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

A2 Impact - Orphan drugs

WEIGHING/misc contentions

CREATES > Affordability

Both the CREATES Act and price controls decrease prices for consumers in the short term. What the CREATES Act does uniquely is it still retains the incentive for innovation in the long term. With price controls, companies know that their future drugs are still going to be sold with a lower than desired price, thus leading them to cease innovating. However, with the CREATES Act, companies can innovate future drugs and know that they can sell them at a high price, incentivizing future innovation. **Prices go down to the actual value of the DRUG, not pushing it down SO LOW that innovation stops.**

Innovation > Affordability

1. Scope. Arnum finds that the US contributes the most of biopharmaceutical innovation, which means any decline in US innovation affects the entire globe, while price controls only affect domestic accessibility
2. Strength of link. Even when prices go down, that doesn't necessarily mean people have access to effective drugs, which is ultimately what matters. We get the best of both worlds - Pipes of Forbes finds that innovation has decreased mortality of heart disease, stroke, and diabetes to name a few and has progressively pushed down prices. Indeed, for every dollar spend in pharma businesses, there's a $3.65 reduction in healthcare spending.
3. Long term/short term harms. After 20 years, the drug patent expires, and companies can make generics for drugs, meaning prices ultimately end up going down anyway. The difference is whether or not those generics are for effective, cutting-edge tech or for the same ineffective drugs on the market right now.

Patricia Van Arnum [DCATVI], 4-13-2016, ***Biopharmaceutical Innovation: Which Countries Rank the Best?, https://www.dcatvci.org/250-biopharmaceutical-innovation-which-countries-rank-the-best***

A recent industry study examines the extent to which the public investment, intellectual property, and drug pricing policies of 56 countries proactively contribute to or detract from global life-sciences innovation. So what did the report find? **The report finds that the United States places first overall, with policies** (on a per-GDP basis) **that contribute the most to global biopharmaceutical innovation**. followed by Switzerland, Taiwan, Singapore, and Sweden. T Value Chain Insights (VCI) examines the rankings.

Sally C. Pipes [Forbes], 04-18-2011, ***Medical Innovation Critical To Bringing Down Health Care Costs, https://www.forbes.com/2011/04/18/innovation-health-costs.html#21a2b5786109***

The return on past medical innovations has been nothing short of astonishing. For example, at the onset of the baby boom generation, heart disease and stroke were near death sentences. **The chances of surviving each today are 60% and 70% greater [for heart disease and stroke], respectively, thanks to cutting-edge medicines and surgical techniques.** Even for typically non-fatal conditions, the improvements are staggering. Over the past 60 years, **the death rate for a person with Type I diabetes has**

dropped from 20% within 20 years of diagnosis to just 3.5%. What's responsible for this decline? We know more about the science behind diabetes than ever before, **thanks to advanced equipment and the development of a non-animal derived insulin.** By keeping people alive longer, medical innovation has also bolstered human productivity. In fact, longevity **gains from medical innovations are currently worth $2.8 trillion annually**, according to economists Kevin Murphy and Robert Topel of the University of Chicago. Their research found that cumulative gains in life expectancy over the 20th century were worth over $1.2 million per person. Medical breakthroughs don't come cheap, though. For every successful drug, there are many, many more left on the lab-room floor--all of which, individually, cost millions or even billions to research and develop. These scientific breakthroughs never would have happened without a market that encourages and rewards fruitful scientific research. And while novel treatments may carry hefty initial price tags, they more than pay for themselves. Columbia University professor Frank Lichtenberg has shown that new drugs and treatments ultimately lead to lower health care costs. **For every** additional **dollar in pharmaceutical expenditure, there is a reduction of $3.65 in total hospital care expenditures. For every 100 prescriptions, expensive hospital stays declined by 16.3 days**. Reducing hospital stays is crucial to lowering health care costs, as they **[which] account[s] for 42% of all medical spending.**

Affordability > Innovation

Moral FW: We need to prioritize those who can't afford drugs right now. According to the Minnesota Law Review in 2018, because these consumers have no choice but to buy the drug at whatever price the seller wishes to charge, this creates an ethical obligation on the part of the seller not to extract excessive benefits from those who cannot refuse its offer.

1. Strength of Link. Prices prerequisite access because according to Callahan of Hastings, innovative tech is really expensive, which means the only way to make that accessible is to through price controls.
2. Probability. Fleming of Forbes writes in 2018 that R&D productivity has been on the downward tick for years, and a 20% increase in productivity is needed to reverse this trend, concluding that "none of Pharma's past efforts have made any difference at all" to declining productivity. That indicates it's super unlikely that all the money thrown into R&D will tangibly translate into life-saving innovation; it's a lot better to just make current drugs accessible.

http://www.minnesotalawreview.org/wp-content/uploads/2018/07/Mello_MLR.pdf

One line of argumentation proceeds from the fact that patients who depend on life-preserving drugs are highly vulnerable.45 Because they have no meaningful choice but to buy the drug at whatever price the seller wishes to charge, the usual presumptions about market exchanges—such as voluntariness, choice, and bargaining power—are disrupted. This arguably creates an ethical obligation on the part of the seller not to extract excessive benefits from those who cannot refuse its offer.46 A reply to this argument is that this morally distressing situation may generate an obligation on the part of society to ensure that the patient receives the drug, but not on the part of the drug's producer.4

Daniel Callahan [Hastings Center], 2008, ***Health Care Costs and Medical Technology,***
https://www.thehastingscenter.org/briefingbook/health-care-costs-and-medical-technology/

Almost everyone knows that this country has a scandalously large number of people who lack health insurance, now up to 46 million and growing. That number is vivid and evocative. But it has overshadowed another, more serious issue—that of the steady escalation of health care costs. **Largely due to the use of medical technology, those costs are now increasing at an annual rate of 7% a year.** The Medicare program as a consequence is projected to go bankrupt in nine years, and overall health care cost to go from its present $2.1 trillion annually to $4 trillion in 10 years. Those rising costs are an important reason why the number of uninsured keeps going up. Business finds it harder and harder to pay for employee health benefits, and only 61% of employers even provide them now (from a high a decade ago of close to 70%); and the employers who do provide benefits are cutting them and forcing employees to pay more themselves in the form of copayments and deductibles. The 15% who are uninsured are surely faced with both health and financial threats. But the cost problem now threatens everyone else as well, including those using the Medicare and Medicaid programs. Yet even if most people are now aware of the dangers of cost escalation (and many know it from personal experience), the problem has not gripped the imagination of the public, the presidential candidates, or the media with the force of the uninsured (even though recent public opinion polls indicate it is catching up). There are a number of proposed and detailed schemes for universal care, but nothing comparable for cost control, which is implicitly unpopular. That's because cost control will mean that just about everyone will be forced to give up something and accept a different, more austere kind of health care. Consider what serious cost control will require: moving from a 7% annual cost growth down to 3%, which is an inflation of health care costs that is no greater than that of the per annum rise in general inflation. That amounts to a cost reduction of $1.5 trillion over the next decade, so that health care costs settle in at $2.5 trillion in a decade. This would represent an enormous and unprecedented drop in annual costs for a health care system that has never since World War II seen anything more than a short, temporary decline from time to time. The feature of cost escalation that should catch our eye most is the role that medical technology plays. **Health care economists estimate that 40–50% of annual cost increases can be traced to new technologies or the intensified use of old ones. That makes the control of technology the most important factor in bringing costs down.** Ethics comes in at this point because medical technology is highly valued as a beloved feature of American medicine. Patients expect it, doctors are primarily trained to use it, the medical industries make billions of dollars selling it, and the media loves to write about it. The economic and social incentives to develop and diffuse it are powerful, and the disincentives so far weak and almost helpless. Cutting the use of technology will seem wrong—even immoral—to many.

Standish Fleming [Forbes], 2018, Pharma's Innovation Crisis, Part 1: Why The Experts Can't Fix It, https://www.forbes.com/sites/stanfleming/2018/09/06/why-experts-cant-fix-pharmas-innovation-crisis-part-1-and-what-to-do-about-it-part-2/

How much is the industry falling short? A lot. Stott makes an important point that incremental improvements in productivity will not solve the innovation crisis. …improving R&D productivity by 5% or even 10% each year from 2018 would slow, but not reverse the current decline in nominal ROI and IRR. …We would need to increase nominal R&D productivity/ROI by at least 20% each year to reverse the projected decline in P&L performance, and even then, the industry's sales and profits would fall by about one third before they begin to pick up again in 2030. And yet, to fix the problem, Stott calls for another research project, an incremental solution at best. …getting large molecules into cells is perhaps the only way to address the real underlying issue of declining R&D productivity. The industry has worked for decades to improve the delivery of large molecules and still doesn't know how to do it. The we-can-figure-this-out approach that put men on the moon doesn't work here, because drug development is experimentation, not engineering. Progress in the delivery of therapeutic proteins has been slow for good reason. Cells, tissues and organisms evolved to keep foreign proteins out… …none of Pharma's past efforts at continuous improvement has made any difference at all to the rapid and steady decline in R&D productivity over the last 60 years.

A2 Marketing spending

A2W Developing nations first

The obligation of the US government, the actor in this resolution, is it's own citizens first. That's social contract theory. In the status quo, millions of Americans can't afford drugs and die as a result of it, even while paying major taxes to the government and otherwise helping the country as a whole. While we agree that other countries have issues, the US government can't hurt it's own citizens to benefit them.

A2W Patients life = priceless, so high drug prices good

1. Garber of the Lown Institute articulates that "A patient's life is priceless, but setting absurdly high prices for life-saving drugs means we're holding patients hostage."

Judith Garber, xx-xx-xxxx, "Can you measure the value of a life-saving drug?," Lown Institute, https://lowninstitute.org/news/blog/can-measure-value-life-saving-drug/

A patient's life is priceless, but setting absurdly high prices for life-saving drugs means we're holding patients hostage. We need to have conversations about pricing and value that include patients, and more investigations into the real investment of pharma in new research, so we can find a middle ground and an affordable price for life-saving drugs.

A2 PRO (YOU ARE CON)

A2 Misc contentions

A2 Parallel trade

1) **De-link**. Because the government does a good job of tracking down parallel imports, Health Affairs in 2014 explains that that parallel threats are not a major threat to manufacturers and there is no link between parallel trade and the reduction of drug prices.
2) **Non-Unique:** Parallel trade is an effective form of competition. Author Ann Lehnhausen writes that parallel trade forces manufacturers to decrease the prices of drugs RIGHT NOW to stop imports. That's why David Granlund writes that drugs facing competition from parallel trade have 21% lower prices.

"Studies on Competition and Antitrust Issues in the Pharmaceutical Industry - Ann-Kathrin Lehnhausen - Google Books", https://books.google.com/books?id=JB1_DQAAQBAJ&pg=PA31&lpg=PA31&dq=parallel+trade+does+not+exist&source=bl&ots=rwPNsPEzSN&sig=gOgqyMXY_6yPax1z2iJuJySkym8&hl=en&sa=X&ved=2ahUKEwitjPqNhfXeAhXhw1kKHRzKCAY4MhDoATABegQIBxAB#v=onepage&q=parallel%20trade%20does%20not%20exist&f=false

out of pocket. As consumers' willingness to pay differs across countries, various maximum prices arise. To price discriminate in each country, originator producers set the maximum price they are able to charge in order realize maximum profits possible (Bennato and Valletti 2014: 83; Kyle, Allsbrook, and Schulman 2008: 1308). If parallel trade occurs, manufacturers are not able to raise the price in the low-price country further, as they are already charging the maximum prices. This is why they can only reduce prices charged in the high-price countries in order to prevent arbitrage (Kyle, Allsbrook, and Schulman 2008: 1310). This is consistent with the findings of Guo, Hu, and Zhong (2013: 346), stating that parallel trade decreases prices of drugs.

"EU Enlargement, Parallel Trade and Price Competition in Pharmaceuticals What's to Blame? Derogation or Perception?1 David Granlund2 and Miyase Yesim Köksal3 ", http://www.konkurrensverket.se/globalassets/forskning/projekt/2009-60-eu-enlargement-parallel-trade-and-price-competition-in-pharmaceuticals.pdf

Given the cost of trade and availability of pharmaceuticals, the driving force for parallel trade is the price difference between the source (exporting) and the destination (importing) country. An increase in the price difference or in the availability of pharmaceuticals for parallel trade should increase price competition in the destination country. Using 2003-2007 data from Sweden we investigated whether EU enlargement in 2004, when new countries with low pharmaceutical prices joined the EU, increased competition from parallel imports. **Drugs facing competition from parallel imports are found to have on average** 17% to **21% lower prices than they would have had if they had never faced such competition.** But, contrary to expectation, EU enlargement is not found to have increased this effect, which might be explained by derogations and changes in consumer perceptions of parallel imports.

"Prices Of Pharmaceuticals In Poor Countries Are Much Lower Than In Wealthy Countries | Health Affairs", https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0923#EX3 The price effects of parallel trade in pharmaceuticals are influenced by the extent to which the participating importers undercut established prices. If importers are unable to expand their sales by lowering their prices further, they are unlikely to do so. Instead, importers are more likely to set prices that largely track those of their competitors. In that case, the price effects of parallel trade would be relatively minor. The evidence on these issues is limited to trade within the European Union. **Margaret Kyle and colleagues studied the effect of parallel trade there between 1993 and 2004 and report little indication of a link between parallel trade and subsequent reductions in drug prices.** 28 Similarly, Panos Kanavos and coauthors find that parallel imports had little effect on prices for the twenty top-selling drugs in the European Union. 29 And in a study of imports of the statin drug simvastatin in three of the main parallel importing countries—Germany, the Netherlands, and the United Kingdom—between 1997 and 2002, Joan Costa-Font and Panos Kanavos find that the market share for imported simvastatin increased, but that price differences between imported and domestically produced versions were small. 30 However, Mattias Ganslandt and Keith Maskus report that **legalizing parallel trade in pharmaceuticals in Sweden in 1995 led to a 4 percent drop in average drug prices. 31 This finding suggests that parallel trade can still represent a substantial form of competition for drug manufacturers.**

"Prices Of Pharmaceuticals In Poor Countries Are Much Lower Than In Wealthy Countries | Health Affairs", https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0923#EX3

One possible impediment to maintaining these price differentials between industrialized countries and those whose populations are less well off is the prospect of increased parallel trade, in which drugs that carry low prices in one country are resold to more-developed countries. However, **we find that parallel trade is not a major threat to either manufacturers' revenue or to price discounts. Not only is the evidence of such effects weak, but various mechanisms are available to governments and manufacturers alike to ensure that drugs can be sold at lower prices in less-developed countries.**

"University of Calgary Department of Economics Working Paper 2009-01 An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries Sean Flynn, Aidan Hollis, & Mike Palmedo* January 2009", https://econ.ucalgary.ca/sites/econ.ucalgary.ca/files/unitis/publications/162-34146/FHP-Jan_15_2009.pdf

Figure 4.2 shows the total sales revenue a firm will gain if it sells at each price on the demand curve. The firm maximizes its sales in South Africa by selling at the price that only the top 10% can afford.34 At this price, the firm makes $814.6 million in total revenue. **If the firm lowers its price to be able to make sales to 20% of the affected individuals (at $396 per patient), then it will sell twice as many medicines at a price less than half of the profit-maximizing price,** earning substantially less ($435.6 million). As the monopolist continues to cut prices and raise production, revenues fall further at almost every level of output and corresponding price. In other words, the firm will maximize its profits by setting a price unaffordable for at least 90% of people in need.

For the sake of simplicity, we assume that disease prevalence is equal among income deciles. We construct graphs of total revenue (quantity demanded times price, for each price along the demand curve) against the quantity sold. The revenue-maximizing price/quantity combination in the two most equitable economies in our sample, Finland and France, is that in which 80% of the people who need the medicines will obtain them. (In each of the tables in Appendix 2, the maximum revenue and corresponding quantity sold are highlighted.) For countries with higher gini coefficients and more convex demand curves, the revenue-maximizing point moves leftward, indicating that monopolies in these countries will earn the most money by charging prices that smaller and smaller segments of the population can afford. **In the most unequal countries, monopolists clearly maximize revenue by selling at high prices to only the wealthiest 10% of the population.**

A2 PBMs

1. Nontopical - price controls would only be placed on the pharmaceutical industry - By definition, PBM's are middlemen between the pharma industry and the insurance industry. They don't face additional scrutiny in the aff world.
2. Nonunique – Squo solving back.
    a. First, The NCPA writes that many businesses are seeking out transparent PBMs that aren't for profit - after Meridian switched their drug spending decreased by $2 million.
    b. Second, Hoffman of the Pharmacy Times writes that 40 corporations have created the Health Transformation Alliance, spending $25 billion annually to replace and fight against PBMs
3. Turn – PBMs lower prices. Forbes in 2018 explains that PBMs decrease the price consumers pay on copays for generic drugs, which incentivizes them to turn to generics over the pricey name brand treatment. Thus, Health Affairs concludes that PBMS decrease annual medical costs for patients by 50%.

Matthew Eyles, Health Affairs, 10-12-2018, On Drug Prices, Pharmacy Benefit Managers Are Not The Problem: A Response To Michael Carrier, https://www.healthaffairs.org/do/10.1377/hblog20181009.878948/full/, 11-8-2018, VK

Contrary to the article's claims, PBMs save payers and patients 40–50 percent on their annual prescription drug and related medical costs compared to what they would have spent without PBMs. That's an average of $941 per person per year, according to an analysis prepared for Pharmaceutical Care Management Association. In fact, an overwhelming body of independent research shows that, thanks to their ability to negotiate, **PBMs are part of the solution to lowering health care costs: This includes research from the Federal Trade Commission (FTC), the Congressional Budget Office, and the Government Accountability Office. By negotiating the cost of prescription drugs, PBMs save plans money—money that is ultimately passed onto the consumer.** In fact, two of the largest PBMs—CVS and Express Scripts—report that they return up to 98 percent and 95 percent of rebates, respectively, to those they serve in the commercial market.

Avik Roy, Forbes, 6-26-2018, Drug Companies, Not 'Middlemen', Are Responsible For High Drug Prices,

https://www.forbes.com/sites/theapothecary/2018/10/22/drug-companies-are-responsible-for-high-drug-prices-not-middlemen/#490450f24947, 11-8-2018, VK

Over time, this complex function of drug utilization management has been taken over by another set of middlemen called pharmacy benefit managers, or PBMs. Insurers contract with PBMs, because PBMs have proven more effective than insurers at the complicated task of keeping abreast of all the clinical evidence and pricing data needed to create these tiered formularies. Insurers make more money if (1) their patients are healthy; (2) if their patients who are sick get the medicines they need at the lowest possible price. **Hence, nearly all insurers contract with PBMs, because PBMs have proven to be the best at keeping drug prices lower than they otherwise would be. Put another way: prescription drug prices, insurance premiums, and overall health spending would all be far higher if PBMs weren't driving more market share to low-cost generic drugs.**

Brittany Hoffman-Eubanks, "The Role of Pharmacy Benefit Mangers in American Health Care: Pharmacy Concerns and Perspectives: Part 3", Feb, 26 2018 ,https://www.pharmacytimes.com/news/the-role-of-pharmacy-benefit-mangers-in-american-health-care-pharmacy-concerns-and-p erspectives-part-3, 10-23-2018, JF

As an alternative to traditional PBMs, some plan sponsors have terminated the use of PBMs for their plan benefit administration. **In 2016,** 20 **large employers** (ex. Coca-Cola and Marriott) **formed the Health Transformation Alliance (HTA) to eliminate the use of wasteful and expensive PBMs.**[3] **Today, HTA includes more than 40 major corporations, covers more than 6 million lives, and has an annual spend of $25 billion.**[4]

NCPA, PBM Resources, https://www.ncpanet.org/advocacy/the-tools/pbm-resources, 11-8-2018, VK

It's important to note that some prescription drug plan sponsors are seeking alternatives to the traditional PBM model. In 2016, 20 large employers – including Coca Cola, Marriott, and American Express – formed the Health Transformation Alliance to break away from "existing marketplace practices that are costly, wasteful, and inefficient," including issues with prescription medications. HTA now consists of over 40 major corporations and covers more than 6 million lives. Not all companies or plans have the market power to form or join such an organization, but there are other options they can turn to in order to achieve greater transparency and lower prescription drug costs. **One option is a Transparent PBM – a PBM that takes a flat administrative fee for each prescription and doesn't profit from spreads on drugs or secret incentives. One plan sponsor saw their prescription drug spend drop by $2 million in the first year after they switched to a transparent PBM.**

A2 Patent monopolies

1. **Nonunique**. Haislmaier of the Heritage Foundation finds that the US can revoke any patent it wants.
2. **There's no solvency in the aff.** Logic out based on link.
    a. Just because we pass price controls doesn't mean the US is going to change patent policy
3. **Generic competition goes away in the aff world.** Small companies are typically the ones that produce generics. If the price remains really low, its even less profitable. This deters generic companies more because small companies need high returns to stay in business.

4. **SPECIFIC TO MERGERS**: TURN: Bansal of the Mckinsey Institute explains in October that mergers actually increase innovation because the buying company provides the capital to fund the research.

Haislmaier '04: Edmund Haislmaier, 5-25-2004, "Compromising Quality: The High Cost of Government Drug Purchasing," Heritage Foundation, https://www.heritage.org/health-care-reform/report/compromising-quality-the-high-cost-government-drug-purchasing

If the government can grant such limited monopolies, it can also extend, reduce, restrict, or eliminate them entirely. Thus, if a government wants to coerce a manufacturer to lower prices across the board, it can do so by threatening to limit or revoke its patent rights. In the most extreme form (called "compulsory licensing"), the government takes away the innovator company's patent protection and allows one or more other companies to make and sell the drug at a price that is acceptable to the government.

Roerich Bansal, Ruth De Backer, and Vikram Ranade, McKinsey & Company, xx-xx-xxxx, ["What's behind the pharmaceutical sector's M&A push", https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/whats-behind-the-pharmaceutical-sectors-m-and-a-push, 11-26-2018]jzl

Large pharmaceutical companies have used M&A to bolster their innovation for a long time, and that isn't likely to change any time soon. Previous McKinsey research has shown that the share of revenues coming from innovations sourced outside of Big Pharma has grown from about 25 percent in 2001 to about 50 percent in 2016 (Exhibit 1). The development of a new drug requires high early-stage investment for what is often a low probability of success. At the same time, late-stage trials also require high investment and an ability to navigate complicated regulatory pathways—capabilities that larger pharma companies typically have. **These dynamics create an industry profile in which smaller, creative companies end up funding innovation. Once their research is more advanced, larger pharmaceutical companies enter the picture, looking for the next "new" thing and ponying up the resources required to fund expensive late-stage trials and large commercial marketing campaigns**. Regardless of trends, innovation in this industry is—and will remain—fragmented.

A2 States work

1. No it's not. What the states are doing isn't a price control. Pear of the New York Times in 2018 explains that the popular tactic is just shining a spotlight on drug price increase. But just pointing out the cost and saying, oh look, that's a thing that's happening, doesn't actually limit the costs or create any change.

Robert Pear, 8-18-2018, "States Rush to Rein In Prescription Costs, and Drug Companies Fight Back," No Publication, https://www.nytimes.com/2018/08/18/us/politics/states-drug-costs.html
A bill passed unanimously this year by the Connecticut General Assembly illustrates a popular tactic: States are shining a spotlight on drug price increases as a first step toward controlling costs.

Under the Connecticut law, drug companies must justify price increases for certain drugs if the price rises by at least 20 percent in one year or 50 percent over three years. Insurers must identify their 25 highest-cost drugs and the 25 with the greatest cost increases when they file their annual rate requests with the state Insurance Department.

A2 Hospitals

1. Delink - The National Health Resources and Services Administration reports in 2018 that some hospitals are already subject to price controls. 340B Pricing programs require manufacturers to agree to provide outpatient drugs to covered entities at significantly reduced programs.
2. Delink - The Moran Company reports in 2017 that 83% of hospitals already charge patients more than double how much it costs for them to buy medicine, and the majority of hospitals markup medicines between 200% - 400% on average. Hospitals already markup drugs and would not be subject to these price controls. Manufacturers aren't the problem, the hospitals are.
3. Delink - Hospitals are already reducing costs in the status quo, through non-drug means. Wealth Management reports that hospitals have successfully implemented policies to achieve this through tracking and classifying operating expenses, applying efficiency practices from other industries, using IT better, reducing redundant testing, and streamlining their bureaucracies. These methods work. Winslow of StatNews reports in 2017 that one of the biggest hospitals in Massachusetts, Brigham and Women's, has managed to cut 50 million from the hospital's 2.6 billion in annual spending by creating a leaner and more efficient organization, not by reducing drug quality.
4. Turn - The Heritage Foundation reports in 2013 that fixing prices would protect hospitals from new competitors that threaten to undercut their prices. They remove the incentive for hospitals to provide more cost-effective care. Artificially low prices also encourage the use of unnecessary,costly procedures and the overuse of diagnostic tests. Imposing price controls just hurts health care further.

