# NC\_UT

## NC\_Longhorns [Stock NC]

### Our first argument is gutting innovation.

Currently, billions of dollars of investment fuel the pharma industry in innovating meaningful drugs. [**Stone of The University of Minnesota**](https://www.thebalance.com/who-funds-biomedical-research-2663193) finds that the United States private sector is the largest contributor to innovation accounting for 60% of all investments. However, in recent years, the industry has shifted away from big corporations towards small and efficient businesses. Indeed, [**Buvailo of BioTrend**](https://www.biopharmatrend.com/post/30-pharma-rd-outsourcing-is-on-the-rise/)finds that drug companies are increasingly handing down their research and development to smaller companies in order to speed up the development process. These smaller companies are more successful than larger ones as they are able to concentrate all their time and energy into innovating new medicine. [**Alsever of Fortune Magazine**](https://www.google.com/url?q=http://fortune.com/2016/05/13/big-pharma-biotech-startups/&sa=D&ust=1542410505985000&usg=AFQjCNHAYTjL4wVohQxLnzYu-E5I220BYg) notes that 64% of new medication originates from small startups, and they “increasingly generate the lion’s share of innovative drugs.” This innovation has been extremely successful. For example, [**Easton of Stat-News**](https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/) finds that Cardiovascular mortality in the U.S. has declined over 50 percent, and other diseases such as HIV and Hepatitis C are now curable. Globally**,** [**Wu of the IFW**](https://itif.org/publications/2017/05/30/pharmaceutical-innovation-accounted-73-percent-increase-life-expectancy-30) finds that American pharmaceutical innovation accounted for 73 percent of the increase in life expectancy in developing nations. Overall, [**Easton**](https://www.google.com/url?q=https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/&sa=D&ust=1542410505976000&usg=AFQjCNGOnvgBMQIjaHwqXf4MreeMu83tPg) furthers that America is the global leader in drug innovation, and our lead has only widened as other countries imposed price controls on their own industries.

Unfortunately, implementing price controls significantly diminishes pharmaceutical profits and in turn the amount of money they invest in research. [**Sood of Stanford University**](https://www.google.com/url?q=https://www.healthaffairs.org/doi/full/10.1377/hlthaff.28.1.w125%23R20&sa=D&ust=1542410505989000&usg=AFQjCNF0yXW9DCT6wGnfP1inh69TCVqnfA) finds imposing price regulations onto the American free market would decrease pharmaceutical revenues by over 20.3%.When company profits are squeezed, research and development is the first to go. [**Francis of the NBER**](https://www.google.com/url?q=https://www.nber.org/digest/may05/w11114.html&sa=D&ust=1542410505984000&usg=AFQjCNHDxz3n--AQwzyowKn_FfOLnv16Uw)writes that cutting United States drug prices by 2% will lead to 3% fewer R and D projects. Crucially, The brunt of these cuts falls on small businesses, as [**Yeoh of the University of Nottingham**](https://l.facebook.com/l.php?u=https%3A%2F%2Fwww.triciayeoh.com%2F2017%2F02%2Ffree-small-businesses-from-price-controls%2F%3Ffbclid%3DIwAR0KbYR8FELV35ZeuYvxJe-U4IwLWH_4Nr6ZZBRzGvIltZmPsHIad5nO2zw&h=AT2mpk4QGQw8lcZGoUQYevdDwkIjCwDzykc_KQIFgdxI7tXw1eKwskPOlFfG_SfKMixZlpL7Qou0Bzs66gXbVARN6rtpyrLr7mhZ1eBRxXUj5VYvVbDAV4M3FP6DsvnCWQNzRQ) confirms that price controls hits these small, innovative, businesses the worst because they don’t have the financial means to adapt as large corporations do.

Historically, [**Vernon of the University of Chicago**](https://www.google.com/url?q=https://sci-hub.tw/https://www.jstor.org/stable/10.1086/426882?seq%3D1%23page_scan_tab_contents&sa=D&ust=1542410505990000&usg=AFQjCNHbCpK48i9kWRiAlJFG_X7eUUxYIg) found that if price controls had been implemented in the 80s, a third of all new drug launches over the next 20 years would’ve never occurred, wiping out an entire generation of cures. For this reason, [**Jena of Harvard University**](https://www.google.com/url?q=https://thehill.com/opinion/healthcare/369727-us-drug-prices-higher-than-in-the-rest-of-the-world-heres-why&sa=D&ust=1542410505977000&usg=AFQjCNGgl286bnA4LfQbu-fFGAUTutIkug) points out that in the long term, price controls would reduce US life expectancy by 0.7 years and raise lifetime medical expenditures per family by $50,000.

### Our Second Argument is Cutting Accessibility

1. **Cutting Accessibility of New Drugs**

Price controls lead companies to release drugs into the market later than usual, as [**Fontes of The University of Barcelona**](https://www.google.com/url?q=https://books.google.com/books?id%3DxX5EAAAAQBAJ%26pg%3DPA86%26dq%3Dprice%2Bcontrols%2Blead%2Bto%2Bdrug%2Bdelay%26hl%3Den%26sa%3DX%26ved%3D0ahUKEwiC_tm9n9LeAhUmUt8KHX6FAYsQ6AEIJzAA%23v%3Donepage%26q%3Dprice%2520controls%2520lead%2520to%2520drug%2520delay%26f%3Dfalse&sa=D&ust=1542410505982000&usg=AFQjCNFxH-fARawXBHuFkxAXlUeS0nlNCg) finds that drug launches are often delayed in countries with price controls imposed. The reason is simple: Price controls are a negotiated price between companies and the government. Sometimes these negotiations take longer, as companies bargain for every possible price increase they can. That is why [**Spiegal of the Hill**](https://thehill.com/blogs/pundits-blog/healthcare/332145-the-tragic-toll-of-drug-price-controls)writes that in Europe, drugs get to the average citizen 3 months slower than it does in the United States. Thus, **Kyle of MIT** explains that the probability of a company releasing new drugs into the US market decreases by 75% with the implementation of price controls.

The impact is preventing premature deaths.. **Daniel Kessler of Stanford University** that delaying a drug’s launch by 5 years decreases life expectancy by 15 weeks per American.

[**Spiegal**](https://thehill.com/blogs/pundits-blog/healthcare/332145-the-tragic-toll-of-drug-price-controls)continues that drug delays in Europe have led to 600,000 premature death every year.

1. **Cutting Access to Generics**

**The FDA** defines generic drugs as drugs that work the same as brand-name drugs, with the same dosage, strength and safety. The importance of generic drugs is that they are more affordable then their counterparts. **Mishori 11** writes that generics are significantly cheaper than brand name drugs for two reasons. First, generic drug manufacturers don’t have to spend any money on inventing the drugs and clinical trials don’t have to be performed as the drug has already been invented. Thus, he concludes that because the cost to produce generic drugs are so cheap, they are significantly cheaper for consumers to purchase. **Woolston** corroborates this, finding that generic drugs cost approximately 30% less than their brand-name counterparts, saving consumers an upwards of 10 billion dollars annually. Additionally, generics are just as effective as brand name drugs. **Huffington Post 15** finds that patients have the same experience taking brand-names versus generics, because they share the same quality and chemical formula.

Unfortunately, voting Aff makes generics harder for patients to acquire. **Sullivan 18** Government price controls on generic drugs limit the manufacturers’ margin to 6%. He furthers thatthese low profit margins make it so companies leave generic market as they want to maximize profits, attain the highest return, and stick to relatively financial stable markets.

**Two impacts:**

**First is affordability**

**Farooq in 2017** writes that during shortages, prices increase by 20% because the demand goes up and the supply goes down.

**Second is mortality**

**Barrett in 2018** finds that during a shortage, mortality increases by 4%, which equates to thousands of death as people don’t have access to cheap medicine.

**Thus we negate.**

## NC\_Longhorns [Cut NC]

### Contention 1 is Accessibility

**There are two reasons why accessibility decreases the aff.**

**First is Delays.**

#### Price controls harm the quality and cost of care

Daniel Kessler,xx-xx-xxxx,accessed 11-16-2018,http://plg-group.com/wp-content/uploads/2014/03/The-effect-of-pharmacetuical-price-controls-on-the-cost-and-.pdf,/ZA

How does government price regulation of pharmaceuticals affect the cost and quality of medical care? In theory, price regulation could improve patient well-being. Lower regulated prices could lead to lower costs per use and therefore greater use, which may in turn lead to higher quality and lower overall costs of care. But regulation may have a number of consequences that mitigate or outweigh this effect: reduced R&D, delays in the launch of new drugs even after they have already been discovered, and distortion of patients’ and physicians’ choices toward compounds with lower therapeutic value. Because the magnitudes of the costs and benefits of price regulation are theoretically indeterminate, its effects have been studied empirically and the subject of considerable debate. In this essay, I review existing empirical research on the effects of price regulation of pharmaceuticals. In summary, empirical research finds that price regulation has adverse effects on the cost and quality of care. The adverse effects of price regulation occur through two channels. First, price regulation depresses firms’ market performance, thereby depressing R&D and the discovery of new drugs. Declines in the number and innovativeness of new drugs, in turn, lead to decreased longevity and higher expenditures on other forms of medical care. Second, price regulation delays drug launches, distorts consumers’ choices toward less innovative drugs, and in some cases actually leads to increases in prices. These effects lead to decreased longevity as well.

**Generics are much cheaper than brand-names. Mishori 11:**

Ranit Mishori,7-11-2011,accessed 11-8-2018,https://www.washingtonpost.com/national/health-science/why-are-generic-drugs-cheaper-than-brand-name-ones/2011/07/05/gIQAwZdL9H\_story.html,/ZA

**Generic makers don’t face the same costs as manufacturers of brand-name drugs. That’s because the brand-name maker often invented the drug, a process that can cost hundreds of millions of dollars.** This is the rationale behind drug patents: They give pharmaceutical companies a period of years when only they can make money on a product in which they have made a large investment. That investment also includes advertising: all those TV commercials and billboards at bus stops**. For a generic manufacturer, no such investment is required — not in development and not in marketing. The drug’s formula is known, the clinical trials are complete; the generic maker’s only requirement is to demonstrate to regulators that its version is as good and effective in humans as the original. That is an enormous economic advantage for these companies, which is why their drugs can be much cheaper.**

**Generic drugs save consumers money. Woolston:**

Chris Woolston,xx-xx-xxxx,accessed 11-8-2018,https://consumer.healthday.com/encyclopedia/drug-center-16/misc-drugs-news-218/generic-drug-savings-646392.html,/ZA

Why would you ever take a generic drug when you could stick with a trusted brand name? In a word: price. **Generic drugs** contain the same active ingredients at the same strength and purity as their brand-name counterparts, but they come at a fraction of the cost. According to the Congressional Budget Office, generic drugs **save consumers an estimated $8 billion to $10 billion a year.** How much you save is up to you. If you ask your doctor about generic drugs and shop around for the best price, you could reduce your medical expenses substantially. The difference in the price between generics and brand name drugs varies widely (the retail price can vary even more). **In most cases, generic drugs cost about 30 percent less than brand name versions.**

**Brand names and generics have no difference in quality. Huffington Post 15:**

HuffPost,2-22-2015,accessed 11-8-2018,https://www.huffingtonpost.com/2015/02/22/generic-prescriptions\_n\_6730194.html,/ZA

“**Most people taking** almost all **drugs would not notice a** **perceptible difference in efficacy or safety** when switching **between brands and generics** or between generics, except in the case of NTIs, which are trickier. If you are on a NTI drug, talk with your doctors about the risks and rewards of switching. For all the other drugs, if you switch and you have mild symptoms, there is a chance that those things will resolve and you should stay the course. If it’s more than a mild inconvenience, then you need to let your doctor know right away.”

