Backlog

Rosenblatt in 2017 writes that the new FDA Commissioner has announced that the FDA will reduce the backlog of generic drug applications to speed these less expensive drugs to market and enhance competition. This is crucial as Baker with Stanford Medicine reports that competition empirically lowers health-care costs

Investor's Business Daily, 2018,
https://www.investors.com/politics/editorials/drug-prices-trump-budget-medicare-price-controls/Meanwhile, the Trump administration is getting attacked because its budget plan, released last week, doesn't push to have the government set prices for Medicare drugs — something Trump himself once advocated — which would be tantamount to federal price controls on all drugs. But Trump is tackling high drug prices. Trump's FDA administrator, Scott Gottlieb, is focused on increasing price-lowering market competition. Gottlieb understands that the more choices there are, the more price competition there will be. So he's **pushed the agency to shorten approval times for generics, particularly when there's only one generic alternative on the market. He's also working to streamline the FDA's approval process for new drugs, and lifting the FDA's prejudice against so-called me-too drugs**. This sort of competition is already working. A few years ago, price-control advocates pointed to Sovaldi, a breakthrough drug that can cure hepatitis C but cost $80,000 to administer, as the poster child for price controls. Instead, the FDA last year fast-tracked approval of a second hepatitis C drug — Mavyret —which cost less than a third of Sovaldi. Suddenly, there was a price war for Hep C treatments. Competition, not price controls, cut costs overnight. **By boosting competition, Trump will be far more effective at lowering drug costs than any regime of federal price controls could ever hope to be.**

F2/ Companies don’t have resources to shift

1. Companies have resources
2. Small Businesses innovate life-saving, Big life-style

F2/ Lifestyle Drugs increase quality of life

Cards

Numbers, xx-xx-xxxx, "High Drug Prices & Monopoly," Open Markets Institute, https://openmarketsinstitute.org/explainer/high-drug-prices-and-monopoly/

Congress and the courts also made several changes to patent law that similarly encouraged monopolization, higher prices, and less innovation. These changes have made it easier for drug companies to patent minor variations in drugs, thereby enhancing the power of patent monopolies to suppress competition. Other changes and loopholes in patent law allow drug companies to pay other firms to keep competing drugs off the market, prolonging their drugs’ exclusive position. The FTC has successfully prosecuted some of these “pay-for-delay” schemes, but drug companies have responded by trading valuables besides cash to achieve the same anti-competitive effects. In addition, companies with branded drugs will stop generic drugs from coming to market by refusing to hand over the samples and safety protocols needed to produce a generic drug. This tactic artificially extends drug companies’ patents and cuts against Congress’s intent to encourage generic drugs. Other policy changes have had similar effects. In 1980, Congress passed the Bayh-Dole Act, which allowed non-profit institutions to claim patents on discoveries funded by government research. This legislation allowed universities and research institutions to privatize and profit from public investment, closing off others’ access to the fruits of public spending and raising the price of drugs that would be markedly cheaper if they weren’t patented. Because this law encourages more researchers to patent more discoveries, Bayh-Dole also means that more drugs, and more research tools, are covered by patents today. That makes it even more difficult for underfunded researchers or small companies to begin developing new drugs, as more materials are locked away by big firms. These policy changes have resulted in many negative effects, starting with monopoly pricing. In the drug industry, as with any industry, consolidation facilitates collusion. *When a few companies control a market, it becomes easier to maintain an effective cartel because no member can step out of the agreement without being quickly detected by the others.* The market for insulin may be a case in point. Since 2010, the three American manufacturers of the drug have all raised their prices by 168 percent, 169 percent, and 325 percent, respectively. *Even without forming cartels, monopolistic companies have a greater ability to raise prices because they don’t face the full pressure of a competitive market. Mylan Pharmaceuticals could raise the price of its Epipen by 450 percent precisely because it held about 90 percentof the market. And this applies to all kinds of drugs, branded and generic alike. Between 2010 and 2015, for instance, nearly a quarter of all generic drugs saw at least one price increase of 100 percent or more, and some saw increases of 1,000 percent or more.*

Colin Holtz, Guardian, 8-1-2016, Who is to blame for the EpiPen hike? Drug monopolies – not evil CEOs, https://www.theguardian.com/commentisfree/2016/aug/29/epipen-price-drug-monopolies-mylan, 11-8-2018, VK