Ron Winslow, 9-28-2017, "An inside look at Brigham and Women's Hospital's struggle to cut costs," STAT, https://www.statnews.com/2017/09/28/brigham-and-womens-hospital-budget/

He was there to sound an alarm: In the 2017 fiscal year that was about to start, he told Walls, operating income wouldn't cover the hospital's expenses; 2018 would be in the red as well.

"Chris, how do the numbers come back up?" Walls said he asked. The CFO, Christopher Dunleavy, was ready with a solution: Cut $50 million from the hospital's $2.6 billion in annual spending.

That conversation set in motion an unprecedented cost-cutting drive that would affect the jobs of hundreds of the hospital's 18,000 employees and reach into every corner of the institution — even overriding nurses' choice of mattress pads. It also led to an aggressive push to boost revenues 4 percent a year.

Healthmanagement.Org, xx-xx-xxxx, "Seven Ways for Hospitals to Control Overhead Expenses," HealthManagement, https://healthmanagement.org/c/hospital/whitepaper/seven-ways-for-hospitals-to-control-overhead-expenses
As the costs of caring for patients continue to rise, hospitals all around the world are struggling to contain their operating expenses. This white paper presents seven strategies that successful hospitals have implemented to do just that:

• Tracking and classifying operating expenses

• Reducing operating expenses that don't contribute to better care

• Applying efficiency practices from other industries

• Streamlining bureaucracy

• Making better use of IT

• Diminishing redundancies in diagnostic testing

• Engaging all staff members in the effort

Christopher Pope, Graduate Fellow in the Center for Health Policy Studies at the Heritage Foundation.
"Legislating Low Prices: Cutting Costs or Care?", August 9, 2013,

http://www.heritage.org/health-care-reform/report/legislating-low-prices-cutting-costs-or-care, SP, October 21, 2018

Overpayment. Fixing prices tends to entrench the dominant position of incumbent firms, protecting them from new competitors that threaten to undercut their prices or to provide more focused solutions to patient needs. Regulated pricing also prevents managed care providers from driving down costs by negotiating discounts with provider networks. Therefore, it removes the incentive for hospitals to provide more cost-effective care in order to compete. Artificially low prices may also encourage use of unnecessary, costly procedures and overuse of diagnostic tests, which insurers may nonetheless be obliged to cover.

Batty Anderson, "Hospital Charges and Reimbursement for Medicines: Analysis of Cost-toCharge Ratios", Moran Company, 2018, http://www.themorancompany.com/wp-content/uploads/2018/09/Hospital-Charges-Reimbursement-for-Medicines-August-2018.pdf , VK, October 18, 2018

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.

Secretary, 8-15-2018, "340B Drug Pricing Program," No Publication, https://www.hrsa.gov/opa/index.html
The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

Manufacturers participating in Medicaid, agree to provide outpatient drugs to covered entities at significantly reduced prices.

Eligible health care organizations/covered entities are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers. See the full list of eligible organizations/covered entities.

To participate in the 340B Program, eligible organizations/covered entities must register and be enrolled with the 340B program and comply with all 340B Program requirements. Once enrolled, covered entities are assigned a 340B identification number that vendors verify before allowing an organization to purchase 340B discounted drugs.

A2 Co-Payments

1. Delink - Williams of the Utah Department of Health explains in 2013 that after doing a statistical analysis of copayments and the utilization of prescription drugs, found that "in most cases, the utilization analyses show that the co-pay requirements had no statistically significant impact on utilization." This is because a lot of people who already have access to copays and insurance are middle class. Because of this, either way, most of them would be able to afford the drug regardless of if they have the co pay or not. Thus, copays are only affecting the portion of the population that already have the drug.

http://www.hpm.umn.edu/ambul_db/db/pdflibrary/DBfile_49007.pdf
Utilization Summary – **In most cases, the utilization analyses show that the co-pay requirements had no statistically significant impact on utilization.** However, in a few cases, there are statistically significant decreases in utilization at the time of implementation or increases in the co-pays, notably: A decrease of about 30 prescriptions per week per 1,000 enrollees for Non-Traditional enrollees at the time of the increase to a $2 co-pay. A decrease of about 21 outpatient claims per month per 1,000 enrollees for Traditional enrollees at the implementation of the $2 co-pay. No increase in emergency room dental claims when dental coverage was eliminated. g Survey Results Summary – Several survey questions address the human toll of the changes. Co-pays: In general the survey results show that for the majority of enrollees the co-pays were not a burden and accomplished the stated objectives. However, for a subset of the population the copays for physician services and pharmacy created a financial burden. Changes in Coverage: The survey suggests that among the services that are no longer covered, loss of dental and vision services created the greatest hardship for enrollees. While some enrollees reported getting needed dental care by paying for it themselves, a greater number had dental needs that were not addressed, primarily due to inability to pay. Coping Strategies: Respondents reported employing a broad range of coping strategies, including cutting back on overall consumption of goods and services, as well as expenditures for nonessentials in nutrition and non-health commodities.

A2 Specific plans

A2 Reference pricing

1. Topicality. Reference pricing isn't even a price control, it's literally just a suggestion from the government or from an insurer who says they will only contribute a certain amount of money to paying for the drug, but patients are free to pay as much as they want

after that point for the drug. This isn't a price control because it doesn't control price directly.

2. Pear of NYTimes explains that Trump's policy isn't even really reference pricing as what Trump wants to do is set prices based on prices in other countries, which is essentially just another price ceiling. Pear furthers that Democrats have doubt that Trump even plans to implement this policy as they find it super suspicious that Republicans are talking about healthcare two weeks before the elections after years of campaigning on stripping back coverage. Because this policy doesn't even look like it's ever going to materialize, we should just default to the most generally accepted definition of a price control which is a price ceiling, which was the framers intent in creating this resolution. We're supposed to debate the idea of forcing prices down, not specific plans construed to fit into the resolution.
3. Farkas of Forbes explains in 2006 that reference pricing would severely hurt the pharmaceutical industry, reaching 30 billion to 35 billion dollars in lost profit over the next three to four years.
4. Turn - Monopolization. Reference pricing means that big companies are incentivized to buy out the smaller other producers of their drug so that they can set their price as high as possible and be the only producers. This is dangerous because more monopolies decreases the incentive to invest.
5. Turn - Ineffective innovation. Farkas continues that one likely consequence will be a shift in research toward diseases not currently treated by multiple drug therapies. The reason is simple: These drugs would be literally incomparable. This is highly dangerous because this means that drug companies will be creating drugs that aren't designed to save the most people.

Investopedia Staff, 3-21-2018, "Price Controls," Investopedia, https://www.investopedia.com/terms/p/price-controls.asp
Price Controls
What are 'Price Controls'
Price controls are government-mandated legal minimum or maximum prices set for specified goods, usually implemented as a means of direct economic intervention to manage the affordability of certain goods. Governments most commonly implement price controls on staples, essential items such as food or energy products. Price controls that set maximum prices are price ceilings, while price controls that set minimum prices are price floors.

Robert Pear, 10-25-2018, "Trump Proposes to Lower Drug Prices by Basing Them on Other Countries' Costs," No Publication, https://www.nytimes.com/2018/10/25/us/politics/medicare-prescription-drug-costs-trump.html
WASHINGTON — President Trump proposed on Thursday that Medicare pay for certain prescription drugs based on the prices paid in other advanced industrial countries — a huge change that could save money for the government and for millions of Medicare beneficiaries.

As part of a demonstration project covering half the country, Medicare would establish an "international pricing index" and use it as a benchmark in deciding how much to pay for drugs covered by Part B of Medicare.

“This is a revolutionary change,” Mr. Trump said in a speech on Thursday at the Department of Health and Human Services. “Nobody’s had the courage to do it, or they just didn’t want to do it.”
Democrats had their own reasons for skepticism.
“It’s hard to take the Trump administration and Republicans seriously about reducing health care costs for seniors two weeks before the election when they have repeatedly advocated for and implemented policies that strip away protections for people with pre-existing conditions and lead to increased health care costs for millions of Americans,” said Senator Chuck Schumer of New York, the Democratic leader.

MONOPOLIZATION

James C., 9-10-2018, "Does Pharmaceutical Reference Pricing Have a Future in the U.S.?," No Publication, https://www.commonwealthfund.org/publications/issue-briefs/2018/sep/pharmaceutical-reference-pricing-future
Issue: Reference pricing is an emerging health insurance benefit design aimed at reducing health costs. In this model, an insurer establishes a maximum payment that it will contribute toward covering the price of a product or service in situations where there is wide price variation for therapeutically similar drugs, diagnostics, or procedures. Experiences to date indicate that reference pricing can influence patients and physicians to switch to less costly options within each therapeutic class, reducing overall drug prices.

Chuck Farkas and Preston Henske, 4-14-2006, "Reference Pricing For Drugs," Forbes, https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx_cf_0414pharma.html
One likely consequence will be a shift in research toward diseases not currently treated by multiple drug therapies. The reason is simple: These drugs would be literally incomparable.

And in the testing phase, reference pricing forces companies to make their own therapeutic comparisons during clinical trialsto cite significant improvements in outcomes compared with competing drugs, not placebos. Since worldwide standards don't exist, that is a gray area.

Chuck Farkas and Preston Henske, 4-14-2006, "Reference Pricing For Drugs," Forbes, https://www.forbes.com/2006/04/13/pharma-reference-pricing-cx_cf_0414pharma.html
The cost could be huge for the pharmaceutical industry as well, reaching $30 billion to $35 billion in lost profits over the next three to four years, according to analysis by Bain & Company. In effect, reference pricing allows payers to impose generic prices on drugs still under patent protection. That power will change the pharmaceutical landscape.

Pfizer learned exactly that in Germany with Lipitor, a statin that can help reduce cholesterol levels. Lipitor quickly gained a market share there when it was introduced, but between 2003 and 2005, as statin drug sales rose dramatically, Lipitor's share of the German market actually collapsed by 75%, and revenues for the entire category declined by 25%.

A2 Value based

1. National Health Council – there are a bunch of legal barriers that would disincentivize value-based healthcare. For example, the FDA's prohibition on discussion of off label uses of drugs is a barrier to outcomes-based pricing contracts. For instance, if a payer wants to look at total hospitalization costs and that isn't on the label, it can't be included in an outcomes-based contract. To understand the true real world risks of a drug, you have to look beyond the label, but companies are prohibited from doing that with the FDA.
2. Bisserbe of WSJ finds that in Italy, because regulators and drug companies tend to disagree on how to measure a drug's efficacy, creating a huge stumbling block between drugs actually being approved and not approved. Additionally, Italy showed that the lack of incentive for doctors to track patient outcomes to measure efficacy lead to even more ambiguity when deciding a price.
3. Spiegel of the Hill in 2017 furthers that reference pricing comes when officials set a price for each class of drug but don't 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 treatmentsand cures.

Andrew Spiegel [Opinion Contributor, The Hill, "The tragic toll of drug price

controls," The Hill, May 5 2017. Available at: hĴps://thehill.com/blogs/pundits-blog/healthcare/332145-the-tragic-toll-of-drug-price-controls

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 "refer-

ence pricing." Officials group drugs into therapeutic classes, based on how the drugs

aJack 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.

https://www.nationalhealthcouncil.org/sites/default/files/011816_Cover_PricingPolitics.pdf

Regulatory barriers to value-based pricing of drugs — both real and perceived — were on display at a forum on pharmaceutical pricing that HHS convened in November. Christi Shaw, U.S. country head at Novartis AG, and Kenneth Frazier, chairman and CEO of Merck & Co. Inc., said **FDA's prohibition on discussion of off-label uses of drugs is a barrier to outcomes-based pricing contracts. "When you run a clinical trial and get approval, what is on the label has to be the basis for outcomes contracts**," Shaw said. For example, she said, if a payer wants to look at total hospitalization and that is not on the label, it can't be included in an outcomes-based contract. Frazier, who also is chair of PhRMA, added, "**In order to have a good sense of what the true real-world risks are, we sometimes have to look beyond what's on the label of the drug. We are restricted from communicating about that by FDA**." However, according to Coleen Klasmeier, a partner at Sidley Austin LLP and former FDA attorney, **it isn't clear whether such communications are actually illegal, and ambiguity can deter companies from taking steps that are legal.** "The current enforcement climate and ongoing regulatory uncertainty makes it hard to determine in advance whether a particular activity is on the right side of the line," Klasmeier told BioCentury. "Even if you have a sound legal risk assessment that's supportive, you're stuck with the risk of an aggressive prosecutor taking a different view. Indeed, there's so much about the current paradigm that's subject to debate that the prosecutors themselves don't always have a good mastery of the relevant legal principles."

Noemie Bisserbe [WSJ], 11-10-2018, For New Trump Drug Plan, a Cautionary Tale in Italy
https://www.wsj.com/articles/italy-serves-cautionary-lesson-for-new-trump-drug-plan-1523959644

The fundamental issue: Regulators and drug companies tend to disagree on how to measure a drug's efficacy. That remains a major stumbling block to contracts being signed, health officials say. Another more pedestrian problem: The success of these programs depends on how well patients' treatments are tracked. In Italy, it falls on doctors to claim back the money from pharmaceutical companies when the drug doesn't work for their patients, but they don't receive a financial incentive to do so. "The money isn't going back to them or their department," said Filippo Drago, a professor at the University of Catania Medical School in Sicily, Italy, and a former member of the Italian Medicines Agency's pricing and reimbursement committee. "The performance of these agreements is very low," he said. For the contracts to yield better savings in the U.S., health insurers or pharmacy-benefit managers also need to ensure that doctors collect

patient data to assess a drug's efficacy. Italy started experimenting with outcomes-based contracts in 2008 mainly in response to conditional approvals for new drugs in Europe. Since 2006, drugs on the continent can receive regulators' green light after relatively short clinical trials if the drug is expected to meet medical needs. "The drug's efficacy isn't always clear when we decide what its price should be," said Simona Montilla, pharmacist manager at the Italian Medicines Agency, the national authority responsible for drugs regulation in Italy. Today, Italy has about 50 outcomes-based contracts with global drug companies, according to its public filings. Publicly available data show only a small amount of money is reimbursed to the country. Reimbursements from drug companies represented on average less than 1% of the Italian regulator's total spending on drugs between 2013 and 2016, according to public filings.

A2 Medicare part D

1. Turn - Medicare is the cause of current high drug prices. According to Sridha of Reason in 2018, Medicare and Medicaid artificially increase demand for drugs by using tax dollars to subside consumption. Thus, big pharma can raise their prices without losing their sales. For instance, three years after Medicare Part D was enacted to help seniors afford prescription drugs, the average retail prices of drugs tripled.
2. Turn - Letting Medicare negotiate prices would create an artificial monopoly. Clancy of The Hill explains in 2018 that medicare has no effective competition if it were allowed to set its own prices, making it a monopoly. It would likely set prices too low, leading drug companies to walk away, resulting in the supply of life saving drugs drying up and innovation slowing down.
3. Turn – Shepherd writes in 2016 that over 40 percent of drugs sold in the U.S. are sold under government programs that mandate price controls. With such a large share of their drugs sold at significant discounts, drug companies have the incentive to charge even higher prices to other *non-covered* patients to offset the discounts.

Joanna Shepherd, 3-13-2016, "Competition, not Price Controls," Truth on the Market, https://truthonthemarket.com/2016/03/13/competition-not-price-controls/

Second, over 40 percent of drugs sold in the U.S. are sold under government programs that mandate price controls. With such a large share of their drugs sold at significant discounts, drug companies have the incentive to charge even higher prices to other *non-covered* patients to offset the discounts. Indeed, numerous studies and government analyses have concluded that required discounts under Medicaid and Medicare have resulted in increased prices for other consumers as manufacturers seek to offset revenue lost under price controls.

TheHill, 1-18-2018, "The Creates Act: Lower drug costs without price controls," https://thehill.com/blogs/congress-blog/healthcare/369537-the-creates-act-lower-drug-costs-without-price-controls

Why? Because Medicare is a monopoly. It has no effective competition. If it were allowed to do so, it could pretty much set its own price.

Well, almost. If it set the price too law, as it likely would try to do, the drug companies would have no choice but to walk away. If that happened, the supply of life-saving drugs for seniors would dry up and innovation would slow down. Basically, the goose that lays the golden eggs would get cooked. We'd have artificial scarcity, a la bureaucracy.

Nikhil Sridha, 8-17-2018, "Subsidies and Price Controls Aren't the Answer to Skyrocketing Prescription Drug Prices," Reason, https://reason.com/blog/2018/08/17/subsidies-and-price-controls-arent-the-a
On the demand side, Medicare and Medicaid artificially increase demand for drugs by using tax dollars to subsidize consumption. That enables large pharmaceutical companies to raise their prices without suffering any meaningful decrease in their sales. Medicare Part D, for instance, was enacted in 2003 to help seniors afford prescription drugs, but it has actually trigged the opposite effect. A report from the American Association of Retired Persons, a senior citizens interest group, surveyed 528 medications many older adults take daily and found that "the average retail price was $12,951 in 2015, more than three times the average price for such drugs in 2006."

"Medicare part D has opened the floodgates for higher prescription prices," says Mark Thornton, a senior fellow at the Mises Institute and an expert on drug regulation. "The prices for cancer drugs are simply outrageous, but the government continues to pay despite no guarantee they will work."

In addition, these programs aren't cheap. In 2016, we spent $672.1 billion on Medicare and $565.5 billion on Medicaid, but healthcare and pharmaceutical costs remain stubbornly high, and are increasing.

A2 Generic competition

1. Nonunique – the status quo is solving back. The LA Times reports in 2018 that the FDA has worked to boost the number of generic prescription drugs by prioritizing approval of generic drugs. This is beneficial because generic entry into the markets cuts the cost of drugs by at least 85%. In fact, this is why the New York Times reports in 2017 that the Government Accountability Office reports that generic prices have been on the decline since at least 2010.
2. Decreased competition. Danzon of UPenn in 2002 explains that in Canada, which has price controls, generic drugs tend to actually be more expensive in Canada than in the United States. Winegarden furthers that right now, generic competition makes prices

really low, but since they operate on super small profit margins, with price controls, manufacturers are driven out. Temporary high prices incentivize generic companies to create cheaper alternatives, which disappears in the neg world. Shepherd in 2016 thus concludes that generic competition would do a better job at increasing affordability than price controls.

https://www.nytimes.com/2017/08/08/health/generic-drugs-prices-falling.html

Generic drugs are copycat versions of brand-name products and — to a point — their prices are expected to drop over time. When a brand-name drug first loses its patent protection, prices fall slowly. Over the next couple of years, as more competitors enter the market, the prices drop even more, until the pills become commodities and sell for pennies. Blockbuster drugs that have recently taken this path include Lipitor and Plavix, the cholesterol-lowering and blood-thinning pills that now cost as little as $10 for a monthly prescription.

Generic drug prices have been declining in the United States since at least 2010, according to an August 2016 report by the Government Accountability Office.

They have fallen even in the face of high-profile exceptions: Dozens of old generic drugs have risen in price in recent years, for reasons that include supply disruptions and competitors' leaving the market.

For example, the price that pharmacies paid for the antibiotic doxycycline hyclate increased to $3.65 a pill in 2013 from 5.6 cents in 2012, according to an analysis of pricing data by Adam J. Fein, president of Pembroke Consulting, who researches the drug-distribution industry. The spike in prices of doxycycline and other generic drugs led to a congressional investigation as well as state and federal inquiries into price-fixing that are still underway. A coalition of state attorneys general have accused a number of companies of colluding to keep prices high.

Mr. Fein said the price of doxycycline has since declined to 60 cents a pill. "That's a big switch," he said.

"FDA Says It Will Prioritize Generic Drugs to Help Control Prices." Los Angeles Times, Los Angeles Times, 27 June 2017, www.latimes.com/business/la-fi-fda-drug-prices-20170627-story.html.

http://www.latimes.com/business/la-fi-fda-drug-prices-20170627-story.html

The Food and Drug Administration said it's taking steps to boost the number of generic prescription drugs on the market in an effort to make medicines more affordable and to prevent price gouging.

Copycat pills generally have been much cheaper than original brand-name drugs. But recent high-profile cases have shown how lack of competition and medicine shortages allowed several drug companies to drastically increase prices for generics and some older brand-name products such as EpiPen emergency allergy injectors.

New FDA commissioner Dr. Scott Gottlieb made addressing prices a priority, saying that agency can help by increasing market competition. While the FDA reviews and approves medications, it doesn't have the power to regulate prices.

"No patient should be priced out of the medicines they need, and as an agency dedicated to promoting public health, we must do our part to help patients get access to the treatments they require," Gottlieb said in a statement.

On Tuesday, the FDA said it would now give priority reviews to new generic drugs until there are at least three on the market. That's the level at which prices tend to drop sharply, up to 85% off the brand-name price.

The agency also published its first list of brand-name drugs that no longer have a patent's protection but don't yet have generic competition, a strategy to entice generic drugmakers to develop copycats.

A2 Effective innovation

1. Literally doesn't make sense. If companies could make more money but dropping prices to increase market share, they would have done so already. They haven't because the increase in market size isn't actually enough to offset prices.
2. Siew 2017 - Small and specialty companies with limited infrastructure are playing a bigger role in innovation and early stage product pipelines. Problem is, when these companies take a direct revenue hit due to price controls, they never get a chance to rebound.
    a. AEI Media 2018 - Just the threat of price controls in 1993–took an almost devastating toll on the very companies that conduct the most intensive R&D into new drugs. In the aftermath of the plan's announcement, the more intensely R&D–focused a company was, the more its stocks dropped. Small biotechnology firms' stock prices fell the most and recovered only slowly.
3. Greenhut 2018 - Driving down long term investment. 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. In the long term, you're going to see less people investing in and entering this industry because it is no longer as profitable.
    a. Empirically confirmed. AEI Media 2008 - Europe's tight control over drug spending has led to sharp restraints on drug R&D spending. Between 1986 and 2004, Europe's pharmaceutical industry R&D grew at merely one-half the rate of that in the United States. In the mid 1980s, Europe's drug R&D exceeded that of the United States by 24 percent. By 2004, however, it trailed U.S. spending by 15 percent.
4. [A2A2 Better innovation] Turn: Lamattina in 15 explains that price controls increase me-too drugs because it's so expensive to produce an innovative drug. With less profits, companies are incentivized to pay less to create a old drug, give it a new name, mount a massive advertising campaign, and market it as the latest breakthrough. If you look specifically at US companies, historically, our ITIF card shows you that just the proposal of price controls makes companies switch from producing new drugs to improving their manufacturing process, the manufacturing version of "me-too" drug production.

John Lamattina, 1-19-2015, "Impact Of 'Me-Too' Drugs On Health Care Costs," Forbes, https://www.forbes.com/sites/johnlamattina/2015/01/19/impact-of-me-too-drugs-on-health-care-costs/

"It's expensive to produce an innovative drug. On average, the bill runs to more than $400 million. So drug companies often take a less costly route to create a new product. They

chemically rejigger an oldie but goodie, craft a new name, mount a massive advertising campaign and sell the retread as the latest innovative breakthrough."

5.

Aei Media, 12-17-2008, "Government Price Controls on Drugs Will Reduce Innovation and Cost Lives," AEI, http://www.aei.org/press/government-price-controls-on-drugs-will-reduce-innovation-and-cost-lives/

• Europe's tight control over drug spending has led to sharp restraints on drug R&D spending. Between 1986 and 2004, Europe's pharmaceutical industry R&D grew at merely one-half the rate of that in the United States. In the mid 1980s, Europe's drug R&D exceeded that of the United States by 24 percent. By 2004, however, it trailed U.S. spending by 15 percent.

• America's mere flirtation with heavy government price controls–the Clinton health plan of 1993–took an almost devastating toll on the very companies that conduct the most intensive R&D into new drugs. Vernon and Golec's research shows that in the aftermath of the plan's announcement, the more intensely R&D–focused a company was, the more its stocks dropped. Small biotechnology firms' stock prices fell the most and recovered only slowly.