**Generic drug shortages are costly, but fortunately can be solved by eliminating price controls. Sullivan 18:**

Thomas Sullivan; Medicine,5-6-2018,accessed 11-8-2018,https://www.policymed.com/2012/03/increasing-generic-drug-shortages-linked-to-government-price-controls.html,/ZA

As we previously noted, the Food and Drug Administration (FDA) recently released guidance to industry regarding the reporting of drug shortages to the agency. There has been significant attention lately regarding drug shortages, especially in light of major shortages for two critical cancer drugs. Methotrexate is the essential treatment for one of the most common forms of pediatric leukemia, while Doxil is used to treat ovarian cancer and AIDS-related sarcoma. A recent article from the Wall Street Journal explained that, “The shortages occurred when Benvenue, one of only four domestic suppliers, closed its plant because it could no longer guarantee product safety.” Unfortunately, as the author noted, “These shortages were not rare episodes. Last year, a record of 267 drug shortages were reported, up from 58 in 2004. Even more tragically, most 2011 shortages remain unresolved.” The article explained some of the causes of these shortages. First, the number of suppliers of generic drugs has dwindled. There were 26 U.S. vaccine makers in 1967; today there are only six. Supply disruptions are common, including the possibility that a facility completely shuts down for a protracted time because of quality or safety problems. Second, unlike in most consumer-goods industries, many pharmaceutical manufacturers have failed to invest in the technology and quality-control improvements that would reduce the risks of partial or complete facility shutdowns—and this despite the FDA’s regularly issued current guidelines for good manufacturing practices (cGMPs). Behind both problems [shortages] are the government’s tight price controls for generic drugs, especially when purchased by Medicare and Medicaid. Low prices induce drug makers to exit various markets, or at least to reallocate their manufacturing capacity toward more profitable, patented pharmaceuticals. Low prices also tend to eliminate the rationale for investments in better manufacturing technologies and processes, as shown in a 2009 study conducted by the author and published in the Journal of Management Science. Government price controls on generic drugs limit the manufacturers’ margin to 6% in many cases. In the case of vaccines, for example, the Centers for Disease Control and Prevention (CDC) pays as little for generics as it can negotiate. This results in an average reduction of 40% off the catalog price that applies to sales in the private sector, according to a 2006 study in the journal Clinical Infectious Diseases. As that study noted, the federal government’s own National Vaccine Advisory Committee identified price controls as the primary reason for the dramatic decline in the number of suppliers. Second, the government’s oversight of manufacturing safety and quality is unnecessarily contributing to shortage problems. The pharmaceutical industry generates many applications for new manufacturing facilities and manufacturing processes within existing facilities. The government has failed to allocate the money to hire enough reviewers to analyze the applications or inspectors to visit the facilities. The backlog of applications for new generic drug facilities and manufacturing processes at the FDA remains a year long, according to the Generic Pharmaceutical Association, and generic drug reviews take 15 months longer on average than evaluations of brand-name products. The generic drug industry, tired of the government’s inability to execute, has proposed providing the agency with $299 million in annual fees through the Generic Drug User Fee Act (GDUFA). Conclusion Consequently, the author argued that one “way to resolve the shortage of critical drugs is to relax or eliminate government price controls, and to increase the FDA’s review and inspection capacities. In the latter case the generic drug industry is willing to foot most or all of the bill.” Unfortunately, the Obama administration has thus far pursued the opposite objective, at least as far as price controls are concerned. Last November, it issued an executive order instructing the FDA to report any violations of price controls to the Justice Department. As a result, he asserted that GDUFA should be approved as part of the upcoming renewal of the Prescription Drug User Fee Act (PDUFA V). This may be one of the few areas in which Congress and the Obama administration could find common ground. The benefits are high in relation to the costs. In the fall of 2004, the nation faced a major shortage of the flu vaccine due to an unexpected closure of Chiron Corp.’s plant in the United Kingdom. The problem caused alarm, and with good reason. Even in a year without a vaccine shortage, no less than 200,000 hospitalizations and approximately 36,000 deaths are directly attributed to influenza or resulting complications. The annual economic burden imposed by influenza alone, according to a study in the journal Vaccine, has been estimated at $87 billion, while the part of the FDA budget paid by the taxpayer, amounts to $3.5 billion. In the years since, the number of drugs with major shortages has more than quadrupled. Fortunately, as the article notes, the cure for this problem is Congress approving GDUFA.

#### Increasing drug shortages significantly increases mortality—this is just talking about 1 drug. Barrett 17:

Jennifer Barrett, Pharmacy Times, 4-16-2017 [New Study Highlights Escalated Dangers of Generic Drug Shortages, https://www.pharmacytimes.com/publications/issue/2017/april2017/legislation-targets-prescription-drug-costs-competition-incentives-in-generic-market, 11-16-2018]//DW

**During the 2011 US norepinephrine shortage**, affected **hospitals saw an increase in patient deaths** from septic shock, according to a retrospective cohort study published in the Journal of the American Medical Association. The study included cases from July, 2008 through June, 2013. **During non-shortage periods, the 26 US hospitals saw 35·9% mortality among patients with septic shock, compared with 39·6% during** norepinephrine **shortage periods** (adjusted odds ratio: 1·15; 95% CI: 1·01, 1·30; p=0·03). “The study raises the question if not having the optimal drug for treatment, in this case, norepinephrine, could actually affect clinical outcomes for patients”, commented Deborah A Pasko, Director of Medication Safety and Quality at the American Society of Health System Pharmacists (AHSP, Bethesda, MD, USA). It is unclear whether the unavailability of norepinephrine or the substitution specifically with phenylephrine led to the higher patient mortality, noted study senior author Hannah Wunsch (Department of Critical Care Medicine, Sunnybrook Hospital, Toronto, ON, Canada). Raw material shortages or quality-control issues at generic drug manufacturing plants can yield shortages, though the latter are more frequent, Wunsch told The Lancet Respiratory Medicine. Generic injectables are frequently manufactured at only one location, so manufacturing or quality-control problems that disrupt production can lead to shortages. 2011 saw hundreds of such shortfalls. “Shortages of life-saving medications including critical antibiotics peaked during the study period; however, many medications used in advanced cardiovascular life support protocols are still in episodic periods of shortage”, Pasko said. A 2012 law in response to serious shortages requires manufacturers to notify the US Food and Drug Administration (FDA) of anticipated drug-production disruptions. Shortages have become less common since then but they do continue to occur, according to the FDA. **The study findings are “sobering, as a nearly 4% increase in mortality in a disease that kills hundreds of thousands of people a year in the US equates to thousands of additional deaths annually**”, said Craig Coopersmith (Emory University, Atlanta, GA, USA). “While it is unclear if the shortage of norepinephrine did, in fact, play a role in the observed increase in mortality, the possibility that lack of access to the vasopressor of choice for septic shock could have contributed to patient harm is concerning and will hopefully prompt a concerted effort to find a solution to the common problem of drug shortages”.

#### The DA turns case—prices will only increase during shortages which makes drugs less accessible. Farooq 18:

Iqra Farooq (European Pharmaceutical Review), European Pharmaceutical Review, 09-18-2018 [Drug prices increased twice as fast during shortages, https://www.europeanpharmaceuticalreview.com/news/79261/drug-price-increases/, 11-12-2018]//DW

Researchers from the [University of Pittsburgh](https://www.pitt.edu/) School of Pharmacy, [UPMC Health Plan](https://www.upmchealthplan.com/) and [**Harvard Medical School**](https://hms.harvard.edu/) **identified that prices for drugs under shortage between 2015 and 2016 increased more than twice as fast** than expected in the absence of a shortage. Researchers used the Food and Drug Administration ([FDA](http://www.fda.gov/)) drug shortages database to identify an active shortage of 917 drugs between December 2015 and December 2016. They obtained drug information such as their generic name and National Drug Code numbers. The team went on to use pricing data from [AnalySource](https://www.analysource.com/) to extract monthly wholesale acquisition costs for each drug. After determining the shortage start dates and acquisition costs, drugs without this information were excluded, leaving a total of 617 for investigation by the team. They began in the month that the shortage began, and the 12 months before and after. **In the 11 months after the shortage the expected** [**price increase**](https://www.europeanpharmaceuticalreview.com/news/77305/post-brexit-increased-drug-prices/) **for the drugs was 20 percent**, in comparison to a 9 percent rise in the absence of a shortage. Prescription **drug shortages cause approximately an additional $230 million in costs each year**. This is due to the shortages, and also because of the higher costs of substitution drugs. This substitution of drugs could lead to people taking less effective drugs, delays for patients in treatments vital for their health, or omissions or reductions in doses. Ordinarily, drug companies have increased prices twice a year, once in January and once in the summer, however this has lessened to once a year in recent times due to greater scrutiny. Other drug companies rely on the fact that they are the only manufacturers of a drug, and so increase the price dramatically. First author of the study [Dr Inmaculada Hernandez](http://www.pharmacy.pitt.edu/directory/profile.php?profile=1617) wrote about how these price increases mean an additional $230 million is spent on drugs. The **researchers have speculated that the price increases reflect the behaviour of opportunistic manufacturers during shortages**, thus **leading to an increased willingness to pay when the imbalance between supply and demand persists.**

### Contention 2 is Innovation

#### Biopharma innovation is strong now – but new policies can reverse it. Epstein 17

Epstein 17 (Dewhurst interviewing Epstein, David Epstein, B.S. in pharmacy from Rutgers University and M.B.A. in finance and marketing from the Columbia University, 25 years experience in drug development, currently chairman of Rubius Therapeutics, formerly CEO of Novartis Pharmaceuticals. Martin Dewhurst, senior consultant for Mckinsey, co-convenor for the Pharmaceuticals and Medical Products Practice globally. He advises clients across Europe, Asia and the US, primarily in the pharmaceuticals, healthcare, and consumer goods sectors. “The next horizon of innovation for pharma” http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-next-horizon-of-innovation-for-pharma)//RS