More importantly: the moles come faster than we can whack them down. Today we are upset about EpiPens. Yesterday, it was pharma bro Martin Shkreli, who hiked the price of a life-saving HIV/Aids medicine from $13.50 to $750. On any given day, it could be Gilead Pharmaceuticals spiking the price of Hepatitis C medication while shifting operations offshore to reduce taxes, or the cabal of companies raising prices on insulin in suspicious tandem. **Almost every case of outrage over pharmaceutical prices traces back to a company that has exclusive rights over a medication. We should blame drug monopolies for skyrocketing prices, not evil CEOs.**

Policymakers look to the best option, we would argue this is

https://www.independent.co.uk/news/world/americas/bill-gates-why-do-we-care-more-about-baldness-than-malaria-8536988.html
"the large pharmaceutical companies, which have long been criticised for ploughing money into developing "lifestyle drugs" and neglecting research that could save the lives of the world's poorest."

Ocana 13

With value-based pricing, pharmaceutical companies will realize more profit from developing innovative drugs that provide greater benefit to patients in comparison with other agents that are likely to give small, albeit statistically significant, benefits in large clinical trials. Value-based pricing will lead to greater support of research to develop innovative and truly effective drugs.

Ocana 13 http://cancerres.aacrjournals.org/content/76/11/3127

introduction of value-based pricing to all new approved agents is an approach that would have the benefit of providing a framework to rationalize use of health care resources from public funding systems and those supported by private insurers. **Value-based pricing would also put pressure on pharmaceutical companies to develop innovative drugs that have an impact on patients' outcomes and to halt the development of drugs where there is a signal of only minimal benefit from early clinical studies**. In contrast, if research in cancer is not driven by profit, global investment might be reduced and moved to other areas. However, a substantial proportion of the current cost of drug development is from bringing drugs to expensive phase III trials despite signals of limited benefit from preclinical studies or early-phase clinical trials (**10**). Thus, costs could be reduced and substantial profits could still be obtained from truly effective agent

The Hill - https://thehill.com/opinion/healthcare/354913-the-future-of-drug-pricing-value-over-volume

With a new wave of breakthrough cures and therapies expected in the coming years, ensuring prescription drugs are accessible and affordable will remain an important concern for drugmakers, policymakers, and the broader public. As the drug pricing debate continues, there are some key facts to keep in mind about a **value-based model that highlight why it's important for patients and the future of biomedical innovation.**

…

Biomedical innovation not only saves and improves the lives of patients, it also reduces other forms of health care spending. For example, every $1 spent on medicine for congestive heart failure for adherent patients saves an estimated $8 in other health services. Further, the creation of the Medicare Part D prescription drug program reduced annual hospitalization costs by roughly $1.5 billion. It has been estimated that if researchers could develop a treatment to delay the onset of Alzheimer's by five years, it would generate $367 billion in annual health care savings by 2050.

…

Often policymakers respond to drug costs with calls for heavy-handed government intervention that would stymie innovation and harm patients who rely on new cures and treatments. That's why the Council for Affordable Health Coverage — a coalition including drugmakers, insurers, pharmacy benefit managers, patient groups and employers — introduced a set of consensus reforms to tackle affordability of prescription drugs. **These solutions leverage the power of the free market to promote greater access to affordable medicines and will protect biomedical innovation that saves lives.**

Austin Frakt, 10-19-2015, "To Reduce the Cost of Drugs, Look to Europe," No Publication, https://www.nytimes.com/2015/10/20/upshot/to-reduce-the-cost-of-drugs-look-to-europe.html

There is a way to keep prices low while encouraging drug companies to innovate: Look to Europe and elsewhere, where drug prices are a fraction of those in the United States. Germany, Spain, Italy and a half dozen other countries have pushed drug prices lower with a system called reference pricing. It has led to drug price decreases and significant savings in the Canadian province of British Columbia as well as in Germany, Italy, Norway, Spain and Sweden. A study published in the American Journal of Managed Care found that price reductions ranged from 7 percent to 24 percent.