3. Empirically, countries with PC have less innovation, bc less entrep wanna enter that field long term

Adeline Siew Phd, 11-23-2017, "Small and Specialty Companies Shape Pharma's Evolving Outsourcing Landscape," No Publication, http://www.pharmtech.com/small-and-specialty-companies-shape-pharma-s-evolving-outsourcing-landscape

There is growing demand for "CDMOs" in both pharmaceutical product development and manufacturing. Several major trends are driving this growing demand—small and specialty companies with limited infrastructure are playing a bigger role in innovation and early stage product pipelines. Big and mid-sized Pharma continue to tighten their focus on core discovery and commercialization activities, and thereby align with external partners to advance their promising compounds. Patient-centric and more specialized medicines are driving the need for more complex formulation and processing capabilities. These trends translate into increased need for not only external partners, but those will capabilities that can help advance today's drug development and manufacturing challenges.

Steven Greenhut, 5-11-2018, "Price Controls Will Slow Drug Innovation," Reason, https://reason.com/archives/2016/01/01/price-controls-will-slow-drug-innovation
"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," wrote University of Southern California pharmacy professor Darius Lakdawalla in The New York Times. Drug prices would fall by 20 percent, "but innovation would fall by even more. Patients would see their lives cut short by delayed or absent drug launches."

A2 Lowers prices

A2 Link – Insurance costs

1. Consumers with insurance are buffered from changing prices of drugs. Rosenbaum of the New York Times explains in 2000 that while drug prices have been rising by about 15% a year, private insurance and employers have been increasingly picking up the tab instead of passing the costs on to consumers. Rosenbaum gives the example of Ford, which when drug prices increased, shouldered the burden and increased how much the company spent on drugs instead of passing the cost down onto their employees.
2. No reason to pass on the profits.

A2 Link – Prices down

3. The DRG finds status quo is solving. As of June of this year, major pharmaceutical companies have implemented programs to increase transparency of prices by allowing members to alternative low-cost alternatives, which also increases leverage against drug companies to negotiate lower prices.
4. Delink - Although consumers pay more for brand new drugs, over their lifetimes, the amount they spend on drugs is very similar. Hirschler of Scientific American explains that international price comparisons are misleading because list prices do not take into account the discounts that come from aggressive negotiation from insurance companies. Additionally, nearly all of 90% of new medicines prescribed to US patients are cheap generics, so while Americans pay more for new drugs, they pay less for the majority of drugs they take, evening out US prices with international prices.
5. Turn - Higher drug prices allows for better innovation. As a consequence, Goldberg of the NCAP in 99 explains that dollar for dollar, drugs give us a better return on health care spending than virtually any other health care option and every dollar spent on drugs is associated with $4 decline in spending on hospitals.
6. Turn - Price controls increase the number of drugs people have to buy, because less new drugs are produced. Hais in 2018 explains that price controls in France has resulted in lower individual drug prices, but on net, French people spend more on drugs than people in the United States. The reason this is because price controls stifle originality and induce risk aversion. Narayan gives a similar example in 2007, where in the first 12 months

following a price control implemented in India, drug prices per household increased by 4.6%.

7. Turn - Price controls actually decrease competition, which drives down the price of drugs to the true market value, not an arbitrary value set by the marketplace.
    a. Generics. Danzon of UPenn in 2002 explains that in Canada, which has price controls, generic drugs tend to actually be more expensive in Canada than in the United States. Winegarden furthers that right now, generic competition makes prices really low, but since they operate on super small profit margins, with price controls, manufacturers are driven out. Temporary high prices incentivize generic companies to create cheaper alternatives, which disappears in the neg world. Shepherd in 2016 thus concludes that generic competition would do a better job at increasing affordability than price controls.
    b. Decreasing competition. The FDA, from case, shows that the entry of one additional drug into the market decreases price by 50%. However, price controls decrease competition by reducing innovation. The National Bureau of Economics writes that cutting prices by just 40% would reduce the amount of new drug projects by 30 to 60%.

[A2 Generic price increased by 100% - Nonunique – the status quo is solving back. The LA Times reports in 2018 that the FDA has worked to boost the number of generic prescription drugs by prioritizing approval of generic drugs. This is beneficial because generic entry into the markets cuts the cost of drugs by at least 85%. In fact, this is why the New York Times reports in 2017 that the Government Accountability Office reports that generic prices have been on the decline since at least 2010.]

Thomas A. Abbott John A Vernon 2-2005, "THE COST OF US PHARMACEUTICAL PRICE REDUCTIONS: A FINANCIAL SIMULATION MODEL OF R&D DECISIONS" http://www.nber.org/papers/w11114.pdf National Bureau of Economic Research

Abbott and Vernon apply a new technique to studying this question about research and development (R and D). They maintain that their approach is more closely aligned with the actual structure of R and D investment decisions by firms**. They take account of the uncertainty around R and D research costs, the success rates for drug developments, and the financial returns to those products that are successfully launched onto the market. Their** basic **finding is that cutting prices by 40 to 50 percent in the United States will lead to between 30 and 60 percent fewer R and D projects being undertaken in the early stage of developing a new drug.** Relatively modest price changes, such as 5 or 10 percent, are estimated to have relatively little impact on the incentives for product development - perhaps a negative 5 percent. 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

Joanna Shepherd, 3-13-2016, "Competition, not Price Controls," Truth on the Market, https://truthonthemarket.com/2016/03/13/competition-not-price-controls/
Instead of imposing price controls, the government should increase drug competition in order to reduce drug spending without these negative consequences. Increased drug competition will expand product offerings, giving consumers more choice in the drugs they take. It will also lower prices and spur innovation as suppliers compete to attain or protect valuable market share from rivals.

The recent surge in drug spending must be addressed to ensure that patients can continue to afford life-saving and life-enhancing medications. However, proposals calling for new price controls are the wrong approach. While superficially appealing, price controls may have unintended consequences—less innovation, drug shortages, and higher prices for some consumers—that could harm consumers rather than helping them. In contrast, promoting competition will lower pharmaceutical prices and drug spending without these deleterious effects.

DRG, 06-25-2018, ***Three Drug-Pricing Controls Emerge in U.S. Market – DRG Blog, Health Reform – DRG, https://decisionresourcesgroup.com/drg-blog/health-reform/three-drug-pricing-controls-emerge-u-s-market/***

In an effort to bring more public transparency to drug pricing and net rebates, **both UnitedHealthcare and Aetna have announced direct-to-consumer pharmacy discount programs for their fully insured plan members.** Combined, fully insured enrollment of the two carriers represents about 15 percent of all fully insured lives in the United States. **The move signals that national payers are taking a more active role in addressing transparency.** UnitedHealth's point-of-sale discount program will apply to more than 8 million members enrolled in fully insured commercial group plans when they fill their prescriptions through retail pharmacies or home delivery. **The insurer is launching the program in January 2019, and members can verify the discounted cost of drugs, including savings from rebates, through UnitedHealth's mobile app and website before going to the pharmacy.** Aetna's rebate discount program, also beginning in 2019, will function similarly. Currently, Aetna passes rebates to plan sponsors through reduced premiums. **By connecting the consumer directly to the rebate, these plans should have increased leverage to steer enrollees to lower-cost drugs or drugs that have a more favorable placement on plan formularies—essentially increasing formulary control and increasing plan negotiating clout with drug companies for higher-cost or newer drugs**. In addition, pharmacy benefit managers CVS/caremark and Express Scripts have announced that they offer point-of-sale benefit design to their clients or health plans. The Centers for Medicare & Medicaid Services also is working toward recognizing the value of POS rebates, and some of its recently proposed changes for Medicare and Part D include applying drug manufacturer discounts on the drug price at point of sale. CMS has issued a request for information on policies for manufacturer rebates and direct or indirect remuneration amount.

Winegarden 18 ***[Wayne, Ph.D. a Partner in the economic consulting firm Arduin, Laffer & Moore Econometrics (ALME) where he advises corporations, policy & trade associations, and government agencies on the business and economic implications from changes in economic trends and government policies. "Pharmaceutical Price Controls Will Not Improve Health Care Outcomes in Illinois," 17 May 2018. Forbes. https://www.forbes.com/sites/econostats/2018/05/17/pharmaceutical-price-controls-will-not-improve-health-care-outcomes-in-illinois/#56ed706470d5]***

The competitive environment that generic medicines enable also means that these firms will typically operate with very small profit margins. Due to these thin profit margins, HB 4900's price controls are particularly damaging for these manufacturers. **Consequently, HB 4900 could have the perverse impact of driving out manufacturers. This would worsen the competitive environment and (ironically) lead to higher cost pressures.**

Sandeep Narayan, "PRICE CONTROLS ON PHARMACEUTICAL PRODUCTS IN INDIA", Institute of South Asian Studies, March 19, 2007, https://www.isas.nus.edu.sg/wp-content/uploads/media/isas_papers/20.pdf, SP, October 13, 2018
Therefore, the government controls under DPCO 50 per cent of the pharmaceutical market in India (ICRA, 2000). The impact of prices of drugs during post-DPCO (1995) period evaluated by

the ORG (1996) found that there had been a 4.6 per cent increase in drug prices in the 12 months following the announcement of the 1995 DPCO compared to an increase in the Consumer Price Index (CPI) of 9.8 per cent for the same period. The study also showed that the index of prices on products that had moved from the controlled to the decontrolled category under the DPCO had also registered around 10.7 per cent increase. Though there is a price controls under DPCO, still a majority of drugs in the market are not regulated and the price rise during this period is still considered to be minimal.

Robert Goldberg, NCAP, 10-1-1999, Ten Myths about the Market for Prescription Drugs, http://www.ncpathinktank.org/pub/st230?pg=3, 10-3-2018, AK

In many cases, the use of prescription drugs has reduced the cost of other health care services. Even greater savings are possible. For example, one recent study found that every dollar spent on drugs is associated with a $4 decline in spending on hospitals.2 The decline in total spending due to greater use of prescription drugs is particularly notable in the treatment of cancer, heart disease, Alzheimer's, AIDS and mental illness. The following are some examples.

Edmund Hais, “Why Global Budgets and Price Controls Will Not Curb Health Costs”, The Heritage Foundation, March 8, 1993, https://www.heritage.org/health-care-reform/report/why-global-budgets-and-price-controls-will-not-curb-health-costs, SP, October 12, 2018

France is a good example of how pharmaceutical price controls can backfire in just such a fashion—simultaneously destroying innovation while boosting total costs. One analyst notes that, “In France, the calibre of pharmaceutical research is seen as having deteriorated, because severe price control has encouraged French companies to give priority to small therapeutic improvements which are useful in price negotiations. Such systems tend to stifle originality and induce risk aversion.” (Heinz Redwood, “The Price of Health,” The Adam Smith Institute, London, 1989, p. 42.) Indeed, the French drug industry produced only three of the 66 world class drugs brought to market between 1975 and 1989, while the U.S. drug industry produced thirty—or ten times as many. (Barral, op. cit.) Yet, despite lower drug prices, the French spend considerably more on pharmaceuticals than do Americans. While pharmaceuticals account for 8.3 percent of health spending in the U.S., they account for twice that level, 16.7 percent, in France (See chart on page 7). Measured another way, per-capita drug spending is almost three times greater in France ($492 per person) than in the U.S. ($182 per person) (See chart on page 8).

https://pdfs.semanticscholar.org/a321/3bfc0a4c8b4056f211dce1e563be9591b54b.pdf

. Note that these characteristics are related: .
incentives for generic entry are weak where demand is not price sensitive and
where regulated originator prices decline with molecule age, hence, are very low
by the time of patent expiry. The combined effect of therapeutic substitute
molecules and therapeutic substitute entry lag contributes little to explaining the
magnitude of cross-national price differences, although in general the combined
effect is to reduce prices in other countries relative to the US insignificant Ž
difference for Canada . As discussed earlier, this effect is more plausibly attributed .
to regulation than to competition, at least for France, Italy and Japan.

https://accessiblemeds.org/resources/blog/2018-generic-drug-access-and-savings-report
#DYK that while #generic medicines account for 90% of all prescriptions filled in the U.S., they only account for 23% of prescription spending? Learn more from @accessiblemeds #GRxSavingsReport today. http://bit.ly/RxAccessReport

No Author, 10-7-2002, "Government Price Controls on Prescription Drugs May Be More than Patients Bargain For," No Publication,
http://hinj.org/government-price-controls-on-prescription-drugs-may-be-more-than-patients-bargain-for/
In 1999, Patricia Danzon, a professor at the University of Pennsylvania's Wharton School of Business, conducted a study comparing drug costs in several countries. Here's what she found, "Canadian prices are between 13 percent lower and 3 percent higher than the U.S., depending on the price index used. "

However, her study also concluded that generic drugs — which make up 45 percent of the U.S. prescription drug market — tended to be more expensive in Canada than in the U.S. The biggest problem with implementing price controls, however, may be access. Most Canadian provinces have a review committee that must approve any drug offered for sale. These approved drugs, also known as "formularies," are an integral part of the price control regime. Between 1998 and 1999 only 25 drugs were listed on the formulary for the province of Ontario, even though nearly a hundred drugs were available. Similarly, the Canadian government ruled that only 24 new drugs could be added to the formulary, even though they reviewed 400 drugs!

Ben Hirschler, xx-xx-xxxx, "How the U.S. Pays 3 Times More for Drugs," Scientific American,
https://www.scientificamerican.com/article/how-the-u-s-pays-3-times-more-for-drugs/
The U.S. Pharmaceutical Research and Manufacturers of America (PhRMA) says international comparisons are misleading because list prices do not take into account discounts available as a result of "aggressive negotiation" by U.S. insurers.

These discounts can drive down the actual price paid by U.S. insurance companies substantially. However, similar confidential discounts are also offered to big European buyers such as Britain's National Health Service.

"The U.S. has a competitive marketplace that works to control costs while encouraging the development of new treatments and cures," Holly Campbell, PhRMA's director of communications, said in a statement.

PhRMA also argues that while Americans may pay more for drugs when they first come out, they pay less as drugs get older, since nearly 90% of all medicines prescribed to U.S. patients are now cheap generics.

David E. Rosenbaum, 6-1-2000, "Health Insurance Provides Buffer to Rising Drug Prices for Most Americans," New York Times, https://www.nytimes.com/2000/06/01/us/health-insurance-provides-buffer-to-rising-drug-prices-for-most-americans.html
No one disputes that these new drugs cost much more in the United States than they do abroad. A survey last fall by USA Today found that Prilosec, for instance, cost only $1.47 a day in Canada, $1.67 in Britain, $1.29 in Australia and 99 cents in Mexico. The governments in those countries negotiated the lower prices.

The elderly who have no insurance except Medicare and other Americans without insurance pay the prices. But it is not clear that Americans overall pay more for drugs than people in other countries.

The most recent extensive study, by Patricia M. Danzon, a professor of health management at the Wharton School of the University of Pennsylvania, concluded that Americans might not pay more when factors were counted like the discounts received by American drug companies, the widespread use of generic drugs in this country and the different dosages prescribed in different countries.

David E. Rosenbaum, 6-1-2000, "Health Insurance Provides Buffer to Rising Drug Prices for Most Americans," New York Times, https://www.nytimes.com/2000/06/01/us/health-insurance-provides-buffer-to-rising-drug-prices-for-most-americans.html
More and more in recent years, private insurance has been picking up the cost of prescription medicine. Only about one-quarter of Americans' total drug costs are now paid out of pocket.

That is why there is no general political uproar even though drug prices in the United States have been rising by as much as 15 percent a year, the drug makers are among the most profitable businesses in the world and many new drugs in Canada and Europe cost a small fraction of what they do here.

Imagine the political swivet Americans would be in if that were the case with gasoline or some other staple of daily life.
Employers are paying the tab. At the Ford Motor Company, for example, Dr. Woodrow A. Myers Jr., the director of health care management, calculated that the company's pharmaceutical bill would increase by nearly 25 percent this year alone, to $470 million from $380 million in 1999. The company, he said, paid nearly as much for drugs as for workers' hospitalization.

Ford employees never feel the pinch. Hourly workers pay $5 for each prescription. Salaried workers pay $12 for brand name drugs and $2 for generic drugs. Retirees get the same benefits.

A2 Link - Healthcare costs

1. Mitigate. Goldberg of the IPI in 2013 concludes that price controls in the U.S. would only save .1% of total health care costs. The reason this is the case is that healthcare costs right now are due to the high cost of going to the hospital, not drugs, which only account for something like 2% of our overall healthcare spending.
2. Turn - lower quality drugs propagate. Atella of PMC explains that price controls reduce the incentive of companies to produce higher quality drugs, as producing a high quality drug is more expensive than a lower quality one, resulting in consumers consuming drugs of a lower quality. Thus, Edmund finds that Europeans spend more on drugs because they need to buy more to get the same effect while also having more hospital visits. Estimates that say that US consumers pay more for drugs than Europeans are based on the idea that consumers in both countries purchase the same number of drugs, which is not the case. Europeans need to buy a higher quantity of drugs, forcing them to pay more on net.

Edmund Hais, “Why Global Budgets and Price Controls Will Not Curb Health Costs”, The Heritage Foundation, March 8, 1993, https://www.heritage.org/health-care-reform/report/why-global-budgets-and-price-controls-will-not-curb-health-costs, SP, October 12, 2018

France is a good example of how pharmaceutical price controls can backfire in just such a fashion—simultaneously destroying innovation while boosting total costs. One analyst notes that, “In France, the calibre of pharmaceutical research is seen as having deteriorated, because severe price control has encouraged French companies to give priority to small therapeutic improvements which are useful in price negotiations. Such systems tend to stifle originality and

induce risk aversion." (Heinz Redwood, "The Price of Health," The Adam Smith Institute, London, 1989, p. 42.) Indeed, the French drug industry produced only three of the 66 world class drugs brought to market between 1975 and 1989, while the U.S. drug industry produced thirty—or ten times as many. (Barral, op. cit.) Yet, despite lower drug prices, the French spend considerably more on pharmaceuticals than do Americans. While pharmaceuticals account for 8.3 percent of health spending in the U.S., they account for twice that level, 16.7 percent, in France (See chart on page 7). Measured another way, per-capita drug spending is almost three times greater in France ($492 per person) than in the U.S. ($182 per person) (See chart on page 8).

Vincenzo Atella,, xx-xx-xxxx, "Pharmaceutical Price Controls and Minimum Efficacy Regulation: Evidence from the United States and Italy," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3447248/
On the cost side of the ledger, price controls reduce the availability of the highest quality drugs. In addition, they limit the close link between drug quality and price that is present in a market without price controls. To the extent that developing high-quality drugs is more expensive than developing lower quality drugs, this reduced correlation further undercuts the incentives that pharmaceutical companies face to produce high-quality drugs.

A2 Link – Innovation

1. Innovation is happening right now. The IMS writes that by 2020, we're expected to see a surge of research and development that will increase availability and efficacy of low-cost drugs. For example, Terry of BioSpace finds that Gilead is reaching milestones in the development of HIV cures, proving innovation in unchartered territory is occurring even with high prices.

Murray Aitken [IMS], 2015,
https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-medicines-use-in-2020
Over the next five years, we expect to see a surge of innovation emerging from the research and development pipeline, as well as a range of technology-enabled transformations that will expand the evidence-basis for interventions and bring measurable improvements to health outcomes by 2020. With unprecedented treatment options, the greatest availability of low-cost drugs, and better use of evidence to inform decision-making about the optimal use of medicines, stakeholders around the world can expect to get more "bang for their medicine buck" in 2020 than ever before. This study was produced independently by the IMS Institute for Healthcare Informatics as a public service and without industry or government funding. The contributions to this report of Kim Pennente, Jennifer Lyle, Bernie Gardocki, the IMS Health forecasting team and many others at IMS Health are gratefully acknowledged.

Mark Terry [BioSpace], 3-20-2018, Can Gilead Develop a Cure for HIV?,
https://www.biospace.com/article/can-gilead-develop-a-cure-for-hiv-/

Since its first emergence in the early 1980s, HIV has gone from a terminal and untreatable disease to one that can be managed more like a chronic illness. But so far a "cure" has eluded scientists. But **Gilead Sciences, Inc., one of the leaders in HIV drug development, and the company which essentially created a cure for hepatitis C, may be well on its way to developing a cure for HIV.** Gilead's HIV franchise brought in more than $14 billion in revenue last year. It recently announced preclinical trial results in monkeys where a two-drug combination appeared to actually cure the animals of the disease. One of the drug, GS-9620, is in an early-stage clinical trial and a related drug to the other in the combo, GS-9722, is now beginning human testing. GS-9620 forces latent HIV from the virus's immune cell reservoir. At that point, PGT121 then attaches to the virus and clears it from the blood. Although a long way from approval, and probably a long way from actual proof that it would work in humans, it's promising. Most advanced HIV therapeutics, typically a cocktail of two or three different drugs, are able to knock back the virus and control the disease. But the virus hides in pockets in the immune system, and if the patient stops taking the drugs, or is immuno-compromised or stressed, the virus can make a resurgence. Josh Bloom, writing for the American Council on Science and Health, says, "**Even if things go perfectly we are still (at best) years from a cure, but the synergistic effect of these two drugs provides 'proof of concept,' a critically important milestone in drug development.** Meanwhile, **Gilead** isn't sitting still. The company **discovered GS-9722, a different antibody that may be superior to PGT121, which is now in Phase I trials, as is the GS-9620-PGT121 combination."**

A2 Link - Monopolies

1. Literally doesn't exist. According to the Foundation for Economic Education in 2018, predatory pricing is a myth. Basic economic theory makes clear that a firm that tries to monopolize a market by charging prices below cost inflicts on itself losses larger than those it inflicts on any of the firms it's trying to bankrupt.
2. Nonunique - Big phama is dependent on small pharma**. According to Radcliffe of Healthline in 2017**, big pharma such as Pfizer have invested billions in independent startups because they depend on these companies to create profitable drugs that they can then buy out. Logically, they wouldn't allow these companies to fall because they have a vested interest in them. Small company's goal is to get bought out because their leadership teams want to make money. That's why Public Citizen reports that the past few years have seen the consolidation of the industry is larger, as large companies have now captured 64% of the market up from 28% in 2007.
3. Nonunique - The cause of big companies having monopolies isn't drug profits, it's barriers to entry via research. Sridha of Reason explains in 2018 that the cost for trails demanded by the FDA can cost hundreds of millions of dollars, serving as a formidable barrier of entry to startup drug companies. Massive pharmaceutical companies can afford these regulations but smaller competitors cannot, creating the monopolization of pharmaceutical giants.
4. Turn - the AEI reports in 2001 that price controls actually increase monopolies. They make pharmaceuticals less profitable, discouraging small companies from entering the market.

"The Rising Cost of Generic Drugs | Public Citizen",
https://www.citizen.org/our-work/health-and-safety/the-rising-cost-of-generic-drugs

A large part of the explanation comes from changes to the generic-drug market. The past few years have seen increasing consolidation of this industry, leading to fewer major generics

makers and thus less price competition. In 2007, the top 10 generic-drug companies had just 28.5 percent of global market share,[14] but by 2014, had captured 64 percent of that market.[15] Last year Teva Pharmaceuticals, already the world's largest generic-drug company, announced that it was acquiring the third-largest manufacturer, Allergan's generics unit, for $40.5 billion.[16] Such mergers, and the resulting loss of competition, likely have been a key factor in the dramatic price hikes of many generic drugs.[17]

Donald J., 7-11-2018, "The Myth of Predatory Pricing," No Publication, https://fee.org/articles/the-myth-of-predatory-pricing/
Basic economic theory makes clear that a firm that tries to monopolize a market by charging prices below cost inflicts on itself losses larger than those it inflicts on any of the firms it's trying to bankrupt.
For a firm to drive its rivals out of business by charging "excessively" low prices, it must not only cut its prices but also expand its sales. Remember, the objective is to take so many sales away from rival firms that they all go bankrupt. But when a firm increases its sales at below-cost prices, that firm necessarily incurs huge losses. The predator's rivals, while they might all be obliged to also sell at prices below cost, have an advantage that the predator doesn't: they can reduce their sales during the price war in order to keep their losses to a minimum.

John Calfee, AEI, 1-2-2001, The Unintended Consequences of Price Controls, https://www.aei.org/publication/the-unintended-consequences-of-price-controls/ , 10-3-2018, AK

Those harms are largely invisible to the public in these countries. Worse, price controls systems tend to persist, despite their destructive consequences, because pharmaceutical firms, healthcare providers and healthcare funding agencies can learn to live with and even benefit from a system that reliably protects profits and discourages new entrants, while assuring stability in prices and expenditures. Meanwhile, cutting edge scientists and venture capital quietly retrench in their work on pharmaceuticals for the elderly–to cite one important area–and move on to more profitable arenas.