McKinsey: How do you see the pharmaceutical industry evolving? David Epstein: If our job is to help people live longer and better lives, as I believe it is, then we’ve never had a better understanding of biology or better tools to affect it than we do today. I’m excited about the possibility of addressing diseases in a much more targeted way, with fewer unwanted effects, and identifying the patients who are most likely to respond well to a given intervention and who will benefit most. If we can avoid exposing people to side effects when they won’t get benefits from a given treatment, we can take some of the waste out of the healthcare system, not to mention patient discomfort. Studies show the system has enormous inefficiencies at every level, whether it’s in the use of drugs, the way hospitals are run, or how patients go from doctor to doctor. If we can figure out how to customize treatments by selecting the right therapy for individual patients or by combining therapy with digital interventions, there is an opportunity to use the huge amount of money we spend on healthcare more efficiently—and to help make people healthier and happier in the process. McKinsey: Do you think any of that will happen in the next three to five years? David Epstein: I think it’s already starting on a small scale with targeted drug therapies, particularly in cancer and immunology. Take Gleevec and Herceptin: at first, few believed that targeted cancer therapy could have much impact, but after those two medicines came out, R&D dollars [have] shifted to targeted treatments and spawned dozens of medications, some of which are true breakthroughs. The first generation of cellular therapies should come to market as early as the end of 2017. And diagnostic tests are increasing, too, with academic institutions and companies doing whole-genome screening. An opportunity that will take longer to capture is remote monitoring, where patients are cared for in the comfort of their homes rather than in the doctor’s office or at the hospital. That might mean the doctor is seeing the patient via videoconferencing or the patient is wearing a patch to monitor some bodily function in real time. All that will happen, but it will be slow, because the system needs to adapt to address questions such as how you pay for it and how you build the infrastructure to get the quality of data you need. McKinsey: Over the past decade, the excitement about the next horizon of innovation hasn’t been matched by the rate of delivery of new therapies. Why is that? David Epstein: It’s always that way. Take antibodies. In the beginning, there was a lot of excitement about all the new druggable targets we were going to have and how they were going to change everything. Then there were one or two, and then nothing, and everybody thought that was it. The same goes for proteins. How many missteps have there been in gene therapy and cell therapy? It takes perseverance. Most new approaches take more than ten years in our industry. When you see the idea at the beginning, you’re hoping it’s a year or two away, and then it doesn’t arrive. But scientists and companies are continuing to work on it in the meantime, and eventually there it is. If you watched Star Trek as a kid, think how long it took for many of those fictional devices to become real. It took decades after someone first dreamed them up, but now many of them are here in some form or other. McKinsey: What about industry pipelines over the next five years? Do you think they are getting healthier? David Epstein: They are much better in general. There are fewer me-too drugs. The challenge for many companies is that, because their top line hasn’t been growing, they can’t figure out how to fund everything in their early pipeline. That may create opportunities for spinout companies or other mechanisms to address the shortfall. Increasingly more money has gone into venture capital over the past three or four years to capture the opportunity to find new therapeutics in previously dark spaces. In addition, the ability to take these companies public or address the need to supplement pharmaceutical-company pipelines has made the economics attractive. Attracting talent is now sometimes more rate limiting than the discovery and application of new biology and tools. You also have to look at the external environment and think about what could go wrong. We should always worry when there’s political change. For instance, when payors—which is the government in most parts of the world—come under economic pressure, changes in legislation could disrupt the innovation process. If all of a sudden investors had no hope of being able to take their companies public and make a good return, that money would dry up, as would innovation. If pharma companies saw prices fall so far that their margins came under huge pressure, they would cut costs and reduce R&D as well as other spending. Eventually there would be an industry shakeout, and it would correct itself, but you’d have several years or longer where things slowed down or paused, and that’s an ongoing risk. Last but not least, what’s fundamental in our industry is intellectual property [IP]. It comes under attack from time to time. If IP were not to hold, it could change everything and reduce all incentives that spur research and development, and therefore reduce progress. McKinsey: Let’s discuss innovation. Which areas strike you as having the biggest potential? David Epstein: There are many fertile areas as well as new tools to find new targets. I think we are going to see a series of products addressing liver disease, an area where not much has been available. And right now, the industry is spending a lot of energy and time on degenerative diseases of the brain such as Alzheimer’s. The problem is that we still don’t fully understand the biology of how the mind works or degenerates. If we did, we’d have many additional opportunities to create new interventions. And of course, oncology and autoimmune disease offer a rich opportunity. Thankfully, companies are now beginning to reengage in antibacterial research as well. On top of that, I think cellular therapies will allow us to treat genetic diseasessuch as sickle-cell disease, thalassemia, and hematologic cancers. These are all near-term opportunities.

The AFF makes innovation unsustainable for two reasons:

#### First, Cutting budgets

Easton 18 (Robert J Easton, co-chairman of Bionest Partners, “Price controls would stifle innovation in the pharmaceutical industry”, 1-22-2018, https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/)

Consumer access to affordable and effective medicines is an important issue. As the cost of many drugs continues to rise, sometimes astronomically, some have suggested imposing price controls on the U.S. pharmaceutical industry. Doing that risks crippling our only hope of [cures] curing the many serious diseases that still plague us. The global pharmaceutical industry is among the most profitable, driven by its ability to price[s] to value, especially in the United States. High profits attract investors and generate money for research. The global pharmaceutical industry’s investment in research and development is second, barely, to the computer and electronics industry and well beyond that of most other industries. For comparison, the top 10 pharmaceutical companies spend five times more on research and development as a percent of sales than do the top 18 U.S. chemical companies. The pharma industry’s efforts have been quite productive in attacking some of the most vexing problems in medicine**.** Cardiovascular mortality in the U.S. has declined more than 50 percent since the introduction of propranolol, the first beta blocker, in 1964. Many cancers, such as childhood leukemia, have almost been cured. AIDS is now a chronic disease, as the death rate has declined from near 100 percent to near 0 percent. Hepatitis C is now curable. Even metastatic melanoma, formerly a death sentence for 95 percent of its victims, is now curable for many. Lung cancer may be next. All these miracles have been brought through the clinic and into the market by commercial pharmaceutical companies. Yet there remain huge unmet needs for new and better treatments for most cancers; all neurological problems, especially Alzheimer’s disease; most autoimmune diseases; most major gastrointestinal disorders; macular degeneration; and diabetes — not to mention the global scourge of drug-resistant bacterial and viral infections. Advances in these areas will come if money continues flowing to pharmaceutical companies and their primary sources of innovation, biotechnology startups. But if U.S. drug prices come under bureaucratic control, as they have in most of Europe and Japan, it will be a different story. Little pharmaceutical innovation occurs in price-control jurisdictions. The United States has always, by a large margin, led the world as a source of new drugs, and that lead has widened as Japan and Germany have imposed price controls over the past few decades. All major international pharmaceutical companies, without exception, have instituted R&D and commercial operations in the U.S. to take advantage of its pricing environment. If price controls pressure the U.S. industry into a more conventional process industry model, like that of the chemical industry, pharmaceutical R&D budgets would be slashed. To achieve the chemical industry’s rate of R&D spending, as would be required to achieve profitability competitive with the chemical industry, top pharmaceutical companies would have to reduce their R&D budgets by 80 percent — almost $50 billion in total. This reduction in spending would take a few years to realize, but would be completely evident by 2023 or earlier. An important corollary is that, if profitability and value creation opportunities for new drugs declined, the appetite of the venture community for risky, long-term biopharmaceutical investments would shrink exponentially. Price controls on drugs would have the surprising effect of accelerating the flow of investment into high technology, where timelines to market are shorter, less regulated, and less risky. The venture capital community is flush with cash and anxious to invest where high returns can be achieved — ideally within a much shorter time than is typically possible in the realm of drug R&D. As a society, if we force pharma into a chemical industry model, where there is no biotech equivalent and no venture investing, we will be trading better and sooner effective drugs for better and sooner virtual reality devices and self-driving cars. Squeezing pharmaceutical R&D spending down to one-fifth of what it is today would also have an enormous impact on the problems that drug developers often choose to address. Orphan diseases would be deprioritized, as the returns under price controls would not warrant the investment. Complex diseases would also be deselected. While Alzheimer’s disease and diabetes have huge patient populations, the extremely high cost of conducting the difficult research and the need for huge and complex clinical trials would dissuade all but the largest companies from pursuing those illnesses if the potential pricing upside was to be significantly constrained. Moreover, for difficult diseases like schizophrenia, where today’s treatments are mostly inadequate, the flow of more effective new treatments would slow from a trickle to a rivulet, depriving those with these conditions from the possibility of relief. The upshot is simple. Forcing drug prices down would surely shave a few percentage points off what we spend on health care today. By 2032, drug prices could be half of what they are today, as every drug would be a generic. But our ability to treat or cure the many serious diseases that still afflict us will have been crippled and squandered. In my view that is terrible policy.

#### That’s why Abbott 07 concludes that:

Abbott 07 (Thomas A. Abbott, John A. Wernon, 8-1-2007, Managerial and Decisions Economics, The cost of US pharmaceutical price regulation: a financial simulation model of R&D decisions, https://onlinelibrary.wiley.com/doi/pdf/10.1002/mde.1342, accessed 10-23-2018) ED

Previous empirical studies that have examined the links between pharmaceutical price controls, profits, cash flows, and investment in research and development (R&D) have been largely based on retrospective statistical analyses of firm‐ and/or industry‐level data. These studies, which have contributed numerous insights and findings to the literature, relied upon ad hoc reduced‐form model specifications. In the current paper we take a very different approach: a prospective micro‐simulation approach. Using Monte Carlo techniques we model how future price controls in the US will impact early‐stage product development decisions in the pharmaceutical industry. This is done within the context of a net present value (NPV) framework that appropriately reflects the uncertainty associated with R&D project technical success, development costs, and future revenues. Using partial‐information estimators calibrated with the most contemporary clinical and economic data available, we demonstrate how pharmaceutical price controls will significantly diminish the incentives to undertake early‐stage R&D investment. For example, we estimate that cutting prices by 40–50% in the US will lead to between 30 and 60% fewer R&D projects being undertaken (in early‐stage development). Given the recent legislative efforts to control prescription drug prices in the US and the likelihood that price controls will prevail as a result, it is important to better understand the firm response to such a regulatory change. Copyright © 2007 John Wiley & Sons, Ltd.