John LaMittena - https://www.forbes.com/sites/johnlamattina/2018/03/28/in-battle-to-cut-drug-prices-outcome-based-pricing-carries-big-risks-for-biopharma/#54ad3f405170

But once again, the trendiest idea in drug pricing – outcome-based pricing – has little potential to really bring drug costs down. The idea behind outcome-based pricing seems promising in theory. A drug company could get paid twice as much, say, if its breast cancer drug extended someone's life longer than expected and get paid less in the opposite scenario. But the reason **drug companies support value-based pricin**g is that, under most proposals, **[because] their drug revenues could actually increase, because the bonus for good outcomes could exceed the penalty for bad ones.** Under that regime, 'value-based pricing' won't create value.

https://www.statnews.com/2017/06/08/value-based-drug-pricing/
"Outcomes-based agreements, which ensure that drug companies are paid for actual — not potential — benefits to patients are another way to better align pricing and coverage of drugs with their value."

https://www.ptbreports.org/sites/default/files/10.5530PTB.2016.1.1.pdf
"Pharmaceutical companies have knowledge of product feature that are of great value and can be rewarded. Empowered by this knowledge, pharmaceutical companies can maximize their benefits by directing resources and research efforts towards areas likely to achieve higher price/ reward (away from unrewarded areas)."

Possible second impact (although idk if very good): PWC '18 predicts **medical costs in the insurance market will increase by 6 percent next year because of high drug prices.** Problematically, Davis '18 finds **each 10 percent increase in health insurance costs reduces employment by 1.6 percent, or 4.6 million people, hitting the most vulnerable, low-income Americans hardest.** Fortunately, price controls prevent this by stopping companies from increasing drug prices, averting an unemployment crisis.

Penn Wharton Public Policy Initative, 3-16-2018, "Preventing Price Gouging in the Pharmaceutical Industry: A Comprehensive Policy Approach,"
https://publicpolicy.wharton.upenn.edu/live/news/2390-preventing-price-gouging-in-the-pharmaceutical/for-students/blog/news.php

A price hike occurs when a large biopharmaceutical company can increase prices either over a span of time, or in some cases, overnight, due to a single entity controlling much the market share. Soon after, other companies with similar drugs follow suit, creating a kind of "Shkreli effect," named after the infamous CEO of Turing Pharmaceuticals, who was responsible for the Daraprim price increase. **Price gouging occurs because of pharmaceutical company abuse of patent laws and the current model for drug discovery and development previously mentioned. Although patent protections were created to incentivize innovation, patents actually create "quasi-monopolies" in the pharmaceutical sector by allowing companies loopholes to delay selling to competitors that produce generic drugs. The prevalence of price hikes exemplifies the need to reform the biopharmaceutical market, without disincentivizing innovation or risk-taking in research.**

Currently, bio-pharmaceutical companies in the United States are already required to provide notice of plans to discontinue the production of a potentially life-saving drug [23]. **The addition of price ceiling in transfer agreements will result in more mindful and calculated transfer of drugs, which can confer stability to the market in the future. It will legally preempt price hikes in the industry.**

Future public policy should require bio-pharmaceutical companies choosing to divest from the production of a particular drug to include a price ceiling in the transfer agreement. Price hikes are, in part, facilitated by the original companies' lack of involvement in the future of a compound when they cease production. Often when the patent life of a drug expires, the parent manufacturer will often cease manufacturing the molecule or biologic. They often give up their rights to no longer profitable ventures to other companies, transferring manufacturing knowledge, marketing rights, and even trademarked names [20]. In principle, when a company gives up manufacturing privileges, it should open the market by introducing competition, thereby reducing prices and consequently increase access. However, in many cases, the opposite occurs because companies transfer patents to a single entity, which then has sole control over the drug pricing. For example, Eli Lilly offloaded the rights to produce the antibiotic cycloserine to Purdue University's Chao Center, who soon thereafter, transferred the drug to the company Rodelis in 2015. Rodelis unexpectedly increased the price of the drug twenty-fold. Amidst heavy public scrutiny, Chao regained the manufacturing rights from Rodelis and reduced the price, but the price remained double the original price [21]. However, in the United States, patents are transferable goods because this allows for flexibility in research and manufacturing and recognizes the fact that a creator may not be the entity to bring a product to market [22]. Making patent transfers more regimented may consequently make it more difficult to ensure the continued production of a compound.

Currently, bio-pharmaceutical companies in the United States are already required to provide notice of plans to discontinue the production of a potentially life-saving drug [23]. The addition of price ceiling in transfer agreements will result in more mindful and calculated transfer of drugs, which can confer stability to the market in the future. It will legally preempt price hikes in the industry.