Nikhil Sridha, 8-17-2018, "Subsidies and Price Controls Aren't the Answer to Skyrocketing Prescription Drug Prices," Reason, https://reason.com/blog/2018/08/17/subsidies-and-price-controls-arent-the-a
Trump's FDA Commissioner, Scott Gottlieb, has gained a reputation for his relatively speedy drug approvals, but that doesn't address the underlying cause of having a massive, bureaucratic agency dedicated to limiting competition in the industry. According to the BrightFocus Foundation, a non-profit focused on supporting medical research, the costs for trials demanded by the FDA can cost hundreds of millions of dollars. This serves as a formidable barrier of entry

to startup drug companies looking to introduce potentially life-saving drugs to the marketplace. Massive pharmaceutical companies can afford these regulations, but smaller competitors cannot. This dynamic expands the monopolization of pharmaceutical giants, who can dragoon consumers and insurance companies into paying heavily amplified prices.

A2 – Hep C (Sofosburvir)

2. Pharmacy Times finds that Gilead's already making generics for their hepatitis C treatment that will knock the price down $2500.
3. Pharmacy Times continues over the past five years, insurance and government payers have decreased the price of brand-name Sofosbuvir by 60%.

Pharmacy Times, 9-25-2018, ***Gilead to Sell Authorized Generic Versions of Hep C Treatments,***
https://www.pharmacytimes.com/resource-centers/hepatitisc/gilead-to-sell-authorized-generic-versions-of-hep-c-treatments

Officials with Gilead Sciences, Inc. plan to launch authorized generic versions of sofosbuvir 400 mg/velpatasvir 100 mg (Epclusa) and ledipasvir 90mg/sofosbuvir 400 mg (Harvoni), **Gilead's leading treatments for chronic hepatitis C virus (HCV)**, in the United States, through a newly created subsidiary, Asegua Therapeutics LLC, according to a press release from the company. **The authorized generics will launch at a list price of $24,000 for the most common course of therapy and will be available in January 2019. The brand-name versions have been the subject of much debate since the launch of Gilead's first HCV medication in 2013, but the average price paid for each bottle of medicine in the United States has decreased by more than 60% off of the public list price**s, across health insurers and government payers. "Due to the complexity and structure of the US health care system, however, these discounts provided by Gilead may not always translate into lower costs for patients," according to the statement. Further, existing contracts, together with laws associated with government pricing policies, make it challenging to quickly lower a product's list price once it is on the market. The authorized generics are priced to more closely reflect the discounts that health insurers and government payers receive today, according to information in the press release. Insurers will have the choice of offering either the authorized generics or the branded medications for both Epclusa and Harvoni. In the Medicare Part D setting, the authorized generics could save patients up to **$2,500 in out-of-pocket costs per course of therapy.** The authorized generics will also offer substantial savings to state managed Medicaid plans that do not currently benefit from negotiated rebates and that represent a significant number of people in need, potentially opening up access to our medications to beneficiaries who were previously denied coverage. Beyond the company's efforts to reduce patient costs, Gilead is continuing to pursue innovative collaborations and long-term financing models, such as a potential subscription model, that could not only expand access, but aim to eliminate HCV in the United States and around the world.

A2 Impact - Reducing black market for drugs

1. Delink - Illegal drug demand is inelastic. Dolan of Business Insider reports in 2011 that economic studies of the data surrounding illegal drug use show that increases in the prices of illegal drugs do not reduce consumption by a significant amount, thus making their demand inelastic. The reason for this is that because cocaine, heroin, and the rest are addictive, people who use them don't find it easy to kick the habit just because the price goes up a little bit.
2. Why no skip squo?

Ed Dolan, 3-31-2011, "Why It's Obvious We Are Losing The War On Drugs," Business Insider, https://www.businessinsider.com/econ-101-hayek-and-why-we-are-losing-the-war-against-drugs-2011-3

What is the elasticity of demand for illegal drugs? Intuition suggests that demand should be inelastic. If cocaine, heroin, and the rest are addictive, people who use them will not find it easy

to kick the habit just because the price goes up a bit. Econometric studies of the question are hampered by the fact that drug lords don't post accurate price and revenue data on their web sites, but such research as has been done tends to confirm the hypothesis of inelastic demand. For example, one survey of the literature found that a 1% increase in the price of cocaine would tend to reduce consumption by only 0.51 to 0.73 percent, solidly in the inelastic range.

A2 Lobbying

A2 Link - Marketing decreases

1. [Doctor] N/U squo Desai - Pharmaceutical sales representatives are struggling more than ever to get time with healthcare providers. The number of rep accessible physicians declined in 2016, with only 44% willing to meet with sales reps, down from 80% in 2008.
2. Turn – FDA surveyed doctors and concluded that physicians agreed that consumers who saw DTC ads were more involved in their healthcare and asked more questions but over 90% of physicians did not say they felt pressure to prescribe medications that were grand name over generics.

No Author, xx-xx-xxxx, "Information for Consumers (Drugs) > The Impact of Direct-to-Consumer Advertising," No Publication, https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143562.htm

- Most physicians agreed that because their patient saw a DTC ad, he or she asked thoughtful questions during the visit. About the same percentage of physicians thought the ad made their patients more aware of possible treatments.
- Many physicians thought that DTC ads made their patients more involved in their health care.
- Eight percent of physicians said they felt very pressured to prescribe the specific brand-name drug when asked.
- DTC ads help patients have better discussions with their physicians and provide greater awareness of treatments. The study demonstrated that when a patient asked about a specific drug, 88 percent of the time they had the condition that the drug treated. And 80 percent of physicians believed their patients understood what condition the advertised drug treats

Ashik Desai, xx-xx-xxxx, "Shifting the Pharma Marketing Budget Mix – PM360," No Publication, https://www.pm360online.com/shifting-the-pharma-marketing-budget-mix/ Pharmaceutical sales representatives are struggling more than ever to get time with healthcare providers. A recent study by ZS (http://bit.ly/2f4tiOk) shows the number of rep accessible physicians declined in 2016, with only 44% willing to meet with sales reps, down from 80% in

2008. Surprisingly, 88% of overall pharmaceutical sales and marketing dollars still are allocated to sales representatives.

Ana Swanson, 2-11-2015, "Big pharmaceutical companies are spending far more on marketing than research," Washington Post, https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/
Prescription drugs are a massive market: Americans spent $329.2 billion on prescription drugs in 2013. That works out to about $1,000 per person in the U.S., as John Oliver pointed out in his show on Sunday night.

Oliver also mentioned that nine out of 10 big pharmaceutical companies spend more on marketing than on research. León Markovitz of Dadaviz found and graphed those figures from healthcare research firm GlobalData in the graphic below. The amounts spent on sales and marketing are shown in orange, while the amounts spent on research and development are in blue.

Lisa Lamotta, 9-18-2017, "5 Trends shaping the pharma sales force," BioPharma Dive, https://www.biopharmadive.com/news/spotlight-trends-pharma-sales-force-digital-marketing/504949/
But niche markets mean that brands are no longer the differentiating factor. Now, there is often just one drug available to treat a certain patient population, and sales reps are put in a very different position.

Konzelmann noted that now reps are often in the role of account manager, providing the service of liaison between physicians and companies, and responsible for things including demonstrating new modes of administration (since little white pills have given way to biologics) and explaining reimbursement (because the payer system has gotten increasingly complicated).

Smaller markets also mean that patients are often at a different place in their journey when the sales rep comes into the picture. Previously, patients were easily diagnosed for commonly understood diseases. Now, physicians often need help identifying which patients should be screened for rare diseases or might be eligible for a certain drug.

A2 Link - Lobbying decreases

1. Delink - Lobbying is a small part of pharmaceutical spending. The International Trade Administration finds in 2016 that the pharmaceutical industry made over 300 billion dollars in sales last year. That pales in comparison to the 240 million that Chon of the New York Times in 2016 says that Big Pharma spent on lobbying last year. Lobbying

constitutes such a small part of US drug spending that a slight decrease in drug profits will have no effect on how much these corporations can lobby. Thus, Mereli of Quartz Magazine in 2015 explains that even with only 1% of current investment, the pharmaceutical and insurance industry can still stall attempts at substantial reforms at the federal level.

2. Delink - Acquiescence to pharmaceutical lobbying is on the decline. The Hill explains in 2017 that there is a growing bipartisan consensus to oppose pharmaceutical lobbying, lifting it's almost bulletproof influence over debates on drug policy. For instance, a bill was just introduced to close one of the loopholes big pharma was using to make money, a step unthinkable in the past. Additionally, Forbes reports in 2018 that more than 30 states have proposed bills on drug pricing in 2017 that are slowly starting to pass, further eroding big pharma's grip on legislation.
3. Turn - Lobbying results in lives saved. For instance, the Hill in 2016 explains that the pharmaceutical industry scored a big victory with Obama's 21st Century Cures Act which boosted funding for research and treatment of mental illnesses and expedited the path of these drugs through the FDA. Delays in drug approvals kills. Kazman in 2010 explains that victims of incorrect FDAP approval are highly visible, but victims of incorrect FDA delays are invisible. He gives the example of beta blockers which were approved in Europe but stalled in the FDA approval system, finally getting approval years later at the cost of as many as 100,000 people who could have benefited from the drug.

Arlene Weintraub, 3-30-2018, "The Call For Drug-Price Transparency Is Growing Louder," Forbes, https://www.forbes.com/sites/arleneweintraub/2018/03/30/the-call-for-drug-price-transparency-is-growing-louder-but-will-it-matter/

Skeptics will say that the Big Pharma lobby will counteract any federal efforts to hold down drug prices, but some states aren't waiting around to see who wins that battle. Legislators in more than 30 states proposed bills on drug pricing in 2017.

Two weeks ago, Oregon became the latest state to pass a law on drug-price transparency. The legislation mandates that when the price of a drug is $100 or more for a one-month or shorter supply, and there is a net price increase of 10% or more, the maker of that product must report the factors that contributed to the price increase, the research costs associated with the drug, and what it costs to manufacture and distribute it.

TheHill, 6-26-2017, "A bipartisan consensus against 'big pharma' is growing in Congress," https://thehill.com/blogs/pundits-blog/healthcare/339482-a-bipartisan-consensus-against-big-pharma-is-growing-in
When President Trump, then candidate Trump, first fired a volley of insults and criticism at the pharmaceutical drug industry over their high drug prices, and pledged to use government to get a better deal, the reaction among the establishments of both parties was roughly comparable to that of the pope after reading the 95 Theses.

Unfortunately, if recent rumors about the president's drug policy are any guide, Trump the president seems to have lost the courage of Trump the candidate on this issue. This is saddening, because the rest of Washington seems to have come candidate Trump's way. The ground in Congress has unmistakably shifted on the question of drug pricing. With that shift has come some much-needed skepticism of the previously almost bulletproof pharmaceutical industry's influence over debates on drug policy – skepticism which is slowly but surely making its way into not just op-eds and policy studies, but into actual legislation.
The most recent example of this is the bill that was just introduced by Reps. Gregg Harper (R-Miss.) and Peter Welch (D-V.T.) designed to close the so-called "orphan drug loophole" connected to the 340B drug-pricing program. "Orphan drugs" refer to a category of drug supposedly targeted at such a niche market (sufferers of a rare disease) that they could not be profitable without extra government incentives.

Annalisa Mereli, "The way to fix outrageous drug pricing in the US is simply to do what all other rich countries do", Quartz Magazine, September 25, 2015, https://qz.com/509344/the-way-to-fix-outrageous-drug-pricing-in-the-us-is-simply-to-do-what-all-other-rich-countries-do/ , SP, October 15, 2018

Paradoxically, America's wealth might be what makes it harder to transition. For all its wastage, the current system has "built up very powerful and wealthy stakeholders," Hsiao told Quartz. What he calls a "rampant insurance industry" is worth about $1 trillion—a size large enough that even a 1% investment in lobbying and advertising could stall attempts at substantial reforms at the federal level. These vested interest groups aren't, however, as powerful at the state level, where perhaps lies the real hope for the American system to finally follow the rest of the world's lead.

http://www.jpands.org/vol15no4/kazman.pdf
Unlike in the first scenario, these people do not realize that they too are victims of FDA mistakes. Their suffering or death is simply viewed, by them and others, as reflecting the state of medicine rather than the status of an FDA drug application. In short, victims of incorrect FDA approvals are highly visible, while victims of incorrect FDA delays or denials are practically

invisible. For example, consider FDA's incredibly long delay in approving beta-blockers to reduce the risk of second heart attacks. By the mid-1970s this had been documented in clinical trials, and a number of beta-blockers were approved for this use in Europe. But in the U.S., FDA imposed a moratorium on beta-blocker approvals due to the drugs' carcinogenicity in animals. (Among the staffers involved in this delay was that fastidious driver, John Nestor.) In effect, FDAwas denying needed cardiac drugs to people at high risk of heart attacks because of the unproven possibility that those drugs might cause cancer years in the future
Finally, in 1981 FDAapproved the first such drug, boasting that it might save up to 17,000 lives per year. That meant, of course, that as many as 100,000 people may have died waiting for FDA to act —an explosive point, but one that very few journalists pursued. For all practical purposes, these people were invisible in a very literal sense—we've all seen photographs of thalidomide victims, but I suspect that not one of us has ever seen a photograph of someone who suffered or died because of FDA's beta-blocker moratorium

TheHill, 12-14-2016, "Top 10 lobbying victories of 2016,"
https://thehill.com/business-a-lobbying/310282-top-10-lobbying-victories-of-2016
Signed into law by President Obama on Tuesday, the bill speeds up drug and device regulatory approval, increases funding for the National Institutes of Health and approves money to help fight opioid addition, among other things.
The legislation also boosts funding for research and treatment for mental illnesses.
More than 400 separate interests lobbied on the bill, reflecting its broad scope and impact.
Critics say that the law could speed up the approval process in a way that could bring dangerous products to market.
Winners: Pharmaceutical Researchers and Manufacturers of America; AdvaMed; the Biotechnology Industry Organization; American Medical Association; American Hospital Association; some disease groups like the American Cancer Society; medical schools; and mental health and substance abuse advocates, such as Shatterproof.

Gina Chon, 9-1-2016, "Rising Drug Prices Put Big Pharma's Lobbying to the Test," No Publication,
https://www.nytimes.com/2016/09/02/business/dealbook/rising-drug-prices-put-big-pharmas-lobbying-to-the-test.html
All the while, the pharmaceutical industry has been spreading dollars around the nation's capital. Drug makers doled out $240 million for lobbying purposes last year, according to the Center for Responsive Politics, making it the biggest spender. The insurance industry was second, at $157 million.

At 17.5 percent of G.D.P. in 2014, American health care costs have been rising faster than pharma's political tab. Prescription-drug spending increased by 8 percent last year, to about $322

billion. It's expected to be worse in 2018, when fewer branded products lose patent protection, the Centers for Medicare & Medicaid Services reckons.

https://www.trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf
As a result, prices are comparatively high to make up for lower profits in other countries and to cover R&D costs. The United States also has high per capita incomes, unmatched access to healthcare, a large elderly population, a culture of end-of-life prolongation, high rates of chronic diseases and drug consumption and a strong consumer preference for innovative drugs. All of these factors contribute to it being, by far, the world's largest pharmaceutical market with $333 billion in sales in 2015, about triple the size of its nearest rival, China. The United States will remain the world's most important market for the foreseeable future with healthy growth expected across all product sectors.

A2 Impact - Opioid crisis

1. Squo solving in to ways.
    a. The drug industry is coming around to fighting the opioid crisis. In fact, NPR reports in 2017 that the two largest pharmacy chains in the United States have moved to widen access to Narcan and other products that contain naloxone, an antidote to an overdose that is prescription-free.
    b. Legislation. NBC reports in 2018 that there is bipartisan support to fight the opioid crisis and over 70 bills have passed to curb it. Hellman of the Hill corroborates in 2018 that the Justice Department and Drug Enforcement Administration are proposing an average 10 percent decrease next year in the manufacturing quotas for six frequently misused opioids.

[Jessie], DEA, 8-16-2018, Justice Department, DEA propose significant opioid manufacturing reduction in 2019, https://www.dea.gov/press-releases/2018/08/16/justice-department-dea-propose-significant-opioid-manufacturing-reduction, 11-8-2018, VK

WASHINGTON – The Department of Justice and U.S. Drug Enforcement Administration have proposed a reduction for controlled substances that may be manufactured in the U.S. next year. **Consistent with President Trump's "Safe Prescribing Plan" that seeks to "cut nationwide opioid prescription fills by one-third within three years," the proposal decreases manufacturing quotas for the six most frequently misused opioids for 2019 by**

an average 10 percent as compared to the 2018 amount. The Notice of Proposed Rulemaking marks the third straight year of proposed reductions, which help reduce the amount of drugs potentially diverted for trafficking and used to facilitate addiction.

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-legislationcombat-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.

Bill Chappell, "Narcan Opioid Overdose Spray Is Now Stocked By All Walgreens Pharmacies", NPR, October 26, 2017, https://www.npr.org/sections/thetwo-way/2017/10/26/560180901/walgreens-stocks-narcan-opioid-overdose-spray-in-all-pharmacies

It has the power to save lives by targeting opioid overdoses — something that kills more than 140 Americans every day. And now Narcan, the nasal spray that can pull a drug user back from an overdose, is being carried by all of Walgreens' more than 8,000 pharmacies.

Calling the Walgreens move "an important milestone," Seamus Mulligan, CEO of Narcan maker Adapt Pharma, said that letting people get the medicine "without an individual prescription in 45 states is critical in combating this crisis."

In recent years, both Walgreens, the nation's No. 2 pharmacy chain, and CVS, the No. 1 chain, have moved to widen access to Narcan and other products that contain naloxone, a fast-acting overdose antidote. As of last month, CVS reportedly offered prescription-free naloxone in 43 states. The chain has said that its pharmacies "in most communities have naloxone on hand and can dispense it the same day or ordered for the next business day."

A2 CON (YOU ARE PRO)

A2 Misc contentions

A2 Marketing?

1. [Doctor] N/U squo Desai - Pharmaceutical sales representatives are struggling more than ever to get time with healthcare providers. The number of rep accessible physicians declined in 2016, with only 44% willing to meet with sales reps, down from 80% in 2008.
2. DL – Swanson WAPO – marketing = huge component of budget already. How mnay more ads can you launch? Companies make money off the drug not off of the markets. Better innovation prereq.
3. Turn – FDA surveyed doctors and concluded that physicians agreed that consumers who saw DTC ads were more involved in their healthcare and asked more questions but over 90% of physicians did not say they felt pressure to prescribe medications that were grand name over generics.

A2 Lobbying for loopholes

1. This assumption destroys the purpose of debating a resolution. We aren't here to debate the feasibility of legislation that, both you and I, know is not going to actually pass Congress in the near future. Every resolution could be destroyed because politicans put "loopholes" in them. However, to have an actually productive debate, we should discuss the implications of the policy not the potential ways it could be undermined from a legislative standpoint.
2. Delink - Acquiescence to pharmaceutical lobbying is on the decline. The Hill explains in 2017 that there is a growing bipartisan consensus to oppose pharmaceutical lobbying, lifting it's almost bulletproof influence over debates on drug policy. For instance, a bill was just introduced to close one of the loopholes big pharma was using to make money, a step unthinkable in the past. Additionally, Forbes reports in 2018 that more than 30 states have proposed bills on drug pricing in 2017 that are slowly starting to pass, further eroding big pharma's grip on legislation.
3. Big phama is dependent on small pharma**. According to Radcliffe of Healthline in 2017**, big pharma such as Pfizer have invested billions in independent startups because they depend on these companies to create profitable drugs that they can then buy out. Big pharma is never going to destroy small pharma because they depend on them for new drugs.

A2 Competition

1. **No clarity of link. Make the con prove to you that price controls are the only factor that decreases competition**. Large pharmaceutical companies have several other methods of preventing generic brands from reaching the market. **Baker of NYT 15**

explains that there is even a government-protected patent monopoly already existing in the status quo, meaning that competition has already been inhibited in a CON world.

a. At that point, you vote pro because **Baker** finds that lobbying is one of the root causes of the government-protected patent monopoly restricting competition and a free market. So by voting AFF, we would have a solid chance of decreasing this lobbying by restricting the amount of revenue pharmacies use to manipulate congressmen.

Baker
https://www.nyt.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/end-patent-monopolies-on-drugs

The United States stands out among wealthy countries in that we give drug companies patent monopolies on drugs that are essential for people's health or lives and then allows them to charge whatever they want. Every other wealthy country has some system of price controls or negotiated prices where the government limits the extent to which drug companies can exploit the monopoly it has given them. The result is that we pay roughly twice as much for our drugs as the average for other wealthy countries. This additional cost is not associated with better care; we are just paying more for the same drugs. Giving a drug company a monopoly where it charges what it can is like negotiating firefighters' pay when they show up at your burning house. **This is not an issue about the free market. The free market doesn't have patent monopolies. The monopoly power provided by a patent is a government policy to promote innovation. There are problems with patent monopolies in many areas, but nowhere is the issue worse than with prescription drugs.**

Patent protected drugs are often essential for people's health or even their lives. Allowing a drug company to have a monopoly where it can charge whatever it can force the individual, or more typically the insurer or the government, to pay makes little sense. This is like negotiating the pay of firefighters at the point where they show up at your burning house with your family inside. This would give us much worse fire service and many very wealthy firefighters. A monopoly that allows drug companies to sell their drugs at prices that can be hundreds of times the free market price has all the problems economics predicts when governments interfere with the market. Drug companies routinely mislead doctors and the public about the safety and effectiveness of their drugs to increase sales. The cost in terms of bad health outcomes and avoidable deaths runs into the tens of billions of dollars every year. **Drug companies also spend tens of millions on campaign contributions and lobbying to get every longer and stronger patent protection.**

The pharmaceutical industry is one of the main forces behind the Trans-Pacific Partnership, and its demands for stronger patent protections is one of the main obstacles to reaching an agreement with the other countries. We don't need patent monopolies to support research. We already spend more than $30 billion a year financing research through the National Institutes of Health. Everyone, including the drug companies, agrees that this money is very productive. We could double or triple this spending and replace patent supported research done by the drug companies. With research costs paid upfront, most drugs would be available for the same price as a bottle of generic aspirin. While the measures being proposed by Hillary Clinton and earlier Bernie Sanders don't go this far, they are a big step in the right direction.

A2 Launch lags

1. A straight up price ceiling wouldn't be renegotiated every time a new drug is released. There's no impact coming off of this contention.
2. Turn – reduced prices means that companies have a greater incentive to get drugs to the market to make a profit, meaning launch delays actually go down. I'd contend that companies will work actually get drugs through the FDA process faster, which is the biggest reason why drugs release slowly as testing takes years.
3. [A2 600,000] Bruh, there's a 90 day difference. That's so damn marginal. The card is uncarded. He's a lobbyist for the pharmaceutical industry. Like, what.?

TheHill, 5-5-2017, "The tragic toll of drug price controls," https://thehill.com/blogs/pundits-blog/healthcare/332145-the-tragic-toll-of-drug-price-controls
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.

A2 Recession

1. That's dumb why would the government limit companies to the point of economic collapse. Price controls are flexible and change with the economy.
2. Government bailouts would definitely solve; in the 08 recession, gov spent $700b helping out failing companies because they were key to the economy; because of a dip in pharma profits, Smith from Politico found in October that Trump is already issuing bailouts
3. Healthcare spending is growing so unsustainably right now that without a change in policy, current HC costs will trigger a recession either way since either
    a. Lopez of Business Insider writes that people divert resources away from household spending and toward drugs and treatment
    b. Or so few people can afford the high prices that pharma profits decline anyway
4. A2 Europe PC Petroff of CNN finds Europe's experiencing more growth than US; that means at best link has no impact; at worst impacts are short term

The passage into U.S. law on October 3, 2008, of the $700 billion financial-sector rescue plan is the latest in the long history of U.S. government bailouts that go back to the Panic of 1792, when the federal government bailed out the 13 United States, which were over-burdened by their debt from the Revolutionary War. It also marked the fourth time in 2008 that the government interceded to prevent the ruin of a private enterprise or the entire financial sector. In addition to

the $700 billion bailout, this article will look at five financial crunches in the past century that necessitated government intervention:

Sarah Karlin-Smith [POLITICO], 10-2-2018, ***Why Congress is poised to give the drug industry a $4B windfall, https://www.politico.com/story/2018/10/02/congress-drug-industry-4b-windfall-823416***

Drugmakers took a rare financial hit in the bipartisan budget deal passed in February when they were put on the hook to pay $11.8 billion toward senior medicines over 10 years in the fight over the Medicare drug benefit "doughnut" hole. Now they're trying to soften that blow, seeking relief from at least $4 billion of those costs in what they describe as "a technical correction" to a calculation that made the industry responsible for more money than lawmakers had sought. Congressional aides to senior members of both parties say they have a good chance of success — a stark reminder of how challenging it will be for lawmakers to take on the drug lobby, even as voters across party lines demand lower costs of medicines.