**Third, current ventures become unprofitable.**

#### The AFF makes innovation unsustainable – current ventures become unprofitable.

Grabowski 17 (Henry Grabowski, Duke professor emeritus of economics, 6-2-2017, "Drug Prices And Medical Innovation: A Response To Yu, Helms, and Bach," Health Affairs, http://healthaffairs.org/blog/2017/06/02/drug-prices-and-medical-innovation-a-response-to-yu-helms-and-bach/)

In a recent Health Affairs Blog post, **Nancy Yu, Zachary Helms, and Peter Bach note that prices for top-selling drugs are higher in the United States than in other countries.** They conclude that “**premium pricing [in the United States] exceeds what is needed to fund global R&D.”** They further suggest that “lowering the magnitude of the US premium” would have saved $40 billion **for US prescription drug[s]** purchasers in 2015. Essentially, the authors imply [The idea] that the US price[s] premium could be significantly reduced without affecting research and development investments or having other adverse effects. This is a strikingly bold and unfounded conclusion. There is no sound economic rationale to suggest that price ratios across countries or revenue premiums in the United States should match current research and development spending. Hence, the fact that price differences and research and development spending levels fail this arbitrary test does not offer a basis for sound policy making. The issue of drug prices is always controversial, but in today’s politically charged environment, it seems particularly important to carefully evaluate this post’s methods and conclusions—and to do so through the lens of the economic principles that drive companies to search for new medicines and set prices for them. Thought leaders and policy makers would be well advised to approach this issue with a clear-eyed view of facts and underlying principles that govern economic behavior. The Authors Have A Fundamental Misunderstanding Of The Research And Development Investment Process The research and development investment process in pharmaceuticals is long, costly, and risky. Only a small proportion of new drug candidates that enter clinical trials (around 10 percent) become new drug introductions. It generally takes more than a decade for the maker of a new drug to perform the costly trials and gain Food and Drug Administration approval, and there is uncertainty concerning a drug’s efficacy and safety at every stage of the process. Economic models of investment behavior under uncertainty indicate that spending will be driven by the expected future gains from these investments. If US policy makers were to enact regulations that drive prices down significantly, as Yu and her colleagues suggest, many projects that now have positive expected returns would no longer be profitable. Current prices would be lower but so would the expected level of future innovation. A recent analysis by Ernst R. Berndt and colleagues published in Health Affairs is instructive in this regard. The authors found that research and development investment in pharmaceuticals generally provides competitive returns historically commensurate with other risky investment activities, but there is high variability across products and over time. They also observed a downward trend in pharmaceutical industry returns for the most recent cohorts, a period when research and development investments have plateaued or even declined for many firms. Another failing of the Yu and colleagues analysis is that they analyze research and development investment in isolation from all other activities and expenses associated with new product development and commercialization. These include the costs of production, management, distribution, and provision of information about clinical trial results to physicians and payers. When these other expenses are included along with research and development costs, taxes, and the need for risk-adjusted returns to investors, as in the Berndt and related studies, there is no “excess premium” beyond what is needed to maintain current research and development investment levels as implied by Yu and her colleagues. Drug Price Determinations In The United States And The Other Benchmark Countries The US Market-Based System Ultimately, market-based drug prices will reflect the value and benefits they provide to patients. Drug manufacturers conduct pharmacoeconomic studies to demonstrate the cost-effectiveness of their new drug introductions. In the United States, insurance companies and other agents that administer private employer plans and government insurance plans such as Medicare Part D evaluate these studies and negotiate prices and access conditions. They use various market-oriented instruments in this process, including formulary placements and copayment tiers, rebates, prior authorizations, and step therapy. In this market setting, a new medicine that solves health problems more effectively, or that solves a problem that previously could not be solved, will tend to command a higher price than its alternatives. This explains why new therapies, such as the recently launched hepatitis C drugs, are able to sell at a high price. The new hepatitis C drugs offer something important and valuable that existing therapies simply did not offer. The sellers of these drugs did not charge high prices because they had spent a lot on research and development; they were able to set high prices because the products generated remarkable new value to patients (and to the health care systems that would be less likely to have to pay for higher-cost medical interventions in the future). It is important, but often ignored, that there were multiple contestants in the race to bring these new drugs to market. As succeeding companies have introduced competing hepatitis C drugs, prices have fallen because customers have alternatives to which they can turn if the sellers do not negotiate lower prices (typically in the form of discounts and rebates). The incentives of market-based prices drive invention, which in turn drives prices down. In the case of the first hepatitis C drug, Sovaldi, for example, average rebates to Medicaid and the Department of Veterans Affairs, which receive best-price discounts, resulted in price reductions of more than 50 percent when competitive therapies entered the market. Monopoly Buyers Abroad Regulators abroad also evaluate pharmacoeconomic studies in negotiating prices. However, they are essentially negotiating as monopoly buyers in most instances. Their governments impose various additional mandatory regulatory measures such as price and quantity controls, international reference pricing schemes, and expenditure caps that do not exist in market settings. As with all buyers, the objective generally of national purchasers abroad is to obtain new drug products as close as they can to the seller’s reservation price or marginal cost of supply, to minimize expected drug expenditures. The difference is that, when the negotiating regulator is the only customer, the ability of the seller to bargain or walk away is severely diminished because some returns are better than none. Refusing to sell medicines that stand to benefit patients in a country also presents reputational challenges for a company. For these reasons, regulators in other countries are able to employ mandatory constraints and controls that extract much lower prices than might be available in market settings. However, if all countries, including the United States, behaved in this manner, manufacturers would be unable to cover the high fixed costs of research and development investment and earn a return to sustain future innovation. This is the sense in which price premiums in the United States provide most of the returns to sustain future innovation. Correspondingly, US policy measures to lower prices toward these international values would adversely affect current research and development commitments, in contradiction to the conclusions of Yu and her colleagues.

#### This is empirically proven in the US – even the threat of price controls under Clinton destroyed innovation. Vernon’09

Golec, J., Hegde, S., & Vernon, J. A. (2009). Pharmaceutical R&D Spending and Threats of Price Regulation. Journal of Financial and Quantitative Analysis, 45(01), 239. doi:10.1017/s0022109009990512

Recent **research shows that R&D spending creates R&D assets that investors impound into stock prices.** This study considers whether **[even] a**n increased **likelihood of price regulation reduced R&D asset values** (and stock prices), **leading to reduced R&D spending**. We use **the** **Clinton administration’s** **Health Security Act** (**HSA**) as a natural experiment to test this proposition and **show** that pharmaceutical **firms cut their R&D spending by about $1 billion** (in 2004 dollars) in response to the HSA price controls. **The HSA’s main provision was a cap on new drug prices.** As a way to limit political support for the HSA, the major pharmaceutical firms agreed to keep drug price inflation low. Indeed, we show that real drug price inflation fell sharply in 1993 and remained relatively low afterward. We also find evidence of negative changes in firms’ drug research pipelines in the years 1993–1995. Conversely, the number of new marketing campaigns and drug patent filings rose sharply in those years. Events leading up to the formal presentation of the HSA to Congress in late 1993 could be traced as far back as the Democratic primaries in early 1992. We show that pharmaceutical company stocks sustained significant price declines from then until late 1993. **The average firm experienced a −38% return during the period** (−62% risk-adjusted), while the market index earned 18%. But relatively R&D-intensive firms suffered much larger losses on average. After the HSA was defeated in Congress, the industry as a whole rallied for a few months, but soon after, the R&D-intensive firms again suffered large stock price losses. Only brand name firms enjoyed risk-adjusted gains, perhaps because brand name capital became more valuable compared to R&D capital.

#### The impact is combatting Antimicrobial resistance.

#### Antimicrobial resistance, or AMR, has become a problem because of the lack of global innovation in antibiotics

Eric **Utt et al 16** (Eric Utt, Charles Wells, 11-2016, Pharmaceuticals Policy and Law, The global response to the threat of antimicrobial resistance and the important role of vaccines, <https://www.ifpma.org/wp-content/uploads/2016/11/The-Globalisation-of-the-Pharmaceutical-Industry-Monograph.pdf> CC

**AMR develops when a microorganism** (**bacteria, virus, parasite and fungus**) **no longer responds to a drug to which it was originally sensitive. Drugs for treating infections lose their effect because the microbes change; either they mutate or acquire genetic information from other microbes to develop resistance**. **The phenomenon is accelerated by use**, **and** especially **misuse**, **of antimicrobial medicines** whereby resistant strains survive and aggregate. The problem can be further amplified when antimicrobial agents of substandard or falsified quality are procured and used by patients [4]. The situation translates into standard treatments no longer working – infections are harder or impossible to control; the risk of the spread of infection to others is increased; illness and hospital stays are prolonged, with huge added economic and social costs [5]. By extension, the risk of death is greater – in some cases twice that of patients who have infections caused by non-resistant bacteria [6]. **To make matters worse, the research and successful development of new antibiotics, especially those with novel mechanisms of action vital to combat resistance, has slowed dramatically since the 1980s** [7,8]. For example, the number of antimicrobial agents approved by the FDA steadily dropped from 16 for the period 1983– 1987 down to three for the period 2008–2012. Though the number of approvals has increased somewhat since 2012, most of all antibiotics approved for use in patients today are derived from a limited number of types, or classes, of antibiotics that were discovered by the mid-1980s [9]. **The lack of development** **of new classes of antibiotics** **is** even more **concerning** than the decline of drug approvals **because resistance to one antibiotic** often **leads to resistance to multiple antibiotics** within the same class. Many factors have contributed to this decline, but it is primarily economic factors and regulatory constraints, including the rethinking of statistical principles of non-inferiority trial designs in the 1990s, which disproportionately has affected trials for antibacterial development [10].

#### Critically, Price controls are the root cause – the US is key to maintaining development.

**Franco et al 09** (Beatriz Franco, Martha Sanchez-Rodriguez, 04-2009, ResearchGate, (PDF) The determinants of the antibiotic resistance process, https://www.researchgate.net/publication/51240047\_The\_determinants\_of\_the\_antibiotic\_resistance\_process, accessed 10-28-2018) CC

During the past 20 years, approval of new antibiotics has decreased. Some 50 antibiotics have been developed, and large pharmaceutical companies have provided everimproved new generations of antibiotics. At the same time, the importance of infectious diseases in public health has decreased, and pharmaceutical research has focused increasingly on treatments for chronic diseases.5,32 The fundamental predicament is that antibiotics are a nonrenewable source, because the length of time they are benefi cial and available appears to have a biological limit, something which is not the case with other treatments. Few antibiotics and/or antifungals are currently being developed, in comparison with investment in research and development of antivirals.6 **The main reason that the [global] industry has moved away from antibiotic research and development is** that the investment can no longer be recovered rapidly, partly **because of increased** regulatory conditions **and strict price controls imposed by many governments**.17,20,33 The useful lifetime of current and future antibiotics could depend on the speed with which resistance develops, which in turn depends on the usage model, not only in humans but also in agriculture and horticulture.34 Recent worldwide development of methicillin-resistant Staphylococcus aureus (MRSA) in the community has stimulated the development of new antibiotics. The new developments of antibiotic are summarized in Table 1 as well as the new agent brand names and active principle, antibiotic class, antimicrobial activity, country, and date of approval. Resistance to teicoplanin (Targocid®), a fi rst-generation glycopeptide, has emerged because of its similarity to other glycopeptides, which has motivated research aimed at developing new antibiotics.35,36 Streptogramins are a combination of quinupristin and dalfopristin (Synercid®). An oral streptogramin, pristinamycin in combination with doxycycline, is used in Europe to treat MRSA infections but is not available in the US.33,35,37,38 Second-generation glycopeptides are dalbavancin, telavancin, and oritavancin. The use of these drugs should be limited to treatment of Gram-positive multidrugresistant bacterial infections.33,35,38–40 Telavancin was superior to standard therapy for microbiologic eradication in patients with S. aureus infection (92% versus 78%) and in patients with MRSA. Currently, telavancin is under investigation (phase II).41

#### Keeping innovation alive and stopping AMR is critical – millions will die if we don’t.

Eric **Utt et al 16** (Eric Utt, Charles Wells, 11-2016, Pharmaceuticals Policy and Law, The global response to the threat of antimicrobial resistance and the important role of vaccines, <https://www.ifpma.org/wp-content/uploads/2016/11/The-Globalisation-of-the-Pharmaceutical-Industry-Monograph.pdf> CC

**AMR represent a major threat to global health security with** the potential to have **devastating effects** on global economic development. If current trends in AMR continue unchecked**, upwards of 10 million lives per year and trillions of dollars of losses to the global economy could occur annually by 2050**. Surveillance that generates reliable data is the essential basis of sound global strategies and public health actions to contain AMR, and is urgently needed around the world. Furthermore, **the supply of new anti-microbial agents is insufficient to keep up with the increase in drug resistance** as older agents are used more widely and non-judiciously and microbes further evolve to resist them. As no truly new class of antibiotics has been developed for decades, new drugs to replace the ones that are not working anymore because of resistance are urgently needed. Stewardship programs to avoid non-evidence based use of antibiotics and to promote appropriate dosing are key to preventing further emergence of antibiotic resistance and poor outcomes for patients. **Countries must review carefully how they buy and price antibiotics, to reward innovative new drugs** without encouraging unnecessary use of new antibiotics.