Ronald Baile, 1-30-2018, "Trump's Prescription Drug Price Controls Would Save Us Money. They Would Also Make Us Sicker.," Reason, https://reason.com/blog/2018/01/30/trump-promises-to-fix-the-injustice-of-h

A 2013 study by Dean Baker, co-director of the Center for Economic and Policy Research, ...calculated that drug price controls could save Medicare between $24.8 and $58.3 billion annually. On the other hand, less revenue to pharmaceutical companies means less money devoted to research and development. A separate study, published in Managerial and Decision Economics in 2007, estimated that cutting prices by 40 to 50 percent in the U.S. will lead to between 30 and 60 percent fewer R&D projects being undertaken. Reduced investments in pharmaceutical R&D

consequently results in reduced numbers of new drugs becoming available to patients. A 2009 study in Health Affairscalculated that as a result of fewer innovative pharmaceuticals being developed, average American life expectancy in 2060 would be around 2 years lower than it would otherwise have been.

Pharma Letter, "The state of pharma mergers and acquisitions in 2018", No Publication, 11-2-2018, 12-9-2018 https://www.thepharmaletter.com/article/the-state-of-pharma-mergers-and-acquisitions-in-2018

The cost of developing a new drug, factoring in pipeline failures and operational costs over the years spent doing so, has recently been quoted in excess of $2.5 billion and it can take as long as ten years from synthesis to approval. No wonder the large companies look to ways to cut this time and cost, boosting mid to late-stage pipelines. **With competition fierce, and many large companies cash-rich from high drug prices, they are still willing to consider mega-mergers where they believe a rival can fit in well with their existing structure and therapeutic priorities.** The long-drawn-out collapse of Pfizer's (NYSE: PFE) $160 billion merger with Allergan (NYSE: AGN) in April 2016 put paid to what would have been the industry's largest ever acquisition in terms of money. Yet Pfizer seems unwilling to abandon the deal completely, sensing profitability in Allergan's portfolio and may yet return to do business.

Sarah Kliffsarah@Vox, 18. [Sarah Kliffsarah@Vox, . "The true story of America's sky-high prescription drug prices." Vox. 5-10-2018.] https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained

But it's a conversation that America's exceptionally high drug prices are forcing us to consider, as drug prices skyrocket — and one in four Americans report trouble paying for their prescription drugs. Are we, as a country, comfortable paying higher prices for drugs to get more innovation? Or would we trade some of that innovation to make our drugs more accessible to those of all income levels?

Madeline Twomey, 5-9-2018, "The Cost of Trump's Inaction on Prescription Drug Prices," Center for American Progress, https://www.americanprogress.org/issues/healthcare/news/2018/05/09/450504/cost-trumps-inaction-prescription-drug-prices/

Prescription drug prices have continued to skyrocket under the Trump administration. A recent congressional report found that the prices of the 20 most-prescribed drugs under Medicare Part D have increased substantially, having risen 10 times faster than inflation over the past five years. On average, manufacturers increased prices for these drugs by 12 percent each year. As a result, during the same five-year period, 12 of these drugs saw price increases of over 50 percent, and 6 saw price increases of 100 percent. **These price increases not only affect Medicare beneficiaries; they rack up costs for the federal government and put a strain on the health care system as a whole. Another alarming analysis, which was conducted by Pharmacy Benefits Consultants, found that over the past 14 months, 20 prescription drugs saw price increases of more than 200 percent.* The study found that one prescription skin care cream, SynerDerm, increased by a staggering 1,468 percent. While less extreme than this, some of the most popular prescription drugs also experienced notable price increases. For example, Humira—the world's highest-selling drug, used to treat inflammatory conditions such as arthritis—saw a 19 percent price increase during the same time period. The trend is clear: Pharmaceutical companies are not bringing down drug prices under Trump.**

Installing Rt'S, 11-2-2018, "Price gouging? Cancer drug price spikes from $50 to $768 per pill after change of owner," RT International, https://www.rt.com/business/414344-cancer-drug-price-surge-lomustine/

In 2013, the brand's owner Bristol Myers Squibb sold lomustine to a Miami startup called NextSource. The new owner rebranded the drug, giving it a new name – Gleostine, and multiplied the price by almost sixteen times. Now, the same treatment costs $768 for a single capsule. According to an analysis done for the Wall Street Journal by Truveen Health Analytics and Elsevier, the company raised the price for Gleostine by 12 percent in November following a 20 percent increase in August.

https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html

There is an out-of-control epidemic in the United States that costs more and affects more people than any disease

Americans currently worry about. It's called nonadherence to prescribed medications, and it is — potentially, at least — 100 percent preventable by the very individuals it afflicts.

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 halfthe 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.