Alanna Petroff [CNNMoney], 1-30-2018, Europe's economy grew faster than the U.S. last year, < https://money.cnn.com/2018/01/30/news/economy/gdp-europe-economy-2017/index.html

Sure, the United States is growing at a nice clip. But Europe's economy is expanding at an even faster rate. Economic growth in the 19 countries that use the euro currency was 2.5% in 2017, according to official data published Tuesday. Growth in the 28-member European Union also reached 2.5% last year. It's the best period of growth for both groupings since 2007, putting Europe just ahead of the 2.3% expansion posted by the U.S. in 2017. Europe, which has suffered years of anemic growth caused by a series of debt crises, is part of a global economic resurgence that could continue in 2018.

Linette Lopez [Business Insider], 10-18-2017, Wall Street found a parasite growing in the US economy that could spur the next recession, https://www.businessinsider.com/healthcare-costs-could-spur-the-next-recession-2017-10

So the bet here is simple: America, one way or another, will be forced to confront the parasite that is its healthcare system, and the companies that are using the sleaziest tactics will be picked off first — by prosecutors, lawmakers, insurance companies, or the press — leaving sick customers in the lurch. Short sellers (investors who bet that stocks will go down) are talking about this thesis at conferences and sending it around in their email newsletters. They're learning about scams and picking off weak companies to bet against. They see rising costs as a bubble that will be either gently deflated through federal-government intervention or violently popped by the merciless hand of the market — with a savvy investor making money either way. We have three options for dealing with this problem going forward: We can handle rising cost with good policy and change the way we think about paying for healthcare. We can handle this with bad policy and deliberately shift rising costs to consumers while the government abdicates its responsibility for the health of not only the American people but also the American economy. Or we can do nothing, which would result in more rising costs, more corporate rent-seeking behavior, and ultimately a recession as household resources go toward medicine and treatment instead of new cars, homes, clothes, or toys. The US is hurtling at full speed toward the third

option. That's because, at least realistically, the government has no plan to rein in costs. Healthcare costs today make up a sixth of the economy; the Centers for Medicare and Medicaid Services estimate that the share will grow to a fifth in just eight years.

A2 Generic drugs solve

1. Delink - 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.
2. Delink - Many doctors tend to prescribe brand name medication because large companies give them handouts. According to NPR in 2013, doctors who were surveyed said that they would prescribe brand name drugs even when generics were available. The NPR analysis furthers that these doctor's willingness was associated to their acceptance of free commodities or samples of brand name drugs from the same companies that were influencing their decision to prescribe expensive medication.
3. Nonunique - Generic drugs do not go away in a PRO world. Unless they can uniquely prove why affirming would take away the access to these generics, this argument has no weight in the round.
4. Turn - Generics are getting expensive. Harvard Medical School in 2015 found that 400 different generic drugs have been subject to price increases of over 1000%.
5. Turn - Generics are poor quality. Harvard Medical School found in 2018, that the utilization of generics in emergency room visits resulted in an increase in future hospitalization. Harvard furthers that this is because generics are manufactured with different inactive ingredients and have variations in chemical formula that cause people to react differently

Ramsey, Lydia. "We're Running out of Commonly Used Drugs - and Hospitals Say It's 'Quickly Becoming a Crisis'." Business Insider, Business Insider, 10 Nov. 2017, www.businessinsider.com/drug-shortages-are-getting-worse-american-hospital- association-2017-11.

The ASHP cites a number of reasons for the shortages. Most are related to manufacturing problems. In the cases of saline and dextrose, Baxter's facilities in Puerto Rico were hit by the hurricanes, adding to existing drug shortages. In other cases, some of the companies which make large portions of the drug simply stop making it, or a drug is only being produced by a single manufacturer. **There simply are not enough companies making the drug to keep up with demand.** It's all part of a consolidation of the manufacturers who produce generic drugs. **US generic companies have had a harder time turning a profit on generic drugs** while competing with companies outside the US that are able to make the same drugs at a cheaper cost. **That's caused manufacturers to home in on certain generic drugs and discontinue others that don't make as much money. And if a generic manufacturer has a shortage,** there's no easy fix you can't just pass off the job to another company while the first fixes its problems, since getting approval to take on a new drug can take years. When it comes to this particular shortage, the AHA said in its letter that it would like the FDA to push manufacturers that make these drugs to invest in creating more supplies in the future, as well as find suppliers within the US that aren't as susceptible to natural disasters. The FDA said it will respond directly to the AHA regarding its letter. "However, in general the FDA has an important role to play in working with companies to address product shortages that disrupt patient access to medical products, and we have been closely working on a number of efforts related to the current IV fluids shortage, which actually dates back to 2014, but was recently worsened by Hurricane Maria's impact on Baxter manufacturing facilities in Puerto Rico," an FDA spokeswoman told Business Insider. "The FDA understands the concerns and importance of the ongoing shortages of

Chagpar, Anees. "America's Ongoing Lack of Generic Drugs Is a Matter of Life and Death." Quartz, Quartz, 3 Apr. 2016, qz.com/653136/americas-ongoing-lack-of-generic-drugs-is-a-matter-of-life-and-death/.

Some, like Owen's dad (cancer surgeon Kelly McMasters), believe that **generic manufacturers simply do not have a financial incentive to produce drugs like methotrexate. They cite as evidence the fact that we never seem to run out of the drugs that cost thousands of dollars, and that shortages increased after the 2003 Medicare Modernization Act restricted Medicare reimbursement on these drugs to the average selling price, plus a 6% administrative fee.** Others argue that

increasing regulations imposed by the FDA have created more red tape and propagated shortages, a claim the FDA vigorously denies. Regardless of where the blame is laid, however, it seems clear that the current way of doing things is broken. A House of Representatives oversight committee found that in 2010, 90% of all oncology generic drugs were made by a handful of manufacturers in this country, meaning production disruptions at one factory can cause serious issues nationwide. It's time for a better system. In order to create a sort of emergency pipeline, the generic pharmaceutical industry has started what it calls the "Accelerated Recovery Initiative (ARI)," the goal of which is to limit the number of patients who cannot get a hold of drugs in critical shortage. While the process is long and complicated, it proves this is not an entirely unsolvable issue. Meanwhile, the FDA sent out a press release in February calling for increased modernization in the pharmaceutical industry, and vowing to help provide guidance to companies that are pursuing new technology.

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

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

Ameet Sarpatwari, Jd, Phd, 10-22-2015, "Why many generic drugs are becoming so expensive," Harvard Health Blog, https://www.health.harvard.edu/blog/why-many-generic-drugs-are-becoming-so-expensive-201510228480

The high cost of prescription drugs is big news. You hear about it on television, in your doctor's office, and even on the campaign trail. When you think about expensive drugs, you may think about novel therapies for lung cancer or hepatitis C. But in fact, prices are also skyrocketing for the generic versions of some commonly prescribed drugs. An article published last year in The New England Journal of Medicine reported that between 2012 and 2013, captopril — a generic drug used to treat high blood pressure and heart failure — increased in price from 1 cent to 40 cents per pill. During this same period, the cost of doxycycline, an older antibiotic, increased from 6 cents to $3.36 per pill. Connecture, a health insurance information technology company, reports that while the price of most generic drugs remained constant between 2008 and 2015, **almost 400 generics saw price increases of more than 1,000%.** At a time when 18% of prescription drug costs are paid for out-of-pocket and 8% of Americans report not taking their medications in order to save money, such dramatic increases in generic drug prices place a heavy burden on public health. Why are generics going up in price? Most of us think of generics as the less expensive alternative to the brand-name version of a prescription drug — and that's often the case. **The pharmaceutical companies that make generics can sell them for lower prices** because they didn't have to pay for the research and development that brought the drug to market in the first place. **However, this cost advantage can take a back seat in situations such as the following, in which competition is reduced or delayed, enabling generic manufacturers to increase their prices**: The market for some generic drugs is so small that it does not attract multiple producers, as with pyrimethamine (Daraprim), a very old drug used to treat a parasitic infection called toxoplasmosis. GlaxoSmithKline had long been the only producer of pyrimethamine, but priced it modestly. This August, however, Turing Pharmaceuticals acquired rights to the drug and exploited its monopoly, raising the price 5,000% (from $13.50 to $750 a pill). In some cases, the number of producers of a generic drug decreases because of an ongoing wave of market consolidation within the pharmaceutical industry.

Harvard Health Publishing. "Do Generic Drugs Compromise on Quality?" *Harvard Health*, Harvard Medical School , Jan. 2018, www.health.harvard.edu/staying-healthy/do-generic-drugs compromise-on-quality.

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

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."

A2 Drug companies deserve compensation

1. Nonunique - 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. Turn - Drug companies are exploiting consumers to compensate themselves. The New York Times finds in 2017 that a result of skipping medication due to high costs has resulted in a 10% increase in hospitalization. The weighing is simple here, either we can overcharge patients and benefit corporations because they for some reason "deserve it" or we can lower drug prices and save patients lives.

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

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.

A2 Insurance companies cover the costs of drugs

1. Delink- Chan from Boston University in 2016 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 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 - Their argument doesn't cover low income individuals. The Kaiser Family Foundation in 2017 found that 45% of uninsured adults said that they remained uninsured because the cost of coverage was too high. These are the people that we are impacting out to, who have to cover the costs of drugs themselves.

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.

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?”

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.

A2 Drugs account for little of healthcare spending

1. This is not a reason by itself to negate. If we can prove the impacts from our case [insert impacts] we are still saving lives.
2. Turn - Prescription drug spending is high and increasing. According to a study conducted by the Centers for Medicare and Medicaid Services in 2018, spending growth is projected to be fastest for prescription drugs, averaging an increase of 6.3 percent by 2026. The impact only gets longer the longer you let it run.

"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.

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.

A2 Bioterrorism

1. Nonunique - In the status quo, there are already a ton of alternate causes of bioterrorism. In fact, according to William in 2007, countries like India and China are also major pharmaceutical giants, meaning they should have triggered the impacts of bioterrorism.

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)

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.

A2 Vaccines [Shortages and Research]

1. Nonunique - Vaccine prices are already low from other programs. Frakt of the New York Times writers in 2016 that federal and state programs buy more than half of vaccines at a discount, driving prices down. Furthermore, 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.
2. [SHORTAGES] Delink - Frakt goes on to explain that commercial vaccine prices are higher than government prices, but still not by enough to prevent shortages. The free market isn't enough for vaccines to be profitable enough to prevent shortages, rendering shortages nonunique to price controls.
3. [RESEARCH] Delink - Private sector development is not where vaccines are researched and developed. There are two main sources of vaccine research. First, Caceres in 2018 finds that the majority of vaccine research is done in universities like Harvard, UCLA, and the University of Washington. Second, 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.

4. Turn - More vaccines is useless when people can't 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 vaccines into the market would be useless as consumers are unable to financially access them in the status quo.

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).

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.

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.

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.

Austin Frakt, 6-27-2016, "Low Prices for Vaccines Can Come at a Great Cost," No Publication, https://www.nytimes.com/2016/06/28/upshot/low-prices-for-vaccines-can-come-at-a-great-cost.html

Vaccine prices are held down by government programs, which extend vaccinations to millions of children who might not otherwise get them. Federal and state programs buy more than half of childhood vaccine doses at a discount. The largest federal vaccine program — Vaccines for Children — may adjust prices within a year, but only downward, and it constrains changes in what it pays for some vaccines to below the overall inflation rate. Though the program keeps a six-month backup supply of vaccines on hand, the average shortage lasts three times that long, according to the Duke study.

Commercial market vaccine prices are higher than government ones, but not by enough to prevent shortages.

A2 Developing world
A2 Card – Schweitzer
[Weighing comparison – Marginal cost definition referenced to the US versus marginal cost definition referenced to the developing nations]

1. The sample in this study is awful: it's 30 drugs the vast majority of which are not life-saving medicines or ones that would be parallel traded. For example, the 10 "essential medicines" he studies include aspirin, advil, tylenol, and two kinds of anti-itch. You should prefer our studying all "essential drugs," AIDs, TB, malaria drugs, specific to biggest killers in developing world that say prices are around 6 times as high.

A2 Drug donations

1. Delink at the top – The incentive that drug makers have to donate drugs exists in either world. Corporations have a financial incentive to donate drugs for two reasons.
    a. It's profitable whether or not they sell the drug. Sukkar explains in 2017 that the reason drug companies donate drugs is because they get a tax incentive and it is cheaper to donate a drug than destroy it. Thus, these donations will always occur. CPTEch further elaborates the tax deductive. Corporations get a 70% tax decurion on overseas donated drugs which is worth more to companies because this writeoff lets them recoup the cost of making the drug in the first place, ultimately turning them an easy profit.
    b. They get a foothold in the market. Boosley of the Guardian in 2017 writes that 1.4 billion people in the world right now can't afford life saving drugs and it is the US's fault. The US comes in and creates a foothold in the market, which prevents other companies domestically from producing generics, leading to overall higher prices.
    c. Overall, Maciag of Johns Hopkins writes that US corporations are making a profit in the developing world. Even in one instance in South Africa where a 96% price reduction was triggered, companies suffered no negative financial effect.
2. [A2 Price balancing] I'd contend that if anything, companies will sooner increase prices in the EU than in the developing world. Bollyki gives the reason in 2018 which is that if price controls were implemented, drugmakers would strike better deals with EU countries to drive up prices there, since the U.K will never walk away from providing its citizens a promising cancer treatment.

3. Medicine is ineffective. Chutel of Quartz reports 1/10 medical products sent to developing countries are falsified, which in Sub Saharan Africa alone caused 116,000 additional deaths each year.
4. Even if drugs are given to third-world countries, it doesn't mean access goes up. Pheage reports that the public sector supply is plagued by bad transportation and storage that inhibits distribution of drugs.
5. Other countries can pick up the tab. For example, Pheage continues India accounts for 18% of imports to Africa.
6. WHO finds that drug donations are super inefficient because it's just donation of drugs that we don't need domestically and therefore don't meet needs of third world which is why we don't see huge widespread decline of diseases rn. Thus, Weng finds that tropical diseases, which affect the most people in the developing world, only account for 1% of drug-related research expenditure.

The WHO concludes that drug donations more often cost the recipient countries more than just purchasing the medicines themselves by creating major health problems for local authorities.

Bollyky, Tom. "Drug Marketing Push in Developing Countries Has Upside and Potential Downside for Poor People." Center for Global Development. 07-10-2009. https://www.cgdev.org/blog/drug-marketing-push-developing-countries-has-upside-and-potential-downside-poor-people

This suggests there may be a trend towards more effective international differential drug pricing between developed and developing countries and for a much larger range of products. If so, **U.S. health care reform may be driving the trend. The direct effect of that reform, which the WSJ article notes, is that drug firms are looking to emerging markets to make up for the expected loss in U.S. revenues. The indirect effect of reform may be that drug firms are less concerned about the risks of parallel importation and reference pricing in a world in which on-patent drug prices in the U.S., which has represented roughly 50 percent of world drug market, are no longer expected to remain as anomalously high.** The fact that drug firms are looking to be more creative about taking advantage of the purchasing power of the working poor in developing countries is also positive for the long-term sustainability of drug access in those market segments. **Donor funding won't last forever; long-term, the accessibility of essential medical technologies in poor markets cannot rely on that funding alone. Many of the poor have purchasing power that has remained untapped because potential technology producers and suppliers have not spent the time or energy to understand the needs of that market. If those resources can be tapped in sustainable fashion, long-term access to these technologies in poor market segments would be much improved.**

Leisinger, Klaus. "Improving Access to Medicines in Low and Middle Income Countries: Corporate Responsibilities in Context." Southern Med Review.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3606933/

However, **a third of the world's population (up to 50 percent in parts of Asia and Africa) lack access to essential medicines [6].Average availability of generic medicines is only 38 percent in the public sector in LMIC [7]. Although private sector availability is higher – on average 64 percent – medicines in private pharmacies are often not affordable [7]. Consuming 25-65 percent of total public and private spending on health and 60-90 percent of household expenditure on health in developing countries**, [8] medicines pose an enormous economic burden on health systems and households. Unfortunately, spending on medicines is often not cost-effective: almost half of all medicines are inappropriately prescribed, dispensed, or sold and patients do not adhere to about 50 percent of the medicines they receive [5,9].

Weng, Hong-Bo (professor at Fudan University). "Innovation in neglected tropical disease drug discovery and development." June 2018. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6022351/

It is known that drug discovery and development (DDD) is very costly with inherent risk of failure. The drug innovation outcomes for a particular disease reflect the investment in R&D. Funding limitation restricted the innovation efforts in this area. US$307 million per million disability-adjusted life years (DALYs) is used worldwide on non-infectious respiratory diseases, whereas only US$3 million per million DALYs was for NTDs in 1999 [7]. In 2010, the US$2.4 billion investment in **NTDs accounted for only 1% of overall healthcare-related research expenditure [10].** Fortunately, funding situation for NTDs increased notably to US$3.045 billion in 2011 [11]. However, the increase in investment is still a small amount compared with expenditures on non-neglected disease R&D. Nevertheless, the development of new medical products against NTDs has been promoted. In the period between 2000 and 2013, there were three new approvals of NTD products, and five products targeting NTDs were in phase III clinical trials including one for Dengue fever, three for onchocerciasis/schistosomiasis and one for all three diseases (leishmaniasis, Chagas disease and African sleeping sickness) [12].

"Brief for GSDR – 2016 Update Sustainable drug development for Neglected Tropical Diseases A. Anastasia Kefalidou, United Nations Department of Economic and Social Affairs*", https://sustainabledevelopment.un.org/content/documents/1009560_Kefalidou_Sustainable%20drug%20development%20for%20Neglected%20Tropical%20Diseases.pdf

For almost 100 years, physicians and pharmacists had successfully opposed the idea that drugs are industrial commodities like any other. The incident with penicillin though caused a shift towards patenting drugs that spurred a wave of legal measures establishing procedures for patenting drugs in Europe (Gaudilliere, 2008) and the USA. Thereafter, pharmaceuticals began investing heavily in the discovery of new products, and taking out patents. The expansion of publicly funded biomedical research also provided a boost to the tourists or spreading to the developed world. **To illustrate the extent of the problem, out of 1,223 drugs commercialized worldwide between 1975 and 1996, less than 1% was destined for tropical diseases, of which only a minority were genuine products of their research for this intent (Trouiller and Olliaro, 1999).** On the contrary, diseases that originated in the developing world, but spread in West have received significant attention, as in the case of AIDS/HIV, and the recent outbreaks of Ebola and Zika.

Maciag of John Hopkins "Generic drugs for developing nations Karolina Maciag and Sandeep P. Kishore", https://uaem.org/cms/assets/uploads/2014/08/Maciag-Kishore-Correspondence-NRM-June-2010.pdf

Less than 5% of pharmaceutical profits are earned in the developing world3 , and humanitarian global-access licensing promotes generic competition in this tiny slice of the market. This provides an avenue to affordable, life-saving technologies for the millions of people who live on less than $2 per day, while sustaining the incentive structure that supports the innovative industry. Surprisingly, universities worldwide have an important role in brokering the world's access to life-saving medical technologies. In 2001, for instance, Yale University (New Haven, Connecticut, USA) and its licensee Bristol–Myers Squibb (BMS) agreed to let Aspen Pharmaceuticals of Cape Town, South Africa, produce the widely used antiretroviral stavudine (also known as d4T) off patent. **This deal triggered a 96% price reduction of the drug in South Africa with no negative financial effect** on Yale or BMS4 . Momentum from the agreement jump-started the establishment of Universities Allied for Essential Medicines (UAEM), a non-profit organization — of which we are both members — consisting of students who work with university administrators to ensure that the fruits of academic research will reach patients in resource-poor nations.

Thomas J. Bollyky, Axios, October 29th, 2018, ["Trump's plan to bring down U.S. drug prices misses root causes", https://www.axios.com/trumps-plan-to-bring-down-us-drug-prices-misses-root-causes-53d84e76-edbc-4ba7-969b-bf961a0cde24.html, 10-31-2018]jzl

There is, obviously, an argument that government price setting works. It's just not usually an argument Republican administrations make. But President Trump's public comments on drug prices return frequently to the theme that Europe is taking advantage of the U.S., and we should be paying what they're paying. Between the lines: There's at least some conservative competitive element, as the new plan aims to weaken Europe's price controls before piggybacking off them. **This is a subject of active debate in the health care world, but the economists I spoke to yesterday said the administration is probably correct to say that tying U.S. prices to European prices would drive up European prices, at least a little. How it works: The idea is that, if drugmakers can no longer count on high U.S. prices to subsidize lower reimbursements abroad, they'll simply have to strike more favorable deals with European countries. Sure, a single public payer has a lot of leverage, the argument goes, but will the U.K. really walk away from providing its citizens a promising cancer treatment?**

"Prices Of Pharmaceuticals In Poor Countries Are Much Lower Than In Wealthy Countries | Health Affairs", https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0923

We examine here the extent to which drug prices actually differ across countries. Only a small number of studies have investigated this question, and few of them have looked specifically at price differences between developed and less developed countries. 13 An exception is a study by Frederick Schut and Peter van Bergeijk that compares average pharmaceutical prices in thirty-two countries, both industrialized and developing. The authors report a "strong positive relationship between price level and per capita GDP." 14(p1141) We find a similar relationship. According to their analysis, "a 10% increase in per capita income [is] associated with on average 8% higher drug prices." 14(p1141)

Sarah Boseley, "Rich countries 'blocking cheap drugs for developing world' | Global development | The Guardian", https://www.theguardian.com/society/2006/nov/14/internationalaidanddevelopment.medicineandhealth

In the case study, accompanying the article below, we said that 1.42 billion people in India could not afford the drugs they needed to save their lives. That is the figure Oxfam gives for developing countries such as India, rather than India alone. Poor people are needlessly dying because drug companies and the governments of rich countries are blocking the developing world from obtaining affordable medicines, a report says today. Advertisement Five years to the day after the Doha declaration - a groundbreaking deal to give poor countries access to cheap drugs - was signed at the World Trade Organisation, Oxfam says things are worse. The charity accuses **the US, which champions the interests of its giant pharmaceutical companies, of bullying developing countries into not using the measures in the Doha declaration and the EU of standing by and doing nothing. Doha technically allows poor countries to buy cheap copies of desperately needed drugs but the US is accused of trying to prevent countries such as Thailand and India, which have manufacturing capacity, making and selling cheap generic versions so as to preserve the monopolies of the drug giants**. "Rich countries have broken the spirit of the Doha declaration," said Celine Charveriat, head of Oxfam's Make Trade Fair campaign. "The declaration said the right things but needed political action to work and that hasn't happened. In fact, we've actually gone backwards. Many people are dying or suffering needlessly." The Indian generics firms make most of the cheap drug cocktails that are now being rolled out to people with HIV in Africa and are keeping more than a million people alive. They brought the price of a basic three-drug cocktail down from $10,000 (£5,250) a year to less than $150 (£79). But new Aids drugs will soon be needed because the virus will become resistant to the basic ones now in use - as has happened in the EU and the US. Those newer Aids drugs, together with drugs for cancer and diabetes, are under patent. The Oxfam report points out that 4 million people were newly infected with HIV in 2005

and cancer and diabetes are expanding faster in developing countries than in the richer world. The report says that, since the signing of the Doha declaration on November 14 2001, **"rich countries have failed to honour their promises.** Their record ranges from apathy and inaction to dogged determination to undermine the declaration's spirit and intent. **The US, at the behest of the pharmaceutical industry, is uniqely guilty of seeking ever higher levels of intellectual property protection in developing countries." The US has pursued its own free trade agreements with developing countries, tying them into much tighter observance of patent rights** than anticipated at Doha. **"The USA has also pressured countries for greater patent protection through threats of trade sanctions,"** the report says. The drugs firms are also fighting to have patents observed. Pfizer is challenging the Philippines government in a bid to extend its monopoly on Norvasc, a drug pressure drug. Novartis is engaged in litigation in India to enforce a patent for Glivec, a cancer drug, which could save many lives if it were available at generic prices. The Stop Aids campaign, a coalition of 90 NGOs of which Oxfam is a member, is calling for the government to champion the issue at the G8 summit next year. T**hree-quarters of HIV drugs are still under monopoly and unaffordable in poor countries, it said. More than 75% of those who need HIV treatment urgently are still not getting it.** Only 8% of children with HIV are on drugs, which cost four times more than those for adults. "Sadly, promising words have not translated into life-saving treatments and five years is too long to wait when the stakes are so high," said Steve Cockburn, campaign coordinator. Case study Premavati, a 60-year-old widow living in Delhi who is suffering from non-Hodgkins lymphoma, a cancer of the lymphatic system, has spent around $900 (£470) on medicines. "My husband died two years ago," says Premavati. "We have absolutely no savings. Of my two sons one is a casual labourer, the other has no job. My daughter is 30, has two children and is also a widow." She is one of **1.42 billion people in India who cannot afford the drugs they need to save their lives. Their country is the leading producer of inexpensive generic drugs but about 67% of the output is exported,** and it is under pressure to stop copying new patented drugs. The future looks bleak for Premavati. "How will I raise the money for my treatment?" she says, "Already, I've spent what we had. If nobody helps I will just go back to my daughter and will have to die without medicines."