## NC\_Dev World

**We Negate.**

#### Our Sole Contention is preserving global medical stability.

**Robert Atkinson of The Hill writes in 2018 that** the United States leads the world in global pharmaceutical innovation, but price controls can destroy the industry through cutting revenues. The US industry invests more than 21% of its revenues into R&D, about $56 Billion Dollars. He finds that there is a one-to-one correlation between revenue and the amount of RND that takes place. He concludes that because research in the US spills over into the global arena, the United States accounts for 76% of global pharma innovation. Unfortunately, price controls have historically cdout revenues and they would do the same in the US. **Neeraj Sood of Health Affairs finds in 2008 that** price controls would drastically cut revenues by about 20%, with the harms magnifying over time. [**Wu of the IFW**](https://itif.org/publications/2017/05/30/pharmaceutical-innovation-accounted-73-percent-increase-life-expectancy-30) finds that American pharmaceutical innovation accounted for 73 percent of the increase in life expectancy in developing nations..

#### Decreasing revenues in the US is critical to avoid because it would harm Global Healthcare in Three ways.

#### First, A Decline in Research.

**Suzanne Wolf, citing an index of global pharma innovation, reports in 2014 that** the focus of innovative research has recently shifted to diseases that affect the developing world. She explains that 36% of the development pipeline is dedicated to what are called neglected diseases, which have the biggest impact in developing countries. **Unfortunately, John Tierney of City Journal finds in 2018 that** through cutting revenues, price controls in the US would cut the number of new R&D projects by 60%. He concludes that the US and the rest of the world would pay dearly for the policy. **Heather Hansman of The Smithsonian explains in 2015 that** preserving US research and in turn global research is critical. She finds that innovation will save about 10 million lives every year by 2035.

#### Second, A Decline in Global Access to Medicine.

**Stuart Schweitzer from Health Affairs writes in 2011 that** currently**,** global pharmaceutical prices are much lower than those in the US. On average, in developing countries prices are 20% of those in the US. **But, the Physicians for a National Health Program finds in 2017 that** Price Control policies could lower drug prices by as much as 50%. Unfortunately, global medicine prices are zero-sum, which means that benefits to Americans are harms to the developing world. **Michelle Mello, a professor of Law at Stanford, finds in 2018 that** because Americans pay so much for drugs domestically, pharma companies grant price concessions in low-income countries. That’s why she finds that price control policies would restrict access in poorer countries. Because the global market is propped up by high prices in the US, drug prices here and in poor countries are a zero-sum game. Unfortunately, even small price hikes in poor countries can put millions at risk **as the World Health Organization explains that** the majority of people in the world’s poorest countries pay out-of-pocket for drugs. This is very harmful as people are deterred from buying drugs because they can’t pay for even marginally higher priced drugs. And, this causes people to cut spending on their basic needs to pay for more expensive drugs. That’s why they find that over 150 million people experience financial catastrophe because of high healthcare costs, and 100 million of those people are driven into poverty. This is horrible as **Millennial Legacy explains in 2018 that** 18 million people die every year because of poverty.

#### Third, A Decline in Drug Donations.

**Stephen Dubner explains in 2018 that** the Pharmaceutical Industry is the most charitable industry in America. For every dollar they earn, they give a nickel to charity. He explains that roughly 10% of pharmaceutical revenue goes towards donations. And, Drug donations are critical to the healthcare systems of developing countries. The Global Alliance for Patient Access, or GAFPA, explains in 2018 that millions of people in low-income countries around the world rely on drug donations for medicine, and they are critical to global health. Drug Donations make treatment accessible and strengthen health systems. That’s why they conclude that drug donations have a significant impact on patient access of medicine. That means that any cut in revenues is a direct cut to drug donations because the donation budget comes from revenues, which puts the millions who rely on donations at risk.

#### Thus, we are proud to negate.

## NC\_Dev World [Overviews]

Price Controls have zero affect on the majority of Americans because it wont change insurance copays.

The threat of PC from Trump caused a skydive in pharma stocks

<https://thehill.com/blogs/congress-blog/healthcare/418750-think-the-drug-pricing-debate-addresses-patient-costs-think>

Prefer preserving global medicine for two reasons:

1. The Socioeconomic difference ; The WHO 07 evidence is very clear in saying that 150 million people in the developing world go through financial catastrophe due to the high costs of medicine, which is why they rely on international donors for their medicine. This is because there is such a huge income difference. Phelps 13 finds that the median income of the top ten wealthiest countries in the world is 50 TIMES that of the poorest 10 countries.
2. The Insurance difference ; The WHO 07 evidence in case also tells you that 90% of the people in the developing world don’t have insurance to cover medicine costs, whereas CNBC finds that only 10% of Americans don’t have insurance, but even then there are a ton of patient outreach programs that lower costs. It’s A LOT harder to pay for medicine when you have to shoulder literally all of the cost

Phelps 13:

https://news.gallup.com/poll/166211/worldwide-median-household-income-000.aspx

CNBC:

<https://www.cnbc.com/2017/09/12/maps-show-obamacares-big-on-americans-health-insurance-coverage.html>

## NC\_Dev World [Cut NC]

### Contention One is Preserving Global Medical Stability

#### The US leads the world in global biopharma innovation, but price controls can kill it by cutting revenues.

Robert **Atkinson 18** (TheHill, 11-10-2018, The Hill, Drug price controls will be more pain than gain, https://thehill.com/opinion/healthcare/416068-drug-price-controls-will-be-more-pain-than-gain, accessed 11-30-2018) CC

President Donald Trump and House Democrats may not agree on much, but both seem eager to slash the price of prescription drugs. The most recent signal came shortly before the election when the president [hailed](https://www.whitehouse.gov/briefings-statements/remarks-president-trump-prescription-drug-prices/) plans to experiment with a [new way of setting prices](https://www.washingtonpost.com/politics/trump-to-address-drug-prices-in-speech-shifting-focus-to-health-care-before-midterm-elections/2018/10/25/88e16e0a-d84b-11e8-a10f-b51546b10756_story.html?utm_term=.e4bb45739e43) for most drugs administered through Medicare’s Part B program. A few months earlier, Rep. [Nancy Pelosi](https://thehill.com/people/nancy-pelosi) (D-Calif.) reportedly delivered a [blunt warning](https://www.statnews.com/2018/10/30/what-happens-to-pharma-if-democrats-take-the-house/) directly to the bio-pharmaceutical industry’s representatives in Washington that her party is developing an ambitious price-cutting agenda; so watch out in 2019. Given the increasing costs of health care coupled with an aging population and soaring budget deficit, the instinct is understandable. But make no mistake: **Price controls will slow the pace of drug innovation and patients will pay the price for it in the long run.** Developing a new pharmaceutical compound takes an average of 12 to 14 years of research, development and clinical trials at a cost of about [$2.6 billion](https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66adc758d46b001a996d6/1522952924498/pr-coststudy.pdf). That’s why **the U.S. life-sciences sector invests more than 21 percent of its revenues in R&D** — **over $56 billion** in 2014, according to the latest data from the National Science Foundation. **Drug revenues enable that investment.** Indeed, the Organization for Economic Cooperation and Development [has found](http://www.oecd-ilibrary.org/social-issues-migration-health/pharmaceutical-pricing-policies-in-a-global-market/key-characteristics-of-the-pharmaceutical-sector-in-oecd-economies_9789264044159-2-en) **there is** almost **a one-to-one correlation** (0.97) **between drug sales revenues and R&D expenditures** **and economists have repeatedly found the connection extends to pharmaceutical output, too.** The inverse also will be true: **If** bio-pharma companies’ **revenues decline because of price controls** or other policy measures, **their R&D also will decline** and the pace of drug innovation will falter. So, the debate about price controls isn’t really about whether to lower prices at drug companies’ expense. It’s about whether society should lower drug prices now in exchange for less and slower drug innovation for our children. **One aspect of the U.S.** bio-**pharma industry that many** advocates of price controls **overlook is the extent to which the industry contributes to** the **global** “commons” of knowledge **development**. **In their view, drug research only benefits the companies doing the research, so the consequences of any reduction in R&D that may come with price controls aren’t likely to be all that bad. But the evidence shows otherwise.** Even though new discoveries are protected with trade secrets and patents — which provides the incentive for drug companies to assume the risks involved in developing a new drug — a considerable share of bio-**pharma industry research spills over, contributing to** knowledge discovery and **drug development overall**, **not just in the labs of the firms that conduct the research.** In fact, these knowledge spillovers are **very much like public knowledge generated by government agencies such as the National Institutes of Health.**This knowledge dissemination occurs in three main ways. First, many of the benefits of firm-level R&D spill out to the rest of the industry. In fact, economists Nicholas Bloom, Mark Schankerman and John Van Reenen find that spillovers are significantly greater in large bio-pharma firms compared with smaller ones, because the latter “tend to operate in technological ‘niches’” where fewer other firms operate. The industry also supports broader knowledge generation at American universities. While it accounts for 16.8 percent of U.S. business R&D, it accounts for 61 percent of business R&D funding for universities. In 2016 bio-pharma companies provided [over $2.5 billion in life sciences research funding](https://ncsesdata.nsf.gov/herd/2016/html/HERD2016_DST_28.html) to universities in all 50 states, ranging from $366,000 in Maine to $329 million in California.  Finally, **the industry** is a prolific contributor to open science through publications in science journals. In fact, the largest number of partnerships between corporations and academic institutions in [the 2016 Nature Index](https://www.nature.com/articles/d41586-017-07423-1) was in the life sciences — 13,114 collaborations. One reason for this is intellectual property protection. By obtaining patents for their drugs, companies are more assured their discoveries will be protected, thus lowering the risk of direct copying from information being shared in scholarly journals. **The Information Technology and Innovation Foundation**[**examined**](https://itif.org/publications/2018/11/05/how-biopharmaceutical-industry-contributes-open-scientific-knowledge)**the top 93 companies that**, **in 2016**, **accounted for 76 percent of global life science R&D**. In 2017, researchers from these companies were authors or coauthors of 12,792 papers, many in leading journals such as the Proceedings of the National Academy of Sciences, Nature, Cancer Cell and Nature Medicine. That was up from 8,322 papers in 2007 — an increase of 54 percent. This works out to 116 articles for every $1 billion of R&D invested and 8.8 articles per 1,000 employees. To be sure, this is less than the 95,000 peer-reviewed journal articles published by researchers who had received NIH funding. But given that the vast majority of NIH recipients are academic scholars whose bread and butter are peer-reviewed journal articles, it is not surprising this number is as high as it is. What is perhaps more surprising is that the industry numbers are 13.4 percent of NIH’s numbers. Biomedical innovation is critical to addressing human health challenges. And a healthy life-sciences innovation system depends on robust funding of biomedical R&D, both public and private. Not only are drug company revenues strongly correlated with the amount of R&D they invest in, but much of the R&D they fund spills over both to other firms and to the public domain, thereby helping to spur even more life-sciences innovation. **Price controls** and other steps to **reduce revenues**, like **weakening** intellectual property protection, would stifle **knowledge** generation and **sharing**, **leaving future generations less access to effective new drugs than would otherwise be the case.**