Thomas G. Donlan, 8-11-2017, "Pharmaceuticals: Dangerous Monopoly of Power," No Publication, https://www.barrons.com/articles/pharmaceuticals-dangerous-monopoly-of-power-1502507163

In 1984, Congress passed a law making it much easier for upstart companies to produce copycat versions of drugs after the inventors' patent monopolies have expired. Former Rep. Henry Waxman, a California Democrat, teamed up with Sen. Orrin Hatch, a Republican of Utah, to sponsor the law. *The copycats no longer had to spend three to five years meeting strict Food and Drug Administration requirements for new clinical trials—with paperwork to match—before bringing out cheaper, generic versions of the same drugs. The FDA established a simpler path for turning drug inventions into low-priced commodities. More than 100 drugs with patents that had already expired quickly came onto the market in generic versions, and competition pushed down prices by as much as 90%.* The generic companies had scant development costs and low production costs, so they could prosper with low prices. As Waxman, Hatch, and their allies in organized labor and consumer activism intended, their generic-drug law was for many years the most important piece of pro-consumer legislation in the field. By 2015, generic drugs accounted for 88% of all prescriptions, up from about 20% in 1983. But the expected freewheeling competition turned out to last only a relatively short time. *Competition drove down prices to a bare-minimum cost of production, but that drove out all but the most efficient manufacturers. Then, competitors sorted themselves out into specialties, seeking economies of scope, and many merged to create economies of scale.*

An unexpected result was that big inventive research-oriented pharmaceutical companies began to look like dinosaurs. They reduced their investments in research, closing labs and dismissing staff. Even monopolies couldn't create enough profit to pay for decades of research and decades of compliance with premarket regulations intended to guarantee efficacy and safety. Fortunately for the progress of science, *Wall Street moved in to finance hundreds of speculative companies, each working on one or two drugs for as long as their funding lasts.* The big companies are now primarily marketing and advertising giants, reducing their risk of failure by buying the rights to new products from the successful start-ups. Equally unforeseen was industrial shrinkage: With fewer and bigger generic-drug companies, the market for generics began to look more like the brand-name market. More than 50% of generic drugs are supplied by only one or two manufacturers, so generic prices now are often as firmly fixed and profitable as those of patented drugs. To some, this clearly inefficient market structure smelled like money. People like Martin Shkreli noticed that some drugs lose patent protection but don't attract generic competitors. Such drugs are obscure, except to those patients who need them and to the investors who want to jack up prices.

We affirm.

Our sole contention is restoring affordability.

Currently, pharmaceutical companies can increase drug prices without any limits. **Twomey '18** finds over the last five years, prices of the 20 most-prescribed drugs increased by 12 percent each year, 10 times the rate of inflation over the same time period. With the ever rising prices of drugs, the necessity of affordability is at its highest.

Voting pro switches this trend in 3 key ways

First, by pricing goods for the poor.

Bernstein of the New York Times finds in 2016 that price controls directly place a limit on how much companies can charge for drugs, directly increasing affordability.

In fact, A **2013 study by Dean Baker**, co-director of the Center for Economic and Policy Research calculated that drug price controls similar to European nations could cut prices of pharmaceutical drugs, saving between $24.8 and $58.3 billion annually.

Second, by increasing in competition.

The current healthcare system allows for the formation of patent monopolies. **Amin '18** explains before a prescription drug enters the market, the US patent office awards market exclusivity to drug makers.

As a result, pharmaceutical manufacturers have exclusive power over drug prices, as similar drugs cannot be developed. **Nguyen '18** finds market exclusivity periods last up to 20 years, during which drug manufacturers are free to set high market entry prices and annually increase drug prices with impunity. Consequently, **Kesselheim '16** concludes the most important factor that allows manufacturers to set high drug prices is market exclusivity.

He continues that many large companies that have become rich from high drug prices, are considering mega-mergers where they believe a rival can fit in well with their existing structure and therapeutic priorities. However the only way to prevent this trend from occurring is by voting for pro. By instituting price controls and lowering the price of drugs, companies are incentivized to take part in competition, as price controls restrict the massive profits from blockbuster drugs that only huge companies can put forth.

And the third is a decrease in price spikes.

The **Associated Press** finds that in the past there have been as many as 96 price hikes for every 1 price cut in prescription drug prices.

According to Wharton Public Policy 18' price hiking occurs when a pharmaceutical company abuses patent laws by transferring ownership of patents to other multinational corporations.
The issue comes from the transfer of ownership, in which the proceeding owners then have full rights to spike prices at free will, furthering noncompetitive prices. For example In 2013, Bristol Myers Squibb sold lomustine to a Miami startup called NextSource. The new owner rebranded the drug, giving it a new name – Gleostine, and multiplied the price by almost sixteen times.
However Nath 18' finds as Price controls would have to be taken into account during patent transfer negotiations, companies have an incentive to keep the market stable as they pass along their intellectual property.