Stuart Schweitzer, UCLA, 2011, Prices Of Pharmaceuticals In Poor Countries Are Much Lower Than In Wealthy Countries, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0923 , 11-12-2018, AK

The first and most prominent of these is the price discrimination model. 2 **According to this model, firms maximize their profits by taking advantage of the elasticity of demand and charging consumers different prices according to what they are willing and able to pay.**

http://www.cptech.org/ip/health/econ/taxcode.html?fbclid=IwAR26xGeaSJVtq64orI39ZnEPT4mSA4eBVp497zAsIMkTcHVyBKXij5ys3jU

What are the conditions?

Pharmaceuticals, if they meet several provisions including the following basic conditions:

-the donated product is used solely for the care of the ill, needy or infants

-taxpayer has to get a written statement by the donee stating that the donation is to be used for qualified purposes.

-the charitable organization must be a US 501(c)(3) charitable organization, but can transfer the drugs to another exempt US organization, or a non-US organization that would meet the standards if it were a US exempt organization.

-the donation must be by a C Corporation (one that pays the corporate income tax, not "any" business, such as a partnership, or an individual)

-the donated product comply with FDA rules (such as expiration dates).

IV. How much is the deduction worth?
The financial incentive for corporations could be explained as follows: The maximum US corporate tax rate is 35%. A corporation is able to deduct up to twice its cost basis. Thus, the deduction would lower US income tax by up to 70 percent of the cost basis.

Sukkar, Elizabeth. "The Cost of Donated Drugs" BMJ.
https://www.bmj.com/bmj/section-pdf/186360?path=/bmj/339/7725/Feature.full.pdf
Drug companies are one of the key donors for long term programmes. They do so for several reasons: tax incentives, good public relations, cost saving (it is cheaper to donate a drug than destroy it), surpluses in the market, and a genuine desire to help. The industry's attitude to donating has changed over the past two decades. "Ten or twenty years ago, the industry made more bad donations, but now they are careful because pharmaceutical firms know they are being watched on what they send," says Ms Soulier.

Lynsey Chutelnovember [Quartz Africa], 11-29-2017, ***Africa is the dumping ground for 40% of the world's reported fake medicines, https://qz.com/africa/1140890/one-in-ten-medical-products-sent-to-developing-countries-are-falsified-or-below-standard-who/***

Access to basic healthcare is already out of reach for so many in poor countries, now a new study reveals that the medicines people are able to get hold of may be making them sicker. **One in ten medical products in developing countries are either substandard or completely falsified**, the World Health Organization revealed on Nov. 28. Many of these make their way to Africa, with 42% of the 1,500 reports of such medication coming from the continent. The fake or subpar medications are not only eating into the budgets of the health ministries who buy them in bulk, they're also weakening the immune systems of the individuals who take them. Most of the reported drugs were for antibiotics or anti-malaria treatments. **In sub-Saharan Africa alone,** the London School of Hygiene and Tropical Medicine estimates that **an additional 116,000 deaths are caused each year by falsified or substandard malaria medication. The cost of these fake drugs is about $38.5 million to patients and health ministries.**

WHO has repeatedly drawn attention to what is probably the main issue related to drug donations in the form of development aid and humanitarian assistance: "good procurement – getting quality medicines to people when and where needed".1 According to WHO, "the number of different agencies involved in procuring drugs – including ministries of health, manufacturers and donor agencies – can render the process highly complex and vulnerable to inefficiency and waste". WHO's interagency guidelines for drug donation describe four core principles that should be respected and guaranteed: (i) maximum benefit to the recipient; (ii) respect for the wishes and authority of the recipient; (iii) no double standards in quality; and (iv) effective communication between donor and recipient.2 Regrettably, these guidelines are not international regulations. Recent accounts of emergency relief operations throughout the world reveal that all major donations of pharmaceuticals fail to meet the recipients' real needs.3 The inappropriateness of drug donations comes primarily from their origin (industry surpluses, free medical samples, drugs collected by independent organizations or returned to pharmacies for disposal). Some drugs arrive unsorted and labelled in languages unknown to the professionals in the field. Expired drugs (at the time of their arrival) and drugs close to expiry still comprise a large proportion of donations from nongovernmental organizations, corporations, pharmaceutical

industries and associations.4 This practice is defended by a sad assertion that making use of expired, partially degraded drugs is better than having none at all. It obviously raises an ethical issue about the existence of first-hand/first-class drugs and second-hand/lower-class drugs and a disturbing division between the rights and worth of different populations.

Tefo Pheage [UN],2016-17, ***Dying from lack of medicines, https://www.un.org/africarenewal/magazine/december-2016-march-2017/dying-lack-medicines***

"**Low-income countries experience poor availability of essential medicines in health facilities, substandard-quality treatments, frequent stock-outs** and suboptimal prescription and use of medicines," says the world health body. **Africa's inefficient and bureaucratic public sector supply system is often plagued by poor procurement practices that make drugs very costly or unavailable. Added to these are the poor transportation system, a lack of storage facilities for pharmaceutical products** and a weak manufacturing capacity. Africa's capacity for pharmaceutical research and development (R & D) and local drug production still has a long way to go, say experts. Only 37 out of 54 African states have some level of pharmaceutical production. Except South Africa, which boasts some active local pharmaceutical ingredients, most countries rely on imported ingredients. The result is that Africa imports 70% of its pharmaceutical products, **with India alone accounting for nearly 18% of imports in 2011.** Pharmaceutical imports in Africa include up to 80% of the antiretroviral drugs (ARVs) used to treat HIV/AIDS, according to trade data.

A2 Outsourcing

1. Garguilo reports that the outsourcing of manufacturing is hella fucking non-unique – the sector is growing at 6.6% to a $76 billion industry!! While healthcare itself is only growing at 5.5%
2. ISR writes that 2/3 of manufacturing is already outsourced in the pharma industry because companies always want to cut corners and maximize profits, which means
    a. It's only a matter of time before other companies follow suit
    b. Or other companies won't ever have any incentive to start outsourcing

Louis Garguilo, [Outsourced Pharma], xx-xx-xxxx, ***Outsourced Pharmaceutical Manufacturing Grows To 76 Billion, https://www.outsourcedpharma.com/doc/outsourced-pharmaceutical-manufacturing-grows-to-billion-0001***

The outsourced manufacturing sector should continue its growth at a clip of 6.6% over the next five years, faster than the projected annual growth rate of the overall pharmaceutical industry (5.5%). That's according to a new report from Results Healthcare, Pharma & Biotech 2017 Review of outsourced manufacturing. If my numbers based on this report crunch correctly, this rate of growth propelled the total outsourced manufacturing market to just north of $76 billion through 2016. Let's dig deeper into the data and assign some further analysis.

ISR, 11-18-2016, ***Two-thirds of pharmaceutical manufacturing is outsourced, https://www.isrreports.com/outsourced-pharmaceutical-manufacturing/***

Informing the pharmaceutical drug development, manufacturing and commercialization industry. Cary, NC – November 18, 2016 – A new market research report from Industry Standard Research (ISR), Contract Development and Manufacturing Outsourcing Models, reveals the motivations and strategies behind drug innovators' decision to outsource and how different outsourcing relationships are selected. The report explores how sponsor organizations use

contract manufacturers through various outsourcing models including Tactical or Transactional Outsourcing, Preferred Providers and Strategic Partnerships to streamline costs, better manage capacity, improve efficiencies and decrease time to market. “Currently, only one-third of manufacturing—whether in the development stages or after commercial launch—is conducted in-house. The bulk of work is outsourced, and preferred providers are currently capturing the largest portion of the work,” explained Kate Hammeke, Vice President of Market Research at ISR. “This puts a high level of demand on CMO services, specifically in areas like specialty dosage forms, which often sit at the intersection of lack of capacity and lack of experience and forces the decision to outsource. This report digs into how the internal resources and know-how at sponsor organizations impact both the decision to outsource and which outsourcing model to use in order to gain the stability in supply appropriate to one’s needs.”

A2 Shortages

A2 Link - Price controls lead to drug shortages

[Their argument is that price controls → increased demand → companies can’t keep up]

LOGICALLY → Why would companies who are producing drugs at a given price point, presumably making some amount of profit, not produce more when their supply is less than the demand. If the drug is profitable, then they should make more??

1. Delink - Forbes in 2017 finds that 90% medication is cheap and affordable already and are not suffering from shortages. Just because you enforce price controls on the drugs that are not generic, does not mean they will be subject to special consequences. This is important because unless they can prove that generics, which are already cheap, are suffering from shortages, then there is no link to why other drugs would be affected. Empirically their claims are false.
2. Nonunique - According to the American Medical Association in 2018, there are current efforts to reform drug shortage policy. in order to respond to shortages occurring in the status quo, the AMA adopted policy declaring drug shortages an urgent public health crisis and have urged the Department of Health and Human Services to examine drug shortages as a national security initiative. The FDA chips in as well, with Forbe reporting in 2012 that thanks to an executive order, the FDA has taken action to prevent more than 150 drug shortages. Even if they prove that shortages are a bad thing, there are current efforts in action to solve them.
3. Delink - European countries haven’t seen widespread drug shortages. Europe is known for having price controls on drugs; however, the BMC Health Services found in 2014 that of all the drug shortages that occured in Europe, the main cause of them was production problems, not economic controls, with production problems including technical issues and quality related issues.

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.

Mills, Robert. "New AMA Policy Reflects Frustration over Ongoing Drug Shortages." New AMA Policy Reflects Frustration over Ongoing Drug Shortages | American Medical Association, The American Medical Association, 12 June 2018, www.ama-assn.org/new-ama-policy-reflects-frustration-over-ongoing-drug-shortages.
Responding to ongoing national drug shortages that threaten patient care and safety, physicians gathered at the Annual Meeting of the American Medical Association (AMA) today adopted policy declaring drug shortages an urgent public health crisis. The new declaration strengthens existing AMA policy outlining the physician prescription for a comprehensive solution to ongoing drug shortages. Many of the drugs currently in shortage are everyday products required for patient care in all medical settings, such as sterile intravenous products containing saline or other fluids. Shortages of these basic products, and their containers, increased following hurricane damage to production facilities in Puerto Rico, leaving the health care system scrambling for options that were either limited or risky. In response to hazards that pose a threat to the resilience of drug production, the AMA will urge the Department of Health and Human Services and the Department of Homeland Security to examine drug shortages as a national security initiative. This would result in drug manufacturing sites being designated as critical infrastructure with vital importance to the nation's public health. "Physicians strive to provide the best possible care to their patients, which means being able to obtain the right drugs at the right time," said AMA Board Member William E. Kobler, M.D.

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-reduce- innovation-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."

Delink - The United States has a ton of drug shortages right now that aren't linked back to price controls. Hoffman of The Conversation explains in 2018 that currently, the US is short on 182 drugs and medical supplies, ranging from IV bags to electrolytes. Drug shortages aren't unique to price controls and have many other factors that contribute to them.

Sharona Hoffman, 6-18-2018, "Drug shortages pose a public health crisis in the US," Conversation, https://theconversation.com/drug-shortages-pose-a-public-health-crisis-in-the-us-98295
Currently, the U.S. is short on 182 drugs and medical supplies, according to the American Society of Health-System Pharmacists. The list includes IV bags, injectable morphine and other powerful painkillers, anesthetics, antibiotics, electrolytes, cancer drugs and much more. All of these are of critical importance to patients with serious illnesses.

https://www.researchgate.net/publication/266242636_Drug_shortages_in_European_countries_A_trade-off_between_market_attractiveness_and_cost_containment
Only a limited proportion of
the reported shortages were mentioned in advance, complicating
early anticipation by health care workers and
jeopardizing patient care. For the cause of drug shortages,
it is unclear whether particular causes do not occur
in a country or if the reporting system is not sufficiently
specified to identify these causes. Causes of drug shortage
are categorized in broad groups and could only be
analyzed summarily in this study. Considering drug
shortages for which information about the cause is available,
production problems take the lead. It is generally
assumed that injectables are most susceptible to production
problems and quality defects compared to other formulations,
due to the complexity of the manufacturing

A2 Link - Life saving drug shortages

1. Delink - Dranove of Northwestern explains in 2014 that the demand for life-saving products is inelastic. The reason that this is the case is that in general, people will pay any price in order to save their lives.

https://www.kellogg.northwestern.edu/faculty/garthwaite/htm/medicare_pharma_innovation.pdf
The profits of pharmaceutical firms receive a large amount of attention and have caused many in the popular press and policymaking community to propose various policies to limit them (e.g. Rome, 2013). Critics claim that firms selling branded drugs under patent protection set prices at many multiples of marginal costs, excessively exploiting both their monopoly power and the inelastic demand for these often life-saving products. Industry defenders counter that high prices are necessary to offset expensive and uncertain research and development, and that if profits were to fall, incentives for future innovation would suffer. Danzon (2000) provides the quintessential defense of the industry: "[a]ny form of price regulation, including the setting of uniform prices within the United States or cross-nationally, would discourage innovation." Similarly, discussing the re-importation of low-price pharmaceuticals to the United States, Bast (2004) wrote "increasing importation means cutting off the stream of investment that makes this system sustainable. It means fewer new lifesaving drugs."

A2 Link - Prescription drug shortages

1. Delink - Prescription drug demand is inelastic. Cox of American Health and Drug Benefits explains in 2009 that numerous studies over the years has shown a price elasticity of demand being less than one, meaning demand for these drugs is inelastic even with a 10% increase in price or in copayments.

Emily Cox, Phd, xx-xx-xxxx, "Why Financial Incentives Aren't Enough to Move the Needle on Compliance," American Health & Drug Benefits, http://www.ahdbonline.com/issues/2009/january-2009-vol-2-no-1/272-article-272
Let us examine this by starting with some basics. The metric economists use to represent the relationship between price and demand is called "price elasticity of demand" and is expressed as the relative change in quantity demanded over relative changes in price. When it comes to demand for prescription drugs, numerous studies have found that the price elasticity of demand is less than 1, ranging from -0.18 to -0.60, a situation referred to as "inelastic demand." This means that the relative change in quantity demanded is always less than the relative change in price. For prescription drugs, a 10% increase in price or in copayments leads to a decrease of 1.8% to 6.0% in utilization, all else being equal.

A2 Example - Medicare Part B drug payment system

1. Delink - Medicare Part B didn't affect shortages. Cannon of CATO explains in 2012 that Medicare Part B didn't impose binding price controls, as evidenced by markups of 650% or more for drugs that went short, leading him to conclude in conjunction with the U.S.

Department of Health that the shortages came from the inherently high prices of bringing a new drug to market.

2. Delink - The US Department of Health and Human Services continues in 2011 that shortages of drugs under Medicare Part B were produced by the fact that neither consumers nor manufacturers are very responsive to short term changes in drug prices, meaning that product disruptions turn into shortages instead of higher prices.
    a. [2011 shortage] Specifically referencing the 2011 shortage, the Department of Health attributed that one to an expansion in products produced by the industry without a corresponding increase in manufacturing capacity.

https://aspe.hhs.gov/system/files/pdf/108986/ib.pdf
Sporadic and class-wide shortages of sterile injectable drugs occur because neither the quantity of these products needed by consumers nor the quantity of these products produced by manufacturers is very responsive to short term changes in price. This means that product disruptions, however caused, translate into shortages rather than simply higher prices.
The current class-wide shortages in the industry appears to be a consequence of a substantial expansion in the scope and volume of products produced by the industry that has occurred over a short period of time, without a corresponding expansion in manufacturing capacity. While several manufacturers are currently expanding capacity, most of this capacity will not become available for several years.

Michael F. Cannon, 3-16-2012, "What Is Causing Drug Shortages?," Cato Institute, https://www.cato.org/blog/what-causing-drug-shortages
I initially suspected these drug shortages were caused by Medicare's Part B drug-payment system. Others, including Scott Gottleib and the Wall Street Journal, have made that claim. However, this study and a lengthy discussion with the U.S. Department of Health and Human Services' assistant secretary for planning and evaluation have persuaded me that not only is Medicare's Part B drug-payment system not the cause, that system doesn't even impose binding price controls. Rather, it controls the margins that physicians earn for administering a drug. (If Medicare did impose binding price controls, would we see mark-ups of 650 percent or more for the shortage drugs?)

A2 Impact - Black Market

1. Turn - The incentive to shift to black markets is accessibility. Saranak in 2017 found that 14% of insured Americans did not fill prescriptions due to high costs. According to my

opponents, they should have gone to the black market, right? That didn't happen. The New York Times furthers in 2017 that skipping medication or not filling prescriptions due to high costs has resulted in 125,000 deaths. People are not shifting to black markets, they are dying due to high drug costs

Sarnak, Dana O. "Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?" Prescription Drug Spending Why Is the U.S. an Outlier?, The Commonwealth Fund, 5 Oct. 2017, www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier

Despite the differences among them, all countries do more than the U.S. does to limit patients' exposure to high out-of-pocket costs. While insured U.S. patients often pay little or nothing for generic prescriptions, they can be billed tens of thousands of dollars for certain high-priced medicines. Even Medicare's Part D prescription drug benefit has no out-of-pocket cap for beneficiaries. Only a handful of U.S. states have passed legislation to limit out-of-pocket spending for insurance sold within their borders; for example, Maryland has a $150 monthly cap for specialty-tier drugs.11 In a 2016 international survey of adults, 14 percent of insured Americans reported that, in the past year, they did not fill a prescription or skipped doses of medicine because of the cost, compared with 2 percent in the U.K. and 10 percent in Canada, the nation with the highest rate after the U.S. (Exhibit 6).12 Among Americans without continuous insurance coverage over the past year, the rate was twice as high: one-third reported they did not fill a prescription for medicine, or skipped doses of medicine, because of the cost.

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

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.

A2 Impact - Death

1. Severely mitigate the impact - Drug shortages don't kill that many people in the United States. Lee in 2011 explains that information specifically on how many deaths are caused by these shortages isn't tracked explicitly by any organization. However, even with the shortages of 182 drugs, in a study of 300 people conducted by the Institute for Safe Medication Practices in 2018, only one instance where a drug shortage might have contributed to a patient's death was highlighted.

Institute For Safe Medication Practices, 1-11-2018, "Drug Shortages Continue to Compromise Patient Care," https://www.ismp.org/resources/drug-shortages-continue-compromise-patient-care
A majority of respondents felt that drug shortages had compromised patient care. Most (71%) were unable to provide patients with the recommended drug or treatment for their condition due to shortages, and nearly half (47%) thought that this resulted in patients receiving a less effective drug. Also, three-quarters (75%) of respondents stated that patient treatments had been delayed because of drug shortages. One example involved a delay in treating sepsis and acidosis using sodium bicarbonate that may have contributed to a patient's death. An additional 5% of respondents reported other types of adverse outcomes related to drug shortages, such as increased pain or discomfort during a procedure due to the unavailability of a required analgesic or sedation agent.

C. Lee, xx-xx-xxxx, "The Drug Shortage Crisis in the United States: Causes, Impact, and Management Strategies," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/#__sec19title
With respect to other cancer drugs, it is unknown whether deaths or complications have occurred because of drug shortages.6 This information isn't traced by any agency, and many confounding variables exist, such as the patient's type of cancer, stage of disease, and whether an equally effective therapy can be identified.6 The relationship between cancer therapies and patient outcomes is also not clear-cut, because no cancer drug is known to be 100% effective.6 These factors make the impact of cancer drug shortages likely to remain undefined.6

A2 Innovation

A2 Link - Investors will invest less

1. Delink - Chen of Forbes writes that healthcare tech is the most profitable industry in the US with a 21% profit margin, meaning even if profits decreased a little, pharmaceuticals still have more than enough money to invest.
2. The Institute of Health and Socioeconomic Policy writes that R&D has been on the downward tick for decades especially since R&D is viewed as risky both by investors and the companies themselves, incentivizing a switch from innovation to financial engineering

Institute for Health and Socio-Economic Policy, 10-20-2016, "The R&D Smokescreen The Prioritization of Marketing & Sales in the Pharmaceutical Industry," https://www.nationalnursesunited.org/sites/default/files/nnu/files/pdf/research/TheRDSmokecreenv1_1.pdf

Drug companies make a conscious decision to reduce the funding and priority of R&D. This directly impacts innovation and is a threat to our public health. **R&D productivity has been on a steady decline for decades** 11 Pharmaceutical analysts note that this decline has occurred for multiple reasons, such as **[because of] stricter FDA regulations, the competition of generics, technology advancement, and mergers and acquisitions.12 In 2015, returns from R&D hit their lowest level in five years.** Deloitte consulting firm warned that although there has been a recent uptick in productivity, forecasted sales declines coupled with a major drop off in return-on-investment from R&D should have many drug companies worried. However, one key reason has been that the return-on-investments from R&D has not given the returns that executives and shareholders have expected. 13 "**Faced with weak returns on R&D,** drug companies have increased the amount of cash returned to shareholders through buybacks and dividends… signaling a possible 'lack of confidence on the part of both investors and companies' in R&D"14 More and **more pharmaceutical executives view R&D as risky, with even the slightest delay in drug development potentially causing a decline in shares.** In a recent case with Catalyst Pharmaceuticals and their drug Firdapse, the FDA gave the company a "refusal to file" because they needed to show an additional "adequate and well-controlled" study with particular patients. This delayed study caused company shares to drop by 52%. The severity of the decline of return-on-investment from R&D has led many companies to cut or downsize their R&D departments. 15 **Financial markets have rewarded companies for cutting their R&D departments** In 2008, former consultant and past Chairman and CEO of Valeant, Michael Pearson stated, "Cutting R&D meant your stock would go up… If you wanted to make money… dump R&D **and focus[ing] on lower-risk projects and aggressive financial engineering** – like merging with a Canadian company."16 Shortly after making that statement, Valeant merged with Biovail.17 Another reason for the decline in R&D has been the increase of mergers and acquisitions (M&A) within the pharmaceutical industry. This shift from innovation and discovery to maximizing profits through financial engineering has been a major setback for R&D.

A2 Link - Companies depend on drug revenue for investment

1. Delink - Drug companies don't spend a ton of revenue on investment. Hopkins of the University of Chicago explains in 2003 that pharmaceutical companies only spend about 6% of annual revenues on research and development. This is seriously marginal and any change in how much they make isn't going to affect this 6% they have set aside for research and development. This is UPenn in 2015 writes that "even if profits were cut by a half there would be sufficient incentive to assume the risks of drug development."
2. Delink - Price controls won't cut into pharmaceutical profits. According to Levy of the Library of Science, a 20% price cap for instance would increase the number of patients using the drug by 23%, almost completely offsetting the costs that go to the company, resulting in a revenue decrease by only about 1%.
3. Delink - Companies get their breakthroughs from government research, not private funding. Zaithick of Other98 explains in 2018 that of the 210 medicines approved for the market since 2010, all of them have come from research supported by the National Institute of Health, with 64 billion dollars from the NIH specifically going to 84 first-in-class drugs. The way this works is that the NIH conducts years of basic research, gets a breakthrough, which is snatched by a private company and marked up. For instance, after the NIH spent 64 million on creating sofosbuvir, a Hepatitis C drug, the private firm Gilead purchased it and priced a $100 drug up to six figures.
    a. This is evidenced by a study conducted by Lee of the Osong Public Health Project in 2015. Lee found that return on investment and net sales growth, in the Korean pharmaceutical industry, did not have a significant impact on research and

development. Thus, Baker of the New York Times concludes in 2016 that "we don't need" companies to have "patent monopolies to support research."

4. Empirically untrue - Edwards of CBS finds that in Canada, which has strict price controls, there's no relationship between R&D spending and price regulation. That's especially true as Chen of Forbes writes that healthcare tech is the most profitable industry in the US with a 21% profit margin, meaning even if profits decreased a little, pharmaceuticals still have more than enough money to invest.