#### Empirically, price controls have drastically cut revenues and the impact gets worse over time. The same would happen in the US.

Neeraj **Sood 08** (Neeraj Sood, 12-16-08, Health Affairs, NCBI, http://sci-hub.tw/10.1377/hlthaff.28.1.w125, accessed 11-29-2018) CC

In this paper we analyzed trends in **pharmaceutical regulation** and their impact on revenues. Several important patterns emerge from our analysis. First, we found that a majority of **regulations greatly reduce pharmaceutical revenues**, with direct price controls having the biggest impact on revenues. Second, we found that most countries that adopted new regulations already had some regulations in place for controlling costs. We found that such incremental regulation has a smaller impact on further controlling revenues. However, the results also suggest that **introducing new regulations such as price controls in** a largely unregulated market, such as **the U**nited **S**tates, **could greatly reduce pharmaceutical revenues**. For example, if the United States implemented price controls and negotiations similar to those found in other developed countries, then U.S. revenues would fall **by** as much as **20**.3 **percent**. Finally, the results also show that **the impact of regulations on revenues increases over time**. Whether governments should regulate pharmaceutical markets is a contentious and much-debated policy question. **Our results show that introducing price controls and other regulations in largely unregulated markets will greatly reduce costs today. However, it is important to note that revenue reductions will affect future innovation.19 These innovation effects ultimately could hurt consumers.** So the real question is: what is the net impact of regulations on the welfare of current and future generations? Such estimates, beyond the scope of this paper, are discussed in a companion paper.20

#### Decreasing revenues in the US is critical to avoid because it would harm Global Healthcare in Three ways.

#### First, A Decline in Research.

#### The focus of innovative research has shifted to diseases that affect the developing world.

Suzanne **Wolf 14** (Suzanne Wolf, 11-16-2014, Eureka Alert, Pharmaceutical industry improves access to medicine for the poor, but progress uneven, https://www.eurekalert.org/pub\_releases/2014-11/atmf-pii111714.php?fbclid=IwAR0g8QaAXnW3jrQ5wS-dylzhpf0aI6tGL6zbQJ10pHNgSfWAmEWctIE1yiA, accessed 11-29-2018) CC

Amsterdam, the Netherlands: **The world's** leading **pharmaceutical companies are doing more to improve access to medicine in developing countries**, **with** a raft of new initiatives, scale-ups and **innovations over the last** two **years**. However, **the industry** struggles to perform well in some practices that matter, according to the 2014 Access to Medicine Index, published Monday. GSK tops the Index for the fourth time. This is driven by robust performance across most areas, with several innovative practices. It **has an innovative business model focused on Africa,** a large relevant portfolio**, a large share of its pipeline dedicated to relevant diseases, and numerous access-oriented intellectual property sharing partnerships.** Novo Nordisk has made the most progress, improving in five of the seven areas the Index focuses on. This has resulted in a remarkable leap from 6th to 2nd place, which is partly due to the fact that its access activities are well managed, integrated into its business strategy, and well targeted to local needs. It also applies access-oriented pricing strategies to diabetes products in all Least Developed Countries. Eisai has risen steadily with each Index, and ranks 11th, up four places from 15th in 2012. Sanofi and Pfizer fell down the rankings most significantly, while Astellas, Daiichi Sankyo and Takeda remain at the bottom of the league. "After sharpening what and how we measure, we are now able to draw a much clearer picture of the industry's strengths, weaknesses, progress and struggles, and what it takes to be a leader in access to medicine," said Wim Leereveld, founder and CEO of the Access to Medicine Index. "No company is in the top five in all areas we analyse, but the leaders tend to perform well across most of them, even though they differ in their focus. **Top performers innovate constantly**, and usually have to innovate in several areas to maintain their position." The Access to Medicine Index is an independent initiative that ranks the world's leading pharmaceutical companies according to what they are doing for the millions of people in developing countries who do not have reliable access to safe, effective and affordable medicines and vaccines. It is published every two years. It scores companies on their performance, innovation, transparency and commitments across seven areas of activity considered key to improving access to medicine. The companies are graded on 95 factors covering these areas, including product research and development, to what extent they facilitate or resist efforts to create generic versions of their drugs, and how they approach pricing in developing countries. Lobbying activities, marketing ethics and product donations and other philanthropic activities are also evaluated. "Companies that have the biggest market presence are not necessarily at the top of the Index. We found that four companies currently produce 50 percent of all the relevant products. Sanofi produces the most, followed by Novartis, GSK, then Pfizer. However, they are scattered across the Index," said Jayasree K. Iyer, Head of Research at the Access to Medicine Index. "This means that what defines where companies rank has less to do with how many relevant products they have, than with what they do with their products and expertise. We have found that this, in turn, tends to be closely linked to the importance given to access at the top of the company." Lower respiratory infections, diabetes, cirrhosis of the liver (hepatitis), HIV/AIDS and malaria are getting the most attention from companies overall, while maternal and neonatal health conditions get relatively less attention, Iyer said. She added that **neglected tropical diseases are less neglected than they were two years ago, with a scaling up of** donation programmes and a handful of **new drug development projects**, some in partnership with international organisations. Progress on several fronts **The industry has stepped up its efforts on several fronts.** For instance, **it is paying more attention to socioeconomic factors, such as people's ability to pay, increasingly tailoring prices within countries.** Since 2012, **the number of products in the pipeline appropriate for developing countries has grown by 47.** More companies are experimenting with innovative access-oriented business models; three have introduced new models and three have expanded pilots. **Companies are granting more licences to developing country companies** to make and distribute generic versions of their medicines. Meanwhile, **policies and activities to improve access to medicine continue to get better organised.** All 20 companies now have some form of board-level representation for access-to-medicine issues, and the number of companies linking performance incentives to access to medicine has more than doubled since 2012. Performance weak in two areas. However, progress is uneven across the areas of activity that matter, with the industry struggling to perform well in two important areas. Firstly, nearly all companies (18) have been the subject of settlements or judgements regarding breaches in ethical marketing, bribery or corruption standards or competition laws in the last two years. During the period of analysis there were high-profile allegations of corrupt practices against several companies operating in China. The case against GSK, one of those companies, was settled after the period of analysis, and therefore did not affect its score in the 2014 Index. Breaches captured in this Index range from paying or otherwise inappropriately incentivising doctors to prescribe their products, to collusions delaying market entry of generic medicines and misrepresenting the efficacy and safety of their products or those of their competitors. The Index's analysis reveals there is no direct correlation between a company's size, the breadth of its geographical footprint and its incidence of breaches, which indicates that breaches are not simply a cost of doing business. This evidence raises questions over the commitment and effectiveness of company governance of this area. Secondly, companies remain conservative in their disclosure of where patents are active and when they will expire - information that is very useful to medicine procurers and generics manufacturers. Within the reporting period, no company independently and publicly disclosed patent statuses for products relevant to the Index. Research and development analysis Pharmaceutical company research and development (R&D) is a crucial element of enhancing access to medicine. The 2014 Index reveals how concentrated the relevant R&D is. Just five companies are developing 54% of the 327 products in the pipeline. All disease classes are being targeted, but more than half of the products under development target just five diseases: lower respiratory infections, diabetes, hepatitis, HIV/AIDS and malaria. **About 36% of the pipeline targets** non-communicable **diseases**, which are becoming increasingly **important in developing countries**. Encouragingly, **83% of these have reached the stage of development where they are being tested on people, but plans to make them available are limited.** Pricing strategies for them are also limited, and lag behind those for many communicable diseases. More than half of the companies are developing "child-size" medicines, as liquids, chewable tablets, child-appropriate doses, or new formulations. Research projects include an antifungal drug from Merck & Co. that is undergoing clinical trials to investigate whether it works for Chagas disease, a neglected tropical disease affecting South American countries; and GSK's development of a low-cost inhaler for asthma and COPD drugs for use in developing countries. Since the 2012 Index, **at least 30 products from the pipeline**, for 11 diseases relevant to developing countries, **have come to the market**. These include: A new type of pill for multi-drug resistant tuberculosis that is the first new drug for the disease in 40 years. (Johnson & Johnson) A new once-a-day pill that is a complete HIV treatment. Gilead has issued licences allowing distribution of generic versions of the drug in 100 developing countries. A new child-dose HIV tablet (Johnson & Johnson) and approval for an existing HIV drug to be given to children (Bristol-Myers Squibb). Almost all children with HIV live in sub-Saharan Africa. A ground-breaking pill that can cure hepatitis C, which is a high-burden disease in developing countries. The company has issued licences allowing distribution of generic versions of the drug in more than 91 developing countries. (Gilead) "Our company report cards identify a tailored path for each company to follow in order to maximise its opportunities for improving access to medicine, based on its individual strengths and potential. They all address access issues in different ways, but our analysis shows that all companies can do more. Enhancing access to medicine is not the sole responsibility of the pharmaceutical industry, but it is an important player," Leereveld said.