Thus, Nath concludes that **price ceilings legally preempts price hikes, bringing stability to the pharmaceutical market.**

The impact is clear, as when you allow the status quo to continue, people can't afford drugs, depriving them of the medication they need.

Empirically, Kliffsarah 18 finds that more than 25% of Americans report trouble paying for their prescription drugs. **Sumners '16** furthers finds due to high costs, 50 percent of prescribed medications are not taken as directed, while 20 percent of prescriptions are never filled. The impact is scalar, as for every four dollar increase in the price of a drug, medical non-adherence increases by 6.2 percent. This is detrimental, as current adherence is estimated to cause approximately 125,000 deaths and at least 10 percent of hospitalizations, and to cost the American health care system at least $289 billion a year.

Susan Thaul, "Frequently Asked Questions About Prescription Drug Pricing and Policy", Congressional Research Service, April 24, 2018, https://fas.org/sgp/crs/misc/R44832.pdf, SP, October 14, 2018

Prescription drug affordability has gained renewed attention during the past few years as retail drug spending has risen at the fastest pace in more than a decade—growing 12.4% in 2014 and 8.9% in 2015 before slowing to a 1.3% increase in 2016. There are several reasons for the recent volatility in drug spending. Manufacturers have been introducing new drugs at a record rate and raising prices for many existing brand-name products. The introduction of new hepatitis C drugs at the end of 2013 had a major impact on total drug spending in 2014 and 2015. At the same time, fewer brand-name drugs have lost patent protection than in previous years, resulting in less impact from the use of lower-cost generic substitutes. **The Centers for Medicare & Medicaid Services (CMS) forecasts that retail drug spending could average 6.3% annual growth from 2017 to 2026.** Although that growth rate would be a reduction from the average level of the past several years, CMS expects retail drug spending to increase faster than other areas of medical spending in this 10-year period.

Prescription Justice, "45 Million Americans Forego Medications Due to Costs, New Analysis Shows – 9 Times the Rate of the UK", 11-2-2018, 2-6-2017
https://prescriptionjustice.org/press_release/45-million-americans-forego-medications-due-to-costs-new-analysis-shows-9-times-the-rate-of-the-uk/

Litchfield, CT, February 6, 2017 – **About 45 million Americans did not fill a prescription in 2016 due to the costs of pharmaceuticals, a new analysis by Prescription Justice shows,** with 18% of adults reporting this problem in a recent survey. This rate of foregoing medicine due to cost is nine times higher than in the United Kingdom, where medicine is largely covered by national health insurance. The analysis conducted by Prescription Justice —a non-profit organization dedicated to tackling the crisis of high drug prices — is based on data extracted from the Commonwealth Fund's 2016 International Health Policy Survey of Adults.

Jordan Weissman, “Medical Expenses Still Drive an Outrageous Number of Americans Into Poverty”, Slate, September 13, 2016, http://www.slate.com/blogs/moneybox/2016/09/13/medical_expenses_still_drive_more_than_11_million_americans_into_poverty.html, SP, October 17, 2018

Based on an analysis of its so-called Supplemental Poverty Measure, **the Census Bureau reports that 11.2 million individuals were pushed below the poverty line last year thanks to out-of-pocket medical spending, including insurance premiums, prescription drug costs, and doctor's office co-pays.** Overall, those expenses drove up the supplemental poverty rate by 3.5 percentage points, little changed from most recent years.

Currently, about 45.6 million Americans, or 14.32 percent, are in poverty as measured by the SPM (that's slightly higher than the official rate). **Again, the bureau notes that were it not for medical out-of-pocket expenses** (MOOP, on the graph below), **“11.2 million fewer people would have been classified as poor.” That means medical expenses are driving more people into poverty than refundable tax credits or food stamps are pulling out of it.**

Maggie Mcgrath, xx-xx-xxxx, "63% Of Americans Don't Have Enough Savings To Cover A $500 Emergency," Forbes, https://www.forbes.com/sites/maggiemcgrath/2016/01/06/63-of-americans-dont-have-enough-savings-to-cover-a-500-emergency/#61b7Maggie Mcgrath, xx-xx-xxxx, "63% Of Americans Don't Have Enough Savings To Cover A $500 Emergency," Forbes, https://www.forbes.com/sites/maggiemcgrath/2016/01/06/63-of-americans-dont-have-enough-savings-to-cover-a-500-emergency/#61b7a9da4e0d