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.**

Moshe Levy, xx-xx-xxxx, "The Pricing of Breakthrough Drugs: Theory and Policy Implications," PubMed Central (PMC),
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4244177/

We find that mild price regulation can substantially increase consumer surplus and the number of patients using the drug, while having only a second-order effect of the revenues of the pharmaceutical companies. For example, setting the price cap at 20% lower than the optimal monopolistic price increases the consumer surplus by about 10%, and increases the number of patients using the drug by about 23%. This increase in the number of users almost completely offsets the adverse effect of the price regulation from the perspective of the pharmaceutical company – its revenues decrease by only about 1%.

***Jim Edwards [CBS], 6-28-2011,** Hey, Whaddya Know,*
https://www.cbsnews.com/news/hey-whaddya-know-drug-price-controls-dont-kill-medical-innovation/

Drug price controls will punish innovation and drive down R&D spending -- that's the familiar mantra of the pharmaceutical industry. But **a new report from Canada, which has strict price controls, shows no relationship between R&D spending and price regulation.** The report, by Canada's Patented Medicine Prices Review Board, says that **drug prices in the U.S. are about twice as high as most other countries, and that U.S. drug companies spend less on R&D in the U.S. than they do in many countries with strict price regulation.** Drug sales are growing faster in Canada despite price controls, and Canadians spend about the same on drugs as a percentage of GDP as Americans do, the report shows.

***Liyan Chen [Forbes], 09-23-2015,** The Most Profitable Industries In 2015,*
https://www.forbes.com/sites/liyanchen/2015/09/23/the-most-profitable-industries-in-2015/#5db129936b73

To find the most profitable industries, FORBES took a look at the forecasted 2015 net margin of 19 major U.S. sectors. **With a 21% net profit margin, healthcare technology tops the list as the most profitable industry**, according to Factset. Finance and technology services trail with 17.3% and 16.1% net profit margin respectively. On the other end of the spectrum, energy minerals, distribution services, and non-energy minerals occupy the bottom of our list with 2.1%, 1.8% and 1.2%. **While healthcare technology has always been one of the most lucrative sectors, its net margin has been steadily on the rise along with the industry's** top line (**revenue**), as shown in the chart below. Within the broader healthcare technology category, the superstars of profitability go to major and generic pharmaceutical companies, such as Pfizer PFE -0.48% (27.6%), Merck & Co MRK +0.53%. (25.2%), Johnson & Johnson JNJ +0.38% (24.5%).

Greg Hopkins, U Chicago, 2003, Does The Regulation Of Pharmaceutical Drug Prices Discourage Innovation?, http://www.fgcasal.org/politicafarmaceutica/docs/Greg_Hopkins.PDF, AK

How much of the R&D cost of a drug is borne by the manufacturing company? The percent of drugs that come from public universities in the United States is 40% (AAU, 2002). United States pharmaceutical companies receive a 50% tax write off for their R&D expenses, and they only spend about 6% of annual revenues on R&D (Sulston). There are seven variables that I will model that might affect the number of new drug patents issued in a country. First I will look at the population of a country. The second factor in the number of new patents is the percent of Gross Domestic Product spent on Pharmaceuticals. The third factor will be the Analytical business expense research and development or ANBERD. The fourth factor is the amount of business expense research and development financed by the government or BERD financed by government in OECD reports, since government financing of drug company R&D reduces risk to a manufacturer. Fifth, I will look at the amount of research and development being done in higher educational institutions, which the OECD reports as HERD or Higher Educational Research and Development. Many universities do drug research and the successful innovations are then licensed out to the private industries.

Baker, Dean. (economist and the co-director of the Center for Economic and Policy Research), "Should the Government Impose Drug Price Controls?" The New York Times, The New York Times, 10 Jan. 2016, www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/end-patent-monopolies-on-drugs

Drug companies also spend tens of millions on campaign contributions and lobbying to get every longer and stronger patent protection. The pharmaceutical industry is one of the main forces behind the Trans-Pacific Partnership, and its demands for stronger patent protections is one of the main obstacles to reaching an agreement with the other countries. We don't need patent monopolies to support research. We already spend more than $30 billion a year financing research through the National Institutes of Health. Everyone, including the drug companies, agrees that this money is very productive. We could double or triple this spending and replace

the patent supported research done by the drug companies. With the research costs paid upfront, most drugs would be available for the same price as a bottle of generic aspirin. While themeasures being proposed by Hillary Clinton and earlier Bernie Sanders don't go this far, they are a big step in the right direction.

Lee M, Choi M., xx-xx-xxxx, "The Determinants of Research and Development Investment in the Pharmaceutical Industry: Focus on Financial Structures," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4677505/
This study conducted an integrated analysis on the factors influencing R&D investment in the Korean pharmaceutical industry, through a detailed review of the financial structure. To explain the factors influencing R&D investment in pharmaceutical companies, this study reviewed previous theories that have been developed, and then examined the logical basis and validity concerning the application of the financial structure theory to pharmaceutical companies. Based on the above analysis, review, and examination, this study selected factors that could consummately explain the influential factors of R&D investment in pharmaceutical companies, and then established a hypothesis for each factor. TS-2000 was used for the analysis data in this study. The study was conducted in two phases targeting the 'medical substance and drug manufacturing industries' between 2000 and 2012.

The results showed that: (1) the current ratio had a positive influence on R&D investment (2) the debt ratio had a negative influence on R&D investment and (3) ROI and net sales growth rate did not have a significant influence on R&D investment. The summary of the findings and the interpretation of the significance of this are as follows.

Written By, xx-xx-xxxx, "Taxpayers — not Big Pharma — have funded the research behind every new drug since 2010," Other98, https://other98.com/taxpayers-fund-pharma-research-development/
If those cuts had gone through, they would have exposed one of **the biggest lies told about Big Pharma: that the current system of patents and price-gouging is just an unfortunate necessity to cover the cost of all their brave and noble R&D work.**
The CISI study, underwritten by the National Biomedical Research Foundation, mapped the relationship between NIH-funded research and every new drug approved by the FDA between 2010 and 2016. **The authors found that each of the 210 medicines approved for market came out of research supported by the NIH. Of the $100 billion it spent nationally during this period, more than half of it — $64 billion — ended up helping the development of 84 first-in-class drugs.** But the NIH doesn't get to use the profits from these drugs to fund more research, the way it might under a model based on developing needed drugs and curing the sick, as opposed to serving Wall Street. **Instead, publicly funded labs conduct years of basic research to get to a breakthrough, which is then snatched up,**

tweaked, and patented (privatized) by companies who turn around and reap billions with 1,000-times-cost mark-ups on drugs developed with taxpayer money.
As an example, Gay points to new hepatitis C drugs that have become a global rallying cry for an end to drug patent monopolies. After the NIH funded $62.4 million for the basic science behind the breakthrough drug sofosbuvir, it was purchased by the firm Gilead for $11 billion. Gilead then turned around and priced at up to six-figures, even though a 12-week treatment course of costs less than $100 to produce.

A2 Link – Mergers

1. Not necessarily bad in world with price controls if the market price is lowered anyway
2. Turn – More mergers? More incentive to innovate because payout.
3. Turn – STAT News writes in 2017 that mergers are a catalyst for research as they combine the science of the merged organizations and increase the ability of companies to reallocate money from bad projects to more promising projects, overall resulting in an increased amount of research and development. 90% of R/D results in drugs that never make it to market, mergers decrease this percent.

https://www.statnews.com/2017/07/24/mergers-pharma-drug-development/

mergers generally appeared to drive productivity up — and did so significantly. Why might this be so? While mergers undoubtedly bring disruption to research and development, they also can be catalysts for addressing the fatal flaw of most research and development enterprises: the high cost of failure. More than 90 percent of pharmaceutical industry spending on research and development goes into projects that never reach the market. Any intervention that helps reduce this waste can be a real boon to productivity. There are really only two ways to fix the industry's cost-of-failure problem: 1) start with better science, so you have fewer failures; and 2) employ better decision-making about when to stop projects so you can reallocate that capital to more-promising opportunities. Mergers can help with both of these dimensions. **They bring the best combined science of the merged organizations to bear on the difficult questions of which pathways, modalities, and molecules to pursue. Mergers also trigger reviews that drive the leadership of the new company to take a fresh look at research and development. These reviews can offer the leadership an opportunity to soberly and objectively reassess its scientific hypotheses in each disease area and reevaluate the combined research and development portfolio, eliminating those projects least likely to produce advances in treatment.**

A2 Link – Monopolies

1. Nonunique - Big pharma is dependent on small pharma**. According to Radcliffe of Healthline in 2017**, big pharma such as Pfizer have invested billions in independent startups because they depend on these companies to create profitable drugs that they can then buy out. Big pharma is never going to destroy small pharma because they depend on them for new drugs. Small company's goal is to get bought out because their leadership teams want to make money. That's why Public Citizen reports that the past few years have seen the consolidation of the industry is larger, as large companies have now captured 64% of the market up from 28% in 2007.

2. [Venture capital] Mitigate – The Brookings Institute finds that of all money spent on R/D, which is 160 billion, only 3.2 billion came from venture capital, which thus only funds 2% of the industry. The Biomedical Journal furthers that the government is responsible for most of VC drug development, funding 68% of all new projects, which is funding that won't go away.
3. Delink - Chen of Forbes writes that healthcare tech is the most profitable industry in the US with a 21% profit margin, meaning even if profits decreased a little, there is still more than enough of an incentive to invest.

"How does venture capital operate in medical innovation? | BMJ Innovations", https://innovations.bmj.com/content/2/3/111

The innovation policy scholarship posits that venture capital-backed ventures are likely to outperform non-venture capital-backed ventures.6–8 The main arguments are that 'investors can identify firms with hidden value', that their investments operate as a 'signal of the quality of the ventures for uninformed third parties', and that they bring 'external resources and competencies that would be out of reach' without their endorsement.7 Informed by such literature, policymakers rely on 'two pillars' to foster the venture capital market. First, they seek to increase the 'demand' for venture capital by providing 'generous subsidies' and fiscal advantages to entrepreneurs so as to augment 'birth rate' of innovative firms.7 Second, they seek to increase the 'supply' of venture capital through 'co-investment schemes, the launch of new government-owned venture capital companies and favourable tax treatment of capital gains'.7 Along those lines, the UK government created many funds since 2000, including the High Technology Fund, the Early Growth Funds and the Enterprise Capital Funds. Such funds played a particularly important role in early-stage financing in the following years, witnessing a peak in 2008 during which **68% of all early-stage venture capital investments were publicly backed.4**

Liz Sablich, "Who's investing in health care R&D?", https://www.brookings.edu/blog/techtank/2018/04/23/whos-investing-in-health-care-rd/

These are substantial sums of money: A total of $159.9 billion spent on overall health R&D, including $156.7 billion from pharmaceutical companies and $3.2 billion from venture capital. But is it enough and is it being spent in the places that need it most? For more on those questions, explore the many publications of Brookings's Private Sector Global Health R&D Project.

"The Rising Cost of Generic Drugs | Public Citizen", https://www.citizen.org/our-work/health-and-safety/the-rising-cost-of-generic-drugs

A large part of the explanation comes from changes to the generic-drug market. The past few years have seen increasing consolidation of this industry, leading to fewer major generics makers and thus less price competition. In 2007, the top 10 generic-drug companies had just 28.5 percent of global market share,[14] but by 2014, had captured 64 percent of that market.[15] Last year Teva Pharmaceuticals, already the world's largest generic-drug company, announced that it was acquiring the third-largest manufacturer, Allergan's generics unit, for $40.5 billion.[16] Such mergers, and the resulting loss of competition, likely have been a key factor in the dramatic price hikes of many generic drugs.[17]

Shawn Radcliffe, 10-11-2017, "Drug Research by Pharmaceutical Startup Firms," Healthline, https://www.healthline.com/health-news/big-pharma-creating-start-ups-to-do-drug-research

Written by Shawn Radcliffe on October 11, 2017

Pfizer and other pharmaceutical companies are investing in independent startups, hoping to find the next popular and profitable drug.

A2 Card – Lakdawalla, Soor

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

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

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

A2 Card - $2.6billion/new drug

4. Doctors Without Borders finds a more realistic estimate is $50-$186 million – which is as small as 2% of their estimate. Their number, created by industry-funded research, only looks at breakthrough tech, while most new drugs released are simply copycat drugs, and doesn't account for publicly funded research or tax deductions.

Institute for Health and Socio-Economic Policy, 10-20-2016, "The R&D Smokescreen The Prioritization of Marketing & Sales in the Pharmaceutical Industry," https://www.nationalnursesunited.org/sites/default/files/nnu/files/pdf/research/TheRDSmokecreenv1_1.pdf

The drug industry wants us to believe that high drug prices are justified by the extensive amounts of R&D they are doing. **A 2014 study conducted by the industry-bankrolled Tufts Center for the Study of Drug Development concluded that the cost of selling a drug was $2.6 billion. By contrast, Doctors Without Borders calculated the cost of developing a new drug taking failure into account, at $50 million to $186 million.** The Tufts study breaks down the costs into two main categories. One category is "actual costs", which constitute the companies "out-of-pocket" expenses. These are the costs that are reported on the Drug Company's financial statements. The second and very questionably category is **"Opportunity costs" equated at $1.16 billion, about 45% of the cost estimate**. Opportunity costs are the amounts that could have been earned by drug companies had

they decided to invest the money elsewhere while the drug was in development.5 **This amount should not even be considered because it is purely speculative.** Compared to the calculations from Doctors Without Borders, even if you take the reduced amount of $1.44 billion, this amount is still highly questionable. 6 Another major flaw was that **[T]he study only looked at drugs considered New Medical Entities** (NMEs); these are drugs **with new breakthrough biologics in them. However, NMEs only make a very small percentage of the drugs** that are **approved** each year **by the FDA. The vast majority** of the drugs approved by the FDA **are slightly modified versions of already existing drugs called "copycat drugs"** or "me-too drugs". In addition, **the study did not include** any numbers that estimated the amount of **publicly funded research** utilized by drug companies **nor did it mention that R&D costs come from gross profits and create a 100 percent immediate deduction from taxable profits.** This notion of high drug development costs is a diversion from where companies are really spending their money, Marketing & Sales.

A2 Impact - Shutting down factories in other countries

1. Delink - Doesn't make economic sense. Light in 2016 explains that wether or not domestic revenues recover a given country's research and development costs is irrelevant. If this were the case, then small countries like Switzerland, would have shut down all operations long ago due to a small market size.

No Author, xx-xx-xxxx, "," No Publication, http://www.pharmamyths.net/files/BMJ-Foreign_Free_Riders_Oct_05.pdf

The industry's principal claims, as well as being contradicted, are based on false premises. Firstly, counting which country discovers the most new molecular entities is irrelevant in a global market. Companies know that where a good drug is discovered does not matter, and often a discovery comes from research in several countries. Whether domestic revenues recover a given country's research and development costs is also irrelevant. If this were not the case the industry would have shut down operations in Switzerland long ago because of its small market size.

If revenues are inadequate, it would make more sense to conclude they do not cover all marketing costs rather than research costs. Research is central to the industry, and costs associated with it should be deducted first. Pharmaceutical companies report that they invest around three times more in the combination of marketing, advertising, and administration than in research, leaving ample room to cut costs.20

A2 Impact – No drugs

1. Delink - The US does not produce more drugs than other countries if you look at it from a GDP perspective. Keyhani finds in 2010 that if you compare the percentage of US GDP that comes from prescription drug investment to the number of new drugs actually created, the US is on par or even slightly below other countries. Take the UK for example, which has some of the lowest drug prices in the world thanks to price ceilings. The UK actually produced more drugs in comparison to their GDP than the United States, in spite of the price controls. The study concludes that this is the case because pure price considerations matter less to drug development than research resources and infrastructure.
2. Delink - More money doesn't mean smarter innovation. Ginsberg of Health Affairs in 2017 found that innovation increases less than proportionately with market size and new developments are not as forthcoming. The number of new drugs which are labeled as "high priority" for being "truly innovative" by the FDA has remained constant, independent of the amount of money poured into innovation. Blume furthers in 2013 that following the dropping of prices through Medicare Part D, that while there was an increase in drugs entering FDA trials, the number that made it all the way to Phase III trials stayed the same. Revenue has no correlation with the number of new drugs produced.
3. Mitigate - Low hanging fruit drugs are gone. Hesse of Raconteur explains in 2016 that the number of new drugs approved has fallen considerably in recent years thanks to the low hanging fruit being gathered and the remaining diseases, like cancer and Alzheimers, being ones that are incredibly complex to crack. While companies can spend billions of dollars on research and development, there is no guarantee a product will be successful and deliver a return on its investment. This is why Stanford finds that in the past 40 years, only 11 to 15% of the new drugs provided significant clinical improvement over existing ones, while the remaining 85 to 89 percent were clones of existing drugs that were marketed as the latest breakthrough.
4. Turn - Drug companies are using their ability to raise prices as a way to avoid developing new drugs. Pearl of Forbes explains in 2017 that companies are increasingly not putting their profits into R and D. Companies have discovered that its simpler and safer to either buy the rights to drugs or raise prices many times over than developing new drugs.
5. Turn - Price controls increase the effectiveness of new drugs produced in two ways.
    a. 1) A shift toward the public sector. The New York Times explains in 2016 that with price controls, the US would just shift more toward supporting public sector research, such as what is conducted by the National Institue of Health. In fact, McCarty of Forbes finds that in the last proposal for price regulations there was a 39 billion dollar increase in funding for the National Institute of Health. This is key, because New Scientist explains in 2013 that public sector developments are

responsible for 75% of all innovative drugs every year. Public sector innovation is more productive.

a. 2) More effective private sector spending. The Dutch Healthcare Institute confirms in 2018 that with price controls, innovation becomes more strategic. They need to innovate smarter to return the same amount of profits from consumers actually needing the drug. Thus, MIT finds that a 1 percent increase in potential market size leads to approximately a 4 percent increase in the entry of new nongeneric drugs This is why historically, Stanford University writes that from 1982 to 2003 companies, with price controls, discovered more drugs than U.S. companies from 1982 to 2003, overall and in proportion to funding selling them at half the cost

Thus, overall Prada of BMC finds that in Colombia, price regulations decreased drug costs by 43%, but this in turn doubled company profits from increased sales because of more accessibility to drugs, proving if anything, innovation would increase

https://news.stanford.edu/pr/2009/pr-light-pharma-study-082109.html

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.

https://economics.mit.edu/files/4464

increase for drugs mostly consumed by the middle-aged. Our estimates suggest that a 1 percent increase in the size of the potential market for a drug category leads to a 6 percent increase in the total number of new drugs entering the U. S. market. Much of this response comes from the entry of generics, which are drugs that are identical or bioequivalent to an existing drug no longer under patent protection. More important, there is a statistically significant response of the entry of nongeneric drugs, which more closely correspond to new products and "innovation": a 1 percent increase in potential market size leads to approximately a 4 percent increase in the entry of new nongeneric drugs. We also look at the relationship between market size and entry of new molecular entities. These drugs, which contain active ingredients that have not been previously marketed in the United States, provide a measure of more radical innovations (there are 442 new molecular entities compared with 2203 new nongenerics during our sample period). We find that a 1 percent increase in potential market size is associated with a 4–6 percent increase in the entry of new molecular entities. These results together show an important

Mark Mccarty ["Medical Device Daily",
http://www.medicaldevicedaily.com/servlet/com.accumedia.web.Dispatcher?next=bioWorldHeadlin

es_article&forceid=98986, 11-16-2018]jzl
The U.S. Senate passed a spending bill that would provide the National Institutes of Health with roughly $39 billion in the coming fiscal year, but the legislation also provides funding for development of drug pricing regulations. While the Senate must reconcile its bill with the House of Representatives, the Trump administration has frequently promoted the idea of pharmaceutical price transparency, suggesting this provision has only to get past the House of Representatives to become law.

Prada et. Al. 18 ***[Sergio I. Prada, Victoria E. Soto, Tatiana S. Andia, Claudia P. Vaca, Álvaro A. Morales, Sergio R. Márquez and Alejandro Gaviria, Centro PROESA, Universidad Icesi, etc. "Higher pharmaceutical public expenditure after direct price control: improved access or induced demand? The Colombian case," 2 March 2018, Cost Effectiveness and Resource Allocation. BMC, part of Springer Nature. https://resource-allocation.biomedcentral.com/articles/10.1186/s12962-018-0092-0 RY]***

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. Conclusions **We conclude that pricing interventions should be implemented along with a strong market monitoring to prevent market distortions such as inappropriate and unnecessary drug use.**

Marcel Canoy, "Lower drug prices can improve innovation", Dutch Health Care Institute, 2018, https://editorialexpress.com/cgi-bin/conference/download.cgi?db_name=EARIE45&paper_id=550, SP, October 15, 2018
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.

Mariana Mazz, "State of innovation: Busting the private-sector myth", N.S. News, August 21, 2013, https://www.newscientist.com/article/mg21929310-200-state-of-innovation-busting-the-private-sector-myth/ , SP, October 14, 2018

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.

Jared Bernstein, “Drug Price Controls Are Vital in a Market That’s Not Free”, The New York Times, June 29, 2016, 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 , SP, October 14, 2018
Price controls for drugs, which are common in other advanced economies, increase affordability. But even when the mechanism is “cost-plus” pricing — the government allows drug companies some degree of markup — their profits will still decline from current levels. The simplest solution is to take excessive profit out of the equation and ramp up what is already a robust public medical research infrastructure. This could take the form of an expanded National Institutes of Health, where researchers are employed by the government, or private research could be subsidized. Either way, the key outcome is that the patents themselves would be public goods in the public domain, meaning no more price gouging.

"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.

Robert Pearl, M.D., xx-xx-xxxx, "Why Patent Protection In The Drug Industry Is Out Of Control," Forbes,

https://www.forbes.com/sites/robertpearl/2017/01/19/why-patent-protection-in-the-drug-industry-is-out-of-control/#31eadc9b78ca
Increasingly, drug companies are not investing in R&D proportional to the profits they earn from the drugs they bring to market, despite their protests to the contrary. Instead, many have figured out that it's simpler and safer from a financial perspective to either buy the rights to drugs developed by others and raise the prices many times over, as with Sovaldi, or to obtain a medication already in existence and, using monopolistic control, raise the price as much as 500% or more, as in the case of the EpiPen. As a consequence, the patent protection process now primarily serves the drug companies, most often not on behalf of the American people, but, rather, at their expense.

Jason Hesse, xx-xx-xxxx, "Growth after low-hanging fruit has been picked," Raconteur, https://www.raconteur.net/healthcare/growth-after-low-hanging-fruit-has-been-picked
The pharmaceutical industry is faced with a crisis of innovation. While the last 60 years saw huge advances in research and development, the number of new drugs approved has fallen considerably since the turn of the millennium. Between 2000 and 2010, the US Food and Drug Administration (FDA) approved an average of just 24 drugs a year, compared with an average of 31 medicines a year in the 1990s. The days of finding easy cures are over, says Ana Nicholls, healthcare analyst at the Economist Intelligence Unit. **"The low-hanging fruit has already been gathered.** It's increasingly difficult to come up with new solutions for diseases, because as you look more closely at them, the problem becomes more complex." Stefan Gijssels, vice president public affairs of Janssen Pharmaceuticals agrees. "For many diseases, the easiest cures have been found. Now we're looking at tough diseases – Alzheimer's, lung cancer and some infectious diseases. But finding a solution is incredibly complex." As an example of how difficult – and costly – research and development can be for pharmaceutical companies, Mr Gijssels explains how Janssen worked on developing an Alzheimer's drug for more than ten years, until it fell in clinical trials when the drug was tested on a wider group of potential patients. "The drug simply didn't show any significant improvement on the disease," he explains. "It was very frustrating. It was the culmination of ten years of research with hundreds of researchers, but we had to stop its development. Its efficacy was just much lower than expected." **This underscores that, while companies can spend billions of dollars on research and development, there is no guarantee a product will be successful and deliver a return on its investment. There is also a regulatory burden.** For a product to become truly profitable, manufacturers not only need the drug to be approved by the authorities, such as the FDA or European Medicines Agency, but it also needs to be accepted by insurance companies and national health bodies, which subsidise or pay for the products for patients. "It's no longer a given that just because you've got regulatory approval, you'll be able to make money on it," explains Antony Odell, managing director of research and development firm Tissue Regenix. "You can get FDA approval, but it may take another three years for the reimbursement codes which will help get you a decent return. **"And in addition to showing that the product works, you need to demonstrate that it's bringing something to the market that no one else is doing. Launching 'me too drugs' are no longer an option.**" Ms Nicholls adds: "There has been a lot of panic by research and development firms. But by any standards this is still a very profitable industry. It still has the money to invest in its own future. Regulators have been sensitive to pharmaceutical companies getting a return; regulators are not blocking innovation." Professor Stanton Newman, dean of City University London's School of Health Sciences, adds that pharmaceutical companies must also address a "burden of cost effectiveness". "In Britain, there is a £30,000 per treatment threshold for limiting what will go into the National Health Service," he explains. "Then there is a big hurdle from managed care organisations, which look for clear benefits for patients." **A unique historical feature of the market has been its reliance on so-called blockbuster drugs, which bring in billions of dollars in revenue for**

pharmaceutical companies, justifying the billions spent on research and development. For Mr Gijssels, blockbusters are "a thing of the past". Research by McKinsey shows that innovative products are becoming less profitable. Peak-year sales of innovative products are forecast to decline from around $900 million for products launched in 2012 to around $600 million for products launched in 2015. "The industry is changing and adapting to the new environment," says Mr Gijssels. "Most companies try to have a broad portfolio now. Because if you put all your money on blockbusters, it really hurts when the patent expires.