#### Unfortunately, Price Controls would destroy U.S. innovation, thus creating spillover harms to global innovation

John **Tierney 18** (John Tierney, 11-18-2018, City Journal, What the Prescription Drug Debate Gets Wrong, https://www.city-journal.org/price-controls-on-pharmaceuticals, accessed 11-30-2018) CC

They’d be getting an even worse deal if the United States adopted their pricing policies. As it is, people in Europe and elsewhere enjoy benefits from breakthrough drugs developed in America that eventually make it to patients overseas. But what happens to the Pharmacy of the World if its chief customers stop paying? It’s been [estimated](https://healthpolicy.usc.edu/research/global-burden-of-medical-innovation/) that the **price controls in the U.S. would cut the number of new r**esearch **and** **d**evelopment **projects by 30 percent to 60 percent**. **That would mean fewer new drugs to ward off disability and death**, slowing the increase in longevity, **so that Americans in 2060 would die a half-year sooner than if the price controls had never been adopted. That’s not the kind of life-expectancy gap that gets much attention, but it’s worth keeping in mind the next time someone goes on about the longevity of today’s Swedes and Britons.** If **the U**nited **S**tates followed Europe’s example, Americans could save money in the short term, and they’d have the satisfaction of reducing their national villain’s profits, but **they** **and the rest of the world would pay dearly for it.**

#### Preserving U.S. research, and in turn global research, is critical to saving millions.

Heather **Hansman 15** (Heather Hansman, 7-28-2015, The Smithsonian, A New Report Identifies 30 Technologies That Will Save Lives in the Next 15 Years, https://www.smithsonianmag.com/innovation/new-report-identifies-30-technologies-that-will-save-lives-in-next-15-years-180955927/, accessed 11-29-2018) CC

President Obama wasn't the only head of state visiting Ethiopia this summer. In early July, the United Nations brought global leaders to Addis Ababa, for **the third annual International Conference on Financing for Development. The goal of the meeting was to outline what the UN calls Sustainanble Development Goals—a series of financial, social and technological targets that they want countries in the developing world to hit by 2030.** At the conference, the United States Agency for International Development (USAID), the Government of Norway, the Bill and Melinda Gates Foundation and global health nonprofit [PATH](http://www.path.org/about/) released "[Reimagining Global Health](http://ic2030.org/wp-content/uploads/2015/07/ic2030-report-2015.pdf)," a **report** outlining **30** **innovations that will save lives in the next 15 years**. The team spent a year analyzing current and future technology, by reaching out to all the partners they work with in the world of international health. They received 500 nominations from entrepreneurs, scientists and other experts in nearly 50 countries, which a panel of 60 health experts reviewed and whittled down to a short list of easy-to-use technologies that they felt could reduce child mortality, improve maternal health and reproductive rights, and combat both infectious and noncommunicable diseases.By 2030, USAID, the Gates Foundation and PATH want to reduce the global maternal mortality rate to less than 70 per 100,000 live births; end preventable deaths of newborns and children under five years old; reduce premature mortality from noncommunicable diseases by a third; ensure universal access to sexual and reproductive health care services; end the epidemics of AIDS, TB, malaria and neglected tropical diseases; and combat other infectious diseases. The groups want to consolidate investments from philanthropic organizations like the Gates Foundation and from government groups to go to the most high value projects, so that their products and services are cheap and accessible. “Strengthening the capacity of low- and middle-income countries to identify, develop, adapt, produce, regulate, assess, and share innovations is critical for a robust innovation pipeline,” says Amie Batson, Chief Strategy Officer at PATH said in an email. Making communities healthier also makes them more financially resilient. Former U.S. Treasury Secretary Lawrence Summers, who also contributed to the report, says that by **investing in health technology now**, globally we can save significant money and lives down the road. “**With the right investments,** **we could** reach grand convergence in just one generation, **avert**ing **10 million deaths every year by 2035**. But today’s health tools alone won’t get us there,” says Summers in the report.Here are eight of the 30 new drugs, diagnostics, devices and services poised to help the developing world:Chlorhexidine for Umbilical Cord CareIn the developed world, medical professionals clean babies' umbilical cords shortly after birth. But in the developing world, hundreds of thousands of newborns die each year from infections related to lack of antiseptic at delivery. If $81 million was spent on introducing chlorhexidine in home settings in the developing world in the next 15 years, the authors of the report estimate that more than 1 million neonatal lives could be saved, resulting in a 9 percent reduction in deaths due to sepsis.Uterine Balloon TamponadesOne of the biggest causes of maternal death is postpartum hemorrhage, which can be stopped or slowed by inserting an inflatable tamponade into the uterus. Because of cost and lack of training, the devices haven't been used in the developing world. The report highlights one easy-to-use, low-cost option, called [Every Second Matters for Mothers and Babies](http://www.massgeneral.org/emergencymedicineglobalhealth/initiatives/ESM_Ketamine.aspx). Basically, a condom is attached to a catheter that's inflated with water through a syringe and a one-way valve. By investing $27 million in these devices, the group estimates that 169,000 mothers' lives could be saved in the next decade and a half.Neonatal Resuscitators**.** Low-cost neonatal resuscitators could help the one in 10 babies who have trouble breathing at birth. They've been hard to bring into the developing world, because of cost, so these groups are working to identify and develop cheap, reuseable and easy-to-use options, including ones that health care workers can operate by hand.Antiretrovirals for HIV That Can Be Injected Every Two MonthsHIV is virulent and widespread in sub-Sarahan Africa, so, to try to slow the spread, these groups are looking at long-lasting drugs that could be injected into HIV patients every two months to treat symptoms and slow the virus' progression to AIDS. These options could prove more effective than easily forgotten daily pills.

#### Second, A Decline in Global Access to medicine.

#### Currently, global pharmaceutical prices are much lower than those in the US.

Stuart **Schweitzer 11** (Stuart Schweitzer, 08-2011, Health Affairs, Prices Of Pharmaceuticals In Poor Countries Are Much Lower Than In Wealthy Countries, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0923, accessed 12-3-2018) CC

These benchmark figures can be compared with the price data in our study. [Exhibit 3](https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0923#EX3) shows that **the average prices for patented drugs in developing countries are less than 20 percent of those in the United States**, while **prices in middle-income countries average 32 percent of US prices.** These **prices are thus below the benchmark estimates of US marginal costs.** Although it is possible that marginal costs of pharmaceutical production are lower in developing or middle-income countries than in the United States, the effect of such reduced costs could not be large because most patented drugs are manufactured in industrialized countries. For these drugs, therefore, **current prices outside the United States are generally lower than marginal costs.** It is more difficult to draw firm conclusions about the fairness of pricing for drugs that are no longer patented ( [Exhibit 3](https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0923#EX3) ). Although for some of these products, prices in developing countries approach marginal costs, that is not always the case. **For essential drugs**, however, **it is clear that prices are not higher than marginal costs.** There is little indication, therefore, that average drug prices in developing and middle-income countries exceed the standard set by marginal costs. [Exhibit 3](https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0923#EX3) also shows **the large average price difference between the U**nited **S**tates **and the other industrialized countries** combined. The latter **countries receive discounts from US prices** that are similar to those found in middle-income countries. In other words, the price discounts received in many middle-income countries are comparable to those received in industrialized countries apart from the United States. It should be noted that US prices in [Exhibit 3](https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0923#EX3) are overstated because, as mentioned above, the data from IMS Health do not include manufacturers’ discounts and rebates, which are quite common in the United States. Two estimates of the extent of this overstatement are available. Patricia Danzon and Michael Furukawa report that the average US price discount is about 8 percent of the “cash” price. [25](https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0923#B25) And calculations based on data collected by Families USA indicate an average discount of about 47 percent from the nondiscounted levels. [26](https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0923#B26) Although we have made no effort to reconcile these very different estimates, we believe that the correct value probably falls between the two.

#### But, Price Control policies can heavily reduce domestic prices. PHNHP 17:

Physicians for a National Health Program, 2017, Estimated Effects of Proposed Reforms on US National Pharmaceutical Expenditures, 2017, [Accessed 11-01-2018, http://www.pnhp.org/sites/default/files/Pharma\_Table7.pdf]//DW+ASJ

Finally, our estimate is supported by the lower prices paid by the US Veterans Health Administration (VA), which **negotiates for drug prices** and maintains a formulary. A dated estimate from the Congressional Budget Office puts prices paid by the VA for branded drugs at 42% of the average wholesale price.53 Frakt et al., drawing on four studies, assert that the VA obtains drug prices approximately 60% of those paid by Medicare.54 Together, these estimates accord with our estimate of an approximately 50% reduction in drug prices through negotiations and a formulary. It seems likely that the prices paid by these programs would also be reduced, albeit to a lesser extent. **We apply the estimated 17% increase in drug spending from eliminating cost-sharing to our estimate of total drug spending after adjustment for a 50% reduction** in brand-name drug prices for non-discounted payers (i.e. total current estimated 2017 drug spending of **$500.1 billion minus [there would be] estimated savings of $154.6 billion**). Since this includes spending on inpatient drugs (the utilization of which would likely be less affected by the elimination of cost-sharing), our spending estimate likely overstates the cost of eliminating cost-sharing.

#### Unfortunately, global medicine prices are zero-sum – benefits to Americans are harms to the developing world.

Michelle **Mello 18**, June 2018, Professor of Law, Stanford Law School, and Professor of Health Research and Policy, Department of Health Research and Policy, Stanford University School of Medicine; Ph.D., University of North Carolina at Chapel Hill; J.D., Yale Law School; M.Phil., University of Oxford; A.B., Stanford University., Minnesota Law Review, ARTICLE: What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?, <http://www.minnesotalawreview.org/wp-content/uploads/2018/07/Mello_MLR.pdf> CC

Another perplexing **moral problem** is that **tradeoffs** may **exist between improving the affordability of prescription drugs for Americans and** **maintaining their** **affordability to patients in other countries**. [[1]](#footnote-1)53 Branded drug **prices in the U**nited **S**tates **are** generally **higher** than in other countries **because most foreign governments have adopted stronger mechanisms than the United States for controlling prices - for example, more consolidated price negotiations or direct price controls.** [[2]](#footnote-2)54 **Because we pay so much**, **pharma**ceutical **companies** may be more willing or able to **grant price concessions elsewhere, including outright donation of critical medications** **to low-income countries**. **Actions** we take **to restrict price**, therefore, **could** have unintended, but real, **effect**s on **drug affordability in less wealthy countries**. **This prospect raises the question of what obligations, if any, Americans have to patients in the rest of the world.** Some **conceptions of global justice hold that members of relatively wealthy societies have a moral obligation to consider the welfare of individuals in poorer countries in making policy decisions.**55 Other views challenge the notion that such duties exist.56 Some even assert that the status quo is unfair: Americans not only pay more for marketed drugs, they shoulder a disproportionate share of the cost of developing those drugs.57 Pharmaceutical R&D is underwritten both by the high prices Americans pay for medicines and the tax dollars we spend on basic-science research to identify promising new molecules.58 Americans have not openly confronted these clashing viewpoints as a policy, but **strong measures to reduce the cost of prescription drugs here would make the global-justice dilemma hard to ignore.** Further, as with the other moral dilemmas discussed above**, the problem has greater salience in the context of prescription drugs** than in other areas of health policy. It is true that other health policy decisions we make, such as how much of federal agencies’ budgets to devote to health system capacity building in low-income countries, also affect the healthcare costs that poor countries must bear. However, **because the market** for prescription drugs is global but **is propped up by high prices in the United States**, **tamping down drug prices has a zero-sum-game quality** that is unique. **Squeezing one part of the drug-price balloon may cause it to bulge out in other areas**