These are just three of any number of things that could go wrong during the course of the year. Recovering from any one will set you back about $500, which means these scenarios fall closer to the "undesirable inconvenience" category than they do the "massive calamity" one. **And yet, nearly two-thirds of Americans do not have enough money in savings to cover the cost of a single one of these unplanned expenses.** According to a brand new survey from Bankrate.com, just 37% of Americans have enough savings to pay for a $500 or $1,000 emergency. The other 63% would have to resort to measures like cutting back spending in other areas (23%), charging to a credit card (15%) or borrowing funds from friends and family (15%) in order to meet the cost of the unexpected event.

Trump & Azar same plan **https://www.hhs.gov/sites/default/files/ReportOn100DaysofAction_AmericanPatientsFirstBlueprint.pdf**

For years, American patients have suffered under a drug-pricing system that provides generous incentives for innovation, while too often failing to deliver important medications at an affordable cost. The flaws in America’s drug markets have been a topic of discussion in healthcare policy circles for years, but no comprehensive approach to reform has ever been undertaken. **On May 11,**

President Trump and Health and Human Services (HHS) Secretary Alex Azar released the American Patients First blueprint, a comprehensive plan to bring down prescription drug prices and out-of-pocket costs. The extensive number of proposals in the blueprint reflect the scale of the task: restructuring and reforming a fundamentally flawed drug-pricing system that governs a more than $400 billion sector of our economy. Reforms of significant parts of the healthcare market on a similar scale, such as Medicare Part D, have generally taken several years to implement, and several years after that to effect changes across the entire drug market.

Billy Wynne, 1-9-2018, "What Does Alex Azar's Plan for Value-Based Care Really Mean?," California Health Care Foundation, https://www.chcf.org/blog/what-does-alex-azars-plan-for-value-based-care-really-mean/

Azar's Four-Point Plan

In nearly identical speeches that were delivered separately to the Federation of American Hospitals and America's Health Insurance Plans last month, Azar outlined his vision for a "radical reorientation" of the American health care system. The secretary declared that he is "determined that we look back at the years of this administration as an inflection point in the journey toward value-based care," and he warned the groups that he will be "unafraid of disrupting existing arrangements simply because they're backed by powerful special interests."
Secretary Azar laid out a plan under which HHS will strive to spur value-based transformations of the health care industry in four areas by:

- Giving consumers greater control over health information through interoperable and accessible health information technology. This will include the government-wide MyHealthEData Initiative and Medicare's new Blue Button 2.0.
- Encouraging transparency from providers and payers. Azar stated that there is "no more powerful force than an informed consumer" and called on doctors, hospitals, drug companies, and pharmacies to become more transparent about pricing and about the outcomes of their services and products.
- Using experimental models in Medicare and Medicaid to drive value and quality "throughout the entire system." Diverging from his predecessor, Azar said he would not hesitate to use the "tremendous power to experiment with new payment models" developed with the Affordable Care Act's Center for Medicare & Medicaid Innovation (CMMI) and the 2015 Medicare Access and CHIP Reauthorization Act (MACRA).
- **Removing "any government burdens" that impede this value-based transformation. Azar pointed to "certain Medicare and Medicaid price reporting rules," current interpretations of various anti-fraud protections, restrictions on the coverage of wraparound services like transportation, and provider reporting requirements as examples of the regulations he plans to address.**

Azar declared that the four "shifts" he outlined are "going to happen, one way or another" and warned that the changes will require "some degree of federal intervention — perhaps even to an uncomfortable degree." He acknowledged that some may be surprised by such a statement from an administration that "deeply believes in the power of markets and competition." However, he argued that government intervention is necessary to facilitate reform in a system where "the status quo is far from a competitive free market in the economic sense of the term."