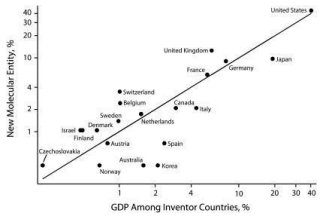
Salomeh Keyhani,, xx-xx-xxxx, "US Pharmaceutical Innovation in an International Context," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2866602/

Results. The United States accounted for 42% of prescription drug spending and 40% of the total GDP among innovator countries and was responsible for the development of 43.7% of the NMEs. The United Kingdom, Switzerland, and a few other countries innovated proportionally more than their contribution to GDP or prescription drug spending, whereas Japan, South Korea, and a few other countries innovated less.

Conclusions. **Higher prescription drug spending in the United States does not disproportionately privilege domestic innovation, and many countries with drug price regulation were significant contributors to pharmaceutical innovation.**

The statements of US government officials and industry representatives imply that the US market is paying for the development of most new drugs. There is ample evidence that domestic profits in several countries that have price or profit control cover research and development expenditures.11 For example, in Canada, domestic sales on average are about 10 times the research and development costs. In the United Kingdom, the pharmaceutical industry invests more of its revenues from domestic sales in research and development than do companies in the United States.11 Statements by US government officials and industry representatives also imply that the United States is becoming a dominant source of innovation because of its lack of drug price regulation. From a purely theoretical standpoint, these statements are troubling because they imply a country-specific source of innovation. The industry is private, however, not government owned, and operates in a worldwide market.3 **It is also doubtful that pure price considerations would affect where a drug was developed, and more strategic considerations such as the availability of drug-specific research resources and infrastructure in a particular country may be a more important consideration.**

Pharmaceutical innovation is an international enterprise. Although the United States is an important contributor to pharmaceutical innovation, we found that more than 20 countries contributed to the development of the 288 NMEs with patents at the time of approval. More than 171 companies were involved in the development of these NMEs, and the vast majority of companies were multinationals with facilities located in more than 2 countries. **We also found that the United Kingdom, Switzerland, Belgium, and a few other countries innovated proportionally more than their contribution to the global GDP or prescription drug spending, whereas Japan, Spain, Australia, and Italy innovated less.**



Note. GDP = gross domestic product; NME = new molecular entity. Axes are on a log scale. **The United States almost falls on the 45 degree line where contribution to GDP and NME development is roughly proportional. Countries above the line develop a higher percentage of drugs compared with their percentage contribution to GDP.** For example, the United States accounted for 40% of the GDP among NME innovator countries and was responsible for

the development of 43.7% of the NMEs. The UK contributed proportionally more NMEs than its national income would indicate, and Australia and Japan proportionally less.

Margaret E. Blume, xx-xx-xxxx, "Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3711884/

Third, like Finkelstein (2004) and Yin (2008), we measure firms' innovative activities via clinical trials, whereas Dubois et al. (2011) and Acemoglu and Linn (2004) evaluate responsiveness of approved and marketed drugs to changes in market size. If we assume diminishing marginal expected returns to investment in pharmaceutical R&D, then new clinical trials added should have lower expected rates of success. For example, we observe a very strong Phase I trials response for protected drug classes most used by dual eligibles (antipsychotic and antidepressant medications), but no significant increase in those drugs entering Phase III. As discussed by Arrowsmith (2011), many of these recently tested products failed to show sufficient efficacy versus placebo. Our estimated elasticities of clinical trials with respect to market size should therefore be larger than corresponding elasticities for new drug approvals.

Richard G., 11-13-2017, "Pharmaceutical Industry Profits And Research And Development," No Publication, https://www.healthaffairs.org/do/10.1377/hblog20171113.880918/full/

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**. Together, these conclusions are consistent with a couple of interpretations. **One is that the science required to produce new drugs in 2017 is harder than it was a decade or two previously and so the "low hanging fruit" has been picked.** A second interpretation, mentioned earlier, is that differentiated competition drives excessive entry and duplication of R&D effort, resulting in overinvestment in certain clinical areas. Both forces can be at work. A third conclusion has recently emerged but it reflects only one research effort. **Using changes in market size stemming from insurance expansion, Dranove and colleagues examined both the number of new drugs brought to market and the degree to which new drugs are "truly innovative," as measured by being aimed at an under treated illness or being rated by the U.S. Food and Drug Administration (FDA) as high priority. Like prior researchers, they found that as markets grow the number of new products increases; the vast majority of increases occur in markets where there are already five or more products being sold. Dranove and colleagues found no meaningful increases in the number of drugs rated by the FDA as high priority as market size grew.** Reactions on the part of the pharmaceutical industry to proposals that would lead to lower drug prices, either through market forces (e.g. faster generic approvals) or regulation (e.g. price controls), have emphasized reductions in future innovation. The relationship between prices and innovations is real, but that is only part of the needed analysis. **Innovation, like everything else, is constrained by the law of diminishing returns.**

Indeed, it is possible that the current magnitude of innovation in pharmaceuticals is already too high in the sense that resources going into it might be better used for infrastructure, education, housing and other priorities. **For those concerned about the growing role of government in the economy, since a large portion of higher drug prices are paid either directly (Medicare, Medicaid) or indirectly (tax subsidies for insurance) by government, higher drug prices inevitably lead to either higher taxes or cuts in spending for other priorities.**

A2 Impact – Inc intl price

1. Delink - Their own logic makes no sense. If price controls are instituted, the pharmaceutical industry is literally restricted from increasing the price on their product, whether that be in the U.S. or Internationally. Their argument lacks logical sense.
2. Delink - International countries are outpacing the U.S. in drug development and would solve for consumer costs in other nations. According to the U.S. International Trade Commission in 2007, India's pharmaceutical industry is quickly outpacing the U.S. and expanding investment. They further that 15 of the world's 20 largest pharmaceutical companies are Indian companies that also spent approximately $1.6 billion to acquire generic drug manufacturing firms in Europe, North America, and Mexico. The Indian market is becoming the pharmaceutical leader of the world which means the cost of drugs would not be affected as global leaders would fill the void.
3. Turn - Companies become more likely to make drugs that will benefit members of developing countries who struggle to afford pharmaceuticals due to high prices. The Independent explains in 2014, that during the Ebola crisis, there was no reason for businesses to make an Ebola vaccine as the people affected couldn't pay the high prices that the companies wanted to set. When price controls go into place, the pharmaceutical industry no longer has a profit disincentive for the deaths of those in developing countries.

Charlie Cooper, journalist for the Independent, 9-6-2014, "Ebola outbreak: 'Big Pharma' failed victims, says leading scientist," Independent, http://www.independent.co.uk/life-style/health-and-families/health-news/ebola-outbreak-big-pharma-failed-victims-why-9716615.html

However, Professor Hill said that the fact that a vaccine had not been available to stop the disease when it emerged in Guinea six months ago represented a "market failure" of the commercial system of vaccine production which is dominated by the pharmaceutical giants.

The scale of the Ebola outbreak and the devastation it is causing in terms of lives lost and social breakdown had led the World Health Organisation (WHO) to order an unprecedented acceleration of normal drug development processes. Experts are looking at 10 different unlicensed and experimental Ebola therapy and vaccine candidates, of which the GSK/NIH vaccine is among the most promising. Regulatory processes that usually take up to 15 years have been abandoned, to fast-track drugs and vaccines into the field. Already, the experimental drug ZMapp, developed by Mapp, a small biopharmaceutical firm in the US, has been used to treat at least seven patients – four of them Westerners – and has shown promising results in trials on primates. Stocks have now run out, but Mapp has been handed $25m (£15m) by the US government to scale up production. On Friday, the WHO met in Geneva to assess the options but concluded that despite the extraordinary measures, "new treatments or vaccines are not expected for widespread use before the end of 2014". As well as the GSK/NIH vaccine, to be tested in healthy volunteers in Oxford within two weeks, a Canadian vaccine has also shown promise and is being tested in the US. Professor Hill explained that the GSK/NIH vaccine, which is based on a strain of chimpanzee cold virus and known as ChAd3, was originally developed in the US for potential use against a bio-terror attack – and only existed because of high levels of funding allocated to vaccines designated for defence. Asked why a fully tested and licensed vaccine had not been developed, Professor Hill said: "Well, who makes vaccines?

Today, commercial vaccine supply is monopolised by four or five mega- companies – GSK, Sanofi, Merck, Pfizer – some of the biggest companies in the world. "The problem with that is, even if you've got a way of making a vaccine, unless there's a big market, it's not worth the while of a mega-company …. There was no business case to make an Ebola vaccine for the people who needed it most: first because of the nature of the outbreak; second, the number of people likely to be affected was, until now, thought to be very small; and third, the fact that the people affected are in some of the poorest countries in the world and can't afford to pay for a new vaccine. It's a market failure." He said that producing a vaccine for Ebola was "technically more doable" than making one for other challenging and more widespread diseases such as TB, HIV and malaria, which receive more funding. "There's a lesson here," he said. "If we had invested in an Ebola vaccine, had it sitting there as the outbreak comes, you could have nipped it in the bud, been able to vaccinate the region where it started.

A2 Impact - Africa

1. Delink - Pheage of the United Nations finds that of the 70% of pharmaceutical products Africa imports, the U.S. is not its biggest trade partner, finding that India alone accounts for 18% of Africa's pharmaceutical imports.

Tefo Pheage, "Dying from lack of medicines", United Nations, March 2017, https://www.un.org/africarenewal/magazine/december-2016-march-2017/dying-lack-medicines, SP, October 30, 2018

The result is that Africa imports 70% of its pharmaceutical products, with India alone accounting for nearly 18% of imports in 2011. Pharmaceutical imports in Africa include up to 80% of the antiretroviral drugs (ARVs) used to treat HIV/AIDS, according to trade data.

A2 Impact – Price declines

1. Turn. Callahan of Hastings writes that costs are increasing at a rate of 7% a year, and up to 50% of that cost is attributed to developing new tech or overuse of old tech, concluding controlling tech is the single most important factor in decreasing healthcare costs.
2. Innovative tech is too expensive. Skinner of MIT writes that just 0.5 percent of studies on new medical technologies evaluated those that work just as well as existing ones but cost less.

Daniel Callahan [Hastings Center], 2008, Health Care Costs and Medical Technology, https://www.thehastingscenter.org/briefingbook/health-care-costs-and-medical-technology/

Almost everyone knows that this country has a scandalously large number of people who lack health insurance, now up to 46 million and growing. That number is vivid and evocative. But it has overshadowed another, more serious issue—that of the steady escalation of health care costs. **Largely due to the use of medical technology, those costs are now increasing at an annual rate of 7% a year.** The Medicare program as a consequence is projected to go bankrupt in nine years, and overall health care cost to go from its present $2.1 trillion annually to $4 trillion in 10 years. Those rising costs are an important reason why the number of uninsured keeps going up. Business finds it harder and harder to pay for employee health benefits, and only 61% of

employers even provide them now (from a high a decade ago of close to 70%); and the employers who do provide benefits are cutting them and forcing employees to pay more themselves in the form of copayments and deductibles. The 15% who are uninsured are surely faced with both health and financial threats. But the cost problem now threatens everyone else as well, including those using the Medicare and Medicaid programs. Yet even if most people are now aware of the dangers of cost escalation (and many know it from personal experience), the problem has not gripped the imagination of the public, the presidential candidates, or the media with the force of the uninsured (even though recent public opinion polls indicate it is catching up). There are a number of proposed and detailed schemes for universal care, but nothing comparable for cost control, which is implicitly unpopular. That's because cost control will mean that just about everyone will be forced to give up something and accept a different, more austere kind of health care. Consider what serious cost control will require: moving from a 7% annual cost growth down to 3%, which is an inflation of health care costs that is no greater than that of the per annum rise in general inflation. That amounts to a cost reduction of $1.5 trillion over the next decade, so that health care costs settle in at $2.5 trillion in a decade. This would represent an enormous and unprecedented drop in annual costs for a health care system that has never since World War II seen anything more than a short, temporary decline from time to time. The feature of cost escalation that should catch our eye most is the role that medical technology plays. **Health care economists estimate that 40–50% of annual cost increases can be traced to new technologies or the intensified use of old ones. That makes the control of technology the most important factor in bringing costs down.** Ethics comes in at this point because medical technology is highly valued as a beloved feature of American medicine. Patients expect it, doctors are primarily trained to use it, the medical industries make billions of dollars selling it, and the media loves to write about it. The economic and social incentives to develop and diffuse it are powerful, and the disincentives so far weak and almost helpless. Cutting the use of technology will seem wrong—even immoral—to many.

Jonathan S. Skinner [MIT Technology Review], 9-5-2013, Unproved Technologies Are to Blame for Health Costs, https://www.technologyreview.com/s/518876/the-costly-paradox-of-health-care-technology/

Other researchers have found that **just 0.5 percent of studies on new medical technologies evaluated those that work just as well as existing ones but cost less.** The nearly complete isolation of both physicians and patients from the actual prices paid for treatments ensures a barren ground for these types of ideas. Why should a patient, fully covered by health insurance, worry about whether that expensive hip implant is really any better than the alternative costing half as much? And for that matter, physicians rarely if ever know the cost of what they prescribe—and are often shocked when they do find out. The implications for innovation policy are twofold. **First, we should pay only for innovations that are worth it, but without shutting out the potential for shaky new ideas that might have long-term potential.** Two physicians, Steven Pearson and Peter Bach, have suggested a middle ground, where Medicare would cover such innovations for, say, three years; then, if there is still no evidence of effectiveness, Medicare would revert to paying for the standard treatment. Like many rational ideas, this one may fall victim to the internecine political struggles in Washington, D.C., where it's controversial to suggest denying even unproven treatments for dying patients. For this reason, the best way technology can save costs is if it is used to better organize the health-care system. **While the U.S. may lead the world in developing costly new orthopedic prostheses, we're far behind in figuring out how to get treatments to patients who want and could actually benefit from them**. Doing so requires a greater emphasis on organizational change, innovations in the science of health-care delivery, and transparent prices to provide the right encouragement. This means smartphone diagnostics, technology to help physicians and nurses deliver the highest-quality care, or even drug container caps with motion detectors that let a nurse know when the patient hasn't taken the daily dose. The overall benefits from innovation in health-care delivery could far exceed those arising from dozens of shiny new medical devices.

A2 Impact - Long term costs of drugs increases

1. Delink - Logically, this argument makes no sense. The long term costs of drugs cannot increase more than the price control enforced by the federal government.

A2 Impact – Antibiotics

1. Squo doesn't solve shit. Simpkin writes that big companies right now are shifting away from ABR investment because there aren't enough profits, and smaller companies don't have the capital to fill the gap.
2. Dall finds that no new antibiotics have been approved since 1984 – literally all of the antibiotics in the past have just been variations of existing drugs, and most of those that are in trials rn won't get approved by the FDA.
1. Logically, the first thing you cut is the marketing not the innovation, because selling the product is what gets you the money. Companies that manufacture are big business who

make excess profits and it makes no sense to cut manufacturing if that is key to making profit.

Victoria L Simpkin [PubMed Central (PMC)], 2017, ***Incentivising innovation in antibiotic drug discovery and development: progress, challenges and next steps, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5746591/***

Scientific and clinical advancements in antibiotic development are inherently challenging, particularly relative to other therapeutic fields. Many large capital companies have exited the antibiotic space in favour of more profitable therapeutic ventures. Small- and medium-sized enterprises (SMEs) have attempted to fill this void but generally lack the capital and resources to undertake intensive and long-term research and development (R&D).9, 10 Consequently, the low hanging fruit of antibiotic development, such as compound redevelopments and combinations, has been tapped. This leaves behind the complex and expensive task of discovering and developing truly novel mechanisms of action that are effective against the most resistant pathogens.11 Some companies are choosing to focus development efforts on alternatives to antibiotics such as antibodies, probiotics, lysins and bacteriophages. During the past decade, over 50 major international and national initiatives aimed at incentivising antibiotic R&D have been implemented such as the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR), the Innovative Medicines Initiative's (IMI's) New Drugs for Bad Bugs (ND4BB) programme, Biomedical Advanced Research and Development Authority's (BARDA) Broad Spectrum Antimicrobials Program and Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X).8 Political momentum for combatting AMR continues to build. Coming out of the 2016 G20 Meeting and the United Nations General Assembly's High-Level Meeting on AMR, political leaders have committed to continued actions that foster antibiotic R&D.12, 13 In March 2017, the UN announced the establishment of an Inter-Agency Coordination Group on AMR to provide practical guidance to ensure sustainable, effective global action to address AMR with a mandate to report back on progress to the United Nations General Assembly 73rd session running from September 2018 to September 2019.14 It remains unclear, however, how to most effectively capitalise on the existing R&D incentive programmes.

Chris Dall [CIDRAP], 7-28-2016, ***Public-private partnership aims to spur new antibiotics, http://www.cidrap.umn.edu/news-perspective/2016/07/public-private-partnership-aims-spur-new-antibiotics***

In an acknowledgment that the world is in serious need of new antibiotics to fight increasingly drug resistant bacteria, US and UK officials have announced a new, multimillion-dollar effort to boost antibiotic research and development. The public-private partnership, called the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), will provide $44 million this year and as much as $350 million over the next 5 years to restock the R&D pipeline and get new antibiotics from labs into human clinical testing. The partners include the US Department of Health and Human Services (HHS), the Wellcome Trust of London, the newly founded AMR Centre in England, and Boston University School of Law. With antibiotic resistance increasing, the need for new antibiotics is growing more urgent. According to the Pew Charitable Trusts, nearly all antibiotics brought to the market over the past 30 years have been

variations on existing drugs. No new types of antibiotics have been discovered since 1984. While 37 new antibiotics are currently in development, Pew estimates that more than half of them won't be approved by the Food and Drug Administration.

A2 Impact - Orphan drugs

1. Delink - Public funding already exists. Vazquez in 2008 explains that the main incentive for orphan drug R and D are public programs, federal regulation, and policies that support them such as FDA fee waivers, tax incentives, and orphan drug market exclusivity. For instance, orphan drugs get a 50% tax credit for costs incurred during the drug production process. As a result, these drugs will continue to be produced regardless of external investment spending.
2. Turn - Incentivizing orphan drug production actually hurts the people who were supposed to be benefited. Gusovsky of Lin explains in 2015 that the orphan drug act has lead to companies gaming the system to use the law for mainstream drugs. For instance, Rituxan, made to treat a type of lymphoma orphan disease is now the 12th most popular drug in the US thanks to alternative uses. Thus, patients with rare cancers and other diseases may suffer due to dilution of the tax incentives and other benefits offered by the rule to spur the development of niche drugs.
3. Turn - encouraging orphan drug research is unethical when it trades off with drugs with a wider potential range of people it can benefit. The Journal of Medical Ethics explains in 2005 that when evaluating the situation from the greatest good for the greatest number of people perspective, orphan drugs don’t stack up. Orphan drug development is extremely uncertain in terms of success and very few people have the condition. Very few resources would have to be allocated to their particular disease to maximize society’s utility.

C A, xx-xx-xxxx, "Ethical issues in funding orphan drug research and development," Journal of Medical Ethics, https://jme.bmj.com/content/31/3/164

Maximising principles require that health care be distributed so as to achieve maximum benefit. Need principles require distribution of resources in proportion to need. Egalitarian principles require resources to be distributed so as to reduce inequality.16 Need is usually understood as capacity to benefit from treatment or in terms of severity of disease.14 This definition of need is difficult to apply to orphan diseases, as capacity to benefit is usually understood to be limited to existing treatments in order to become operational.

According to the second definition individuals with orphan diseases have a need, but since their condition is infrequent, no or very few resources would be allocated to their particular disease for the goal of maximising society’s utility. However, all individuals with orphan diseases taken together represent a substantial number of people. In the EU, an estimated 25–30 million people are affected by one of around 6000 orphan diseases.6 Two separate questions arise:

What level of resources should be devoted to orphan disease research overall?

What level of resources should be allocated to each individual disease?

Another problem with resource allocation for research purposes is the extreme uncertainty of

benefits. In economic evaluation, uncertainty of costs and benefits can be taken into account in a sensitivity analysis. But the future success of research for a particular orphan drug is too uncertain to allow meaningful estimates. This is demonstrated by the fact that on average only one in 10 pharmaceutical compounds developed is successfully marketed, which means that predictions of future benefits were misguided in 90% of cases although substantial amounts of resources are invested for research and development for each new chemical entity. Cost estimates for developing a new drug vary widely. Using confidential industry data of multinational pharmaceutical companies, DiMasi et al estimated the cost of developing a new drug at US$231 million in 1991.17 Subsequent authors who used the same data but changed some assumptions estimated the cost of developing a new drug at US$473 million in 2000.3 More recent, independent estimates for cash outlays including smaller pharmaceutical companies and excluding opportunity costs for developing a new drug are in the order of US$76–115 million including the cost of failure.18 This corresponds to estimates for the minimum size of a potential market of US$100 million for an orphan drug to attract industrial interest.7

Enrique Seoane-Vazquez,1,2, xx-xx-xxxx, "Incentives for orphan drug research and development in the United States," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2631478/

Public programs, federal regulations, and policies support orphan drugs R&D. Grants, research design support, FDA fee waivers, tax incentives, and orphan drug market exclusivity are the main incentives for orphan drug R&D. Although the 7-year orphan drug market exclusivity provision had a positive yet relatively modest overall effect on effective patent and market exclusivity life, economic incentives and public support mechanisms provide a platform for continued orphan drug development for a highly specialized market.

Through the ODA, several economic incentives were created to stimulate orphan drug development and marketing. First, was the availability of grants, of which approximately 12 – 15 grants are awarded annually to academic-based researchers or to companies [8]. Second, was the establishment of a 50% tax credit for expenditures incurred during the clinical testing phase for orphan drugs being evaluated for their therapeutic potential. Congress made the tax credit permanent from May 31, 1997. The tax provisions also have a 20-year carry forward and a 1-year fall back provision. Third, was the 7-year market exclusivity provision granted for FDA-designated orphan drug indications [8]. The ODAs 7-year market exclusivity is a post-approval incentive that begins on the date of FDA approval for the designated orphan indication. This incentive addressed the limited opportunities to recover R&D costs for drugs without patent protection. However, exclusivity does not share the same level of protection as a patent [9]. During the orphan market exclusivity period, the FDA cannot approve a NDA (new drug application) or a generic drug application for the same product and for the same rare disease indication. The FDA could approve a second application for the same drug for a different disease indication.

Jimmy Lin, xx-xx-xxxx, "How a blockbuster drug can become a subsidized 'orphan'," Dr. Jimmy Lin, https://drjimmylin.com/presscov/2017/7/12/how-a-blockbuster-drug-can-become-a-subsidized-orphan

The 41 percent of all FDA approvals for new drugs in 2014 that were designated orphan drugs

compares to six orphan drug approvals of a total 30 new drugs approved by the FDA in 1985 (two years after the Orphan Drug Act, also known as the ODA, was passed). "The loophole means more monopoly power for pharma companies selling common drugs that were snuck through the FDA as orphan drugs," Dr. Marty Makary of Johns Hopkins, the lead researcher and senior author of the study, told CNBC. The new study, published in the American Journal of Clinical Oncology,argues that while the ODA has fostered drug development for patients with rare cancers and other diseases, current data suggest that companies are "gaming the system to use the law for mainstream drugs." For example, Rituxan (rituximab), which is made by Roche and was initially FDA approved for use in the treatment of follicular non-Hodgkin's lymphoma, is the No. 1 selling medication approved as an orphan drug. "It is currently used to treat a wide variety of conditions, ranks as the 12th all-time bestselling medication in the United States, and generated over $3.7 billion in U.S. sales in 2014," the report states. The researchers' concern is not only the "corporate welfare" that is being afforded to blockbuster drugs and highly profitable drug companies, but that "patients with rare cancers and other diseases may suffer due to dilution of the tax incentives and other benefits" offered by the rule to spur the development of niche drugs.