Kurt R. Brekke, Norweigan School fo Economics,
http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.1015.2263&rep=rep1&type=pdf
We now turn to analysing the effect of RP on prices. The results for the price model, for both brand-name drugs and generics, are presented in Table 8. The dependent variables are logged prices, so that the coefficients can be interpreted in terms or relative changes. In columns (1) and (4) we do not control for the number of generics. The estimated effect of RP on prices is negative for both the brand-name drugs (an estimated 32% reduction) and generics products (an estimated 42% reduction). The fact that generic prices drop more than the prices of brandname drugs does not imply that the decline for generics is higher in absolute terms, since generics typically have lower prices. In columns (2) and (5), we control for the number of generics on the market. We do not find a significant coefficient associated with this variable, and the estimated effect of RP on prices does not seem to be strongly affected by its inclusion in the regression. The results on the effect of RP on the originator's market share are presented in Table 7. In columns (1) and (2) we do not control for the number of generics, and we find that the introduction of RP reduces the market shares of the originators by 37 percentage points (35 points if we lag the introduction of RP to take announcement effects into account). This coefficient is statistically and economically significant. However, it may capture two effects. On the one hand, RP shifts demand from the brand-name drugs to generics, and this may lead to a reduction in brand-name market shares for a given number of generics. On the other hand, we have previously shown that RP also encourages generic entry, and this may also have a negative effect on the originators' market shares. In order to disentangle these two effects, in columns (3) and (4) we control for the number of generics. Not surprisingly, the coefficient is negative and significant. In line with our economic intuition, controlling for the number of generics reduces the estimated coefficient for the RP dummy. This result is comparable with the one of the literature, that takes the number of generics as given in assessing the impact of RP.

Wayne Drash, Cnn, 3-26-2018, "Medicare drug prices soar at 10 times rate of inflation, report says," CNN, https://www.cnn.com/2018/03/26/health/report-medicare-drug-prices-soaring/index.html

The prices of the 20 most commonly prescribed brand-name drugs for seniors have risen nearly 10 times more than the annual rate of inflation over the past five years, according to a congressional report released Monday.
"Can you imagine if you went to an auto dealership and last year's exact model was being sold at a 20 percent mark-up, and then you went back the next year and it had happened again?" said Sen. Claire McCaskill, D-Missouri, who released the report as part of a years-long investigation into escalating drug prices."That's exactly what's happening in the prescription drug industry, where the cost of identical drugs skyrockets year after year."

http://www.ncpa.co/pdf/elsevier_wp_genericdrug.pdf

https://deloitte.wsj.com/cfo/files/2012/09/ValueBasedPricingPharma.pdf

Private and public payers around the globe are encouraging increased use of value-based pricing agreements for pharmaceuticals. As discussed earlier, U.S. commercial health plans have engaged with pharma companies on value-based pricing agreements. Government payers and policy makers seem aligned with the move towards value

based pricing. Consider the following examples of payer demand for innovative and value-based pricing agreements: • The U.S. CMS is shifting from a volume-payment to a value-payment system for medical products.33 CMS will use "reasonable and effective" criteria for reimbursing medical devices and pharmaceuticals with an emphasis on patient outcomes.34

We affirm

Our first contention is reaching the less fortunate.

The **Open Markets Institute** explains that the rampant domination of monopolies in the pharmaceutical industry have led to non-competitive markets, cutting research and development while raising prices for consumer drugs. They control an undisputed hold over the industry, and with the help of government sponsorship, show no sign of holding back.

The **National Center for Policy Analysis in 2017** finds that over the past few years, the pharmacy industry has seen unprecedented increases in the prices of generic drugs, causing unexpected cost increases for payers and consumers. **CNN 18'** confirms that the top 20 most prescribed drugs are all seeing increases by over 10 times.

This trend shows no sign of stopping. **Thaul of the Congressional Research Service 18'** forecasts that prescription drug costs will increase by over 6% every year for the foreseeable future.

Fortunately, A **2013 study by Dean Baker**, co-director of the Center for Economic and Policy Research calculated that drug price controls similar to European nations could cut prices of pharmaceutical drugs, saving between $24.8 and $58.3 billion for consumers annually. Definitionally, a price control caps the amount large corporations can charge for *necessary* drugs, forcing affordability for American consumers.

In contrast, **Levy of the Pharma Letter 18'** writes that many large companies that accrue wealth from high drug prices use these excess profits to rapidly expand mergers and acquisitions across the board of the pharmaceutical industry, expanding their monolithic power.

More importantly, **Brekke of the University of Norwegian Economics** writes that by taking away these excess profits, price regulations would decrease the market share of monopolies by 37%, a shift never seen before. He concludes that price controls would finally accelerate an industry transition to generic drugs versus copycat brand-name products, offering cheaper *and* more effective drugs to the American people.

The impact is saving millions of American lives.

PJ Institute 17' quantifies that price controls would have the ability to save 45 million Americans lives through affordability, as these Americans simply don't fill their prescriptions due to high costs.

Weissman of Slate 18' continues that an additional 11 million citizens have been pushed into poverty after filling their prescriptions because of excess medical costs.