#### And, even small price hikes in developing countries puts millions at risk.

**WHO 07** (World Health Organization, 02-2007, World Health Organization, Paying for Health Services, http://www.who.int/mediacentre/factsheets/fs320.pdf, accessed 12-4-2018) CC

PAYING FOR HEALTH SERVICES Q: How do **most people in the world’s poorest countries pay** for health care? In most low-income countries, people pay a high proportion of **their health costs** directly to health care providers **out of** their own **pocket**s. In 47 low-income countries, **out-of-pocket payments represent more than half of total health expenditures.** The remainder is largely funded by governments. Q: How does out-of-pocket spending for health care compare in rich countries versus poor countries? **In** most of **the world’s wealthiest countries, individuals pay few health care costs directly**. In Germany, for example, where the GDP is US$ 32,860 per capita, **11.3% of all medical expenses are borne by households** and the rest by social health insurance or by the government. In the Democratic Republic of the Congo, by contrast, where GDP per capita is only US$ 120, about 90% of the money spent on health care is **paid directly** by households to providers. Q: What impact does high out-of-pocket spending have on people’s health and overall welfare? **High levels of out-of-pocket spending for health care have a variety of harmful effects**. Some **people are deterred from using health services** or from continuing treatment **because they cannot afford to pay.** **People** who use services **may need to cut spending on basic needs** **such as food, clothing, housing and children’s education to meet health costs.** **Each year**, **approximately 150 million people experience financial catastrophe**, **meaning they are obliged to spend on health care more than 40 % of the income available to them after meeting their basic needs. And** **100 million of those people are driven below the poverty line.** Q: How can people be better protected against financial catastrophe or impoverishment related to health care payments? The best approach is to develop a system through which people contribute to the health system before they need health care - through taxes, some form of insurance or a combination of the two - then draw on services funded by these sources when they need them rather than paying out of pocket for them. In general, the greater the proportion of prepayment in overall health financing, the more households are protected from financial catastrophe and impoverishment. Q: What would it cost to finance pre-payment plans that could provide a basic package of **health services** in poor countries? A recent paper suggested that in low- and middle-income countries, governments and individuals would have to jointly contribute US$ 34 1 per person per year for essential preventive and curative services. US$ 11 to US$ 25 would **have to come from international donors.** Q: What is WHO doing to help countries develop their health financing systems? WHO works with countries to help identify ways of moving away from a heavy reliance on out- of-pocket payments and towards prepayment. WHO provides information on best practices and technical support to countries engaged in this process. It also works with the international community to encourage support for recipient countries in developing and strengthening financial insitutions and capacities that will allow prepayment mechanisms to be successful.

#### And, Poverty leads to death.

**Millennial Legacy 18** (Millennial Legacy, 2018, The Millenial Legacy, Poverty, http://themillenniallegacy.com/issues/poverty/#.XAgpqGhKg2w, accessed 12-5-2018) CC

Poverty is a very serious global problem that gets far less attention than it deserves. Almost half the world–over 3 billion people–lives on less than $2.50 a day, and at least 80 percent of the world lives on less than $10 a day. **Every day, 50,000 people die simply because they live in poverty. That’s** **18 million people every year**. And sadly, worldwide more people **die from** extreme **poverty** than any other cause. Moreover, poverty is linked to many other problems such as hunger; illiteracy; war; the spreading of deadly diseases like HIV/AIDS; inadequate access to basic human needs like healthcare, clean water and sanitation; and rampant inequality. So by eliminating poverty, we could also eliminate or at the very least decrease many of these problems as well. Below are some startling statistics about global poverty. Hunger and Poverty: \*Eight million people die from lack of food and nutrition every year. That’s about 24,000 deaths each day. (Source: FAO Hunger Report 2008) \*Every year, 5.8 million children die from hunger related-causes. Every day, that’s 16,000 young lives lost. (Source: FAO Hunger Report 2008) \*For the first time in history, over 1.02 billion people do not have enough to eat. That’s one sixth of humanity and more than the population of the United States, Canada and the European Union combined. (Source: FAO Hunger Report 2008) \*There are around one billion hungry people in the world: 642 million live in Asia and the Pacific, 265 million in Sub-Saharan Africa, 53 million in Latin America and the Caribbean, and 42 million in the Near East and North Africa. However, fifteen million people in developed countries go hungry, which is around 1.5 percent of the total population. (Source: FAO 2010) \*The number of undernourished people in the world increased by 75 million in 2007 and 40 million in 2008, largely due to higher food prices. (Source: FAO 2008)

#### Third, A Decline in Drug Donations.

#### The Pharmaceutical Industry is the most charitable Industry in America

Stephen J. **Dubner 18** (Stephen J. Dubner, 5-23-2018, Freakonomics, The Most Vilified Industry in America Is Also the Most Charitable, http://freakonomics.com/podcast/most-vilified-industry/, accessed 12-4-2018) CC

Our latest Freakonomics Radio episode is called “The Most Vilified Industry in America Is Also the Most Charitable.” (You can subscribe to the podcast at[Apple Podcasts](https://itunes.apple.com/podcast/freakonomics-radio/id354668519),[Stitcher](http://www.stitcher.com/podcast/freakonomics-radio), or[elsewhere](http://freakonomics.com/2014/07/24/a-podcast-users-guide-for-people-who-dont-use-itunes-or-iphones/), get the [RSS feed](http://feeds.feedburner.com/freakonomicsradio), or listen via the media player above.) **Pharmaceutical firms donate an enormous amount of their products** (**and some cash too**). But it doesn’t seem to be helping their reputation. We ask Pfizer’s generosity chief why the company gives so much, who it really helps, and whether all this philanthropy is just corporate whitewashing. Below is a transcript of the episode, modified for your reading pleasure. For more information on the people and ideas in the episode, see the links at the bottom of this post. If I asked you to guess **the least popular business sector in the United States**, what would you say? Here’s a hint: **the very low approval rating of this industry nearly ties it with the federal government.**[According to Gallup](http://news.gallup.com/poll/12748/business-industry-sector-ratings.aspx), only about a third of Americans give this industry a positive rating. It’s so unpopular that even the very, very unpopular federal government attacks it all the time. Politicians of every leaning. From [Rand Paul](https://www.paul.senate.gov/), the Republican Senator from Kentucky: Rand PAUL: Big Pharma manipulates the system to keep prices high. To [Elizabeth Warren](https://www.warren.senate.gov/), the Democratic senator from Massachusetts: Elizabeth WARREN: And a lot of that money that is spent lobbying Congress is to keep drug prices high. From [Donald Trump](https://www.whitehouse.gov/people/donald-j-trump/): President TRUMP: The drug companies, frankly, are getting away with murder. To [Bernie Sanders](https://www.sanders.senate.gov/): Bernie SANDERS: I have been fighting the greed of the prescription drug industry for decades. And as far as I can tell, the pharmaceutical industry always wins. And here’s an interesting twist: **the pharma**ceutical **industry is** also **the most charitable industry in America**. [According to a survey](http://www.businessinsider.com/most-generous-companies-in-america-2015-2016-6/#25-mondelez-international-1) by the Chronicle of Philanthropy, **the top three American companies for charitable contributions are Pfizer, Gilead Sciences, and Merck. Also in the top 10: Bristol-Meyers Squibb and Eli Lilly.** It’s hard to imagine that being so charitable is what makes them unpopular. It probably makes more sense to think that their charity is meant to mitigate their unpopularity. Although it doesn’t seem to be working so well. [In our previous episode](http://freakonomics.com/podcast/corporate-social-responsibility/), we looked at some of the surprising consequences of corporate social responsibility, or C.S.R., programs. Which, as the economist [John List](https://economics.uchicago.edu/directory/john-list) told us, are very popular: John LIST: You gave 90 percent of G250 companies — this is global Fortune 250 companies — 90 percent of them are now publishing annual C.S.R. reports. C.S.R. can take many forms in a company: volunteerism, environmentalism, and, of course, charitable contributions. LIST: **Every dollar [they] we earn, [they] we give a nickel to charity.** List also told us that promoting C.S.R. is a great sorting mechanism for companies: it attracts more employees who are willing to work hard for less money. LIST: Exactly. But List also found that C.S.R. can lead to what’s called “moral licensing”: the idea that doing good can give you license to be bad. For employees at C.S.R. firms, that can take the form of cheating and stealing. Another group of economists looked into the politics of C.S.R. They found that a lot of firms use corporate philanthropy as a form of “tax-exempt lobbying” — that is, firms increase their giving in congressional districts when representatives from those districts get seats on committees related to the firms’ business. So: a little skepticism about the true intentions of corporate social responsibility is probably in order? On the other hand, wouldn’t it be nice to hear directly from someone who runs C.S.R. at one of these firms? Maybe someone at **the most charitable firm in America?** ROAN: My name is [Caroline Roan](https://www.insidephilanthropy.com/insider-guide-to-program-offic/caroline-roan-pfizer-foundation.html), and I wear two hats for **Pfizer**. One is vice president of corporate responsibility for the company, and the other is president of the Pfizer Foundation, which is a separate legal entity. Pfizer, based in New York City, is a huge company, with more than 90,000 employees around the world. It sells its products in 125 countries. There are a lot of over-the-counter brands you’re probably familiar with — like Advil, ChapStick, Centrum, Dimetapp, Preparation H, and Robitussin. But Pfizer’s big money-maker is prescription drugs. ROAN: You’ve probably heard of Lipitor. Diflucan, which is an antifungal. Prevnar 13, which is a pneumococcal vaccine. Lyrica, which is for pain. And of course we also contributed Viagra, which was for a very serious disease. The company was founded in 1849 by two German immigrants. **It considers corporate social responsibility, or C.S.R., to be part of its D.N.A**. ROAN: And really, the first significant contribution was unlocking the ability to mass-produce penicillin. And it was a wonder drug, but nobody had sorted out the specifics of how you take it to mass production. And Pfizer did that. And at the time of World War II, they actually ran the plant 24 hours a day and partnered with the United States Government to ensure that we had enough penicillin that our troops could take it ashore on D-Day. Pfizer created its foundation in 1953 and their department of corporate responsibility in 2001. That’s the same year Roan joined the company; today, she’s in charge of both C.S.R. and the foundation. Pfizer has a wide range of helping initiatives, from medicine giveaways to R&D addressing diseases common in low-income populations to a project called [Global Health Fellows](https://www.pfizer.com/purpose/responsibility/healthcare-access/global-health-fellowships). ROAN: We call it Pfizer’s Peace Corps, if you will. And we will literally donate our colleagues to go work at non-governmental organizations to support the efforts on the ground and in the fields. I’ve literally had people come to the company and tell me, “I came to this company because I knew you had this program. And I’ve waited for my three years in to be able to participate.” DUBNER: Caroline, did you have a stint in this Peace Corps-type project?ROAN: I haven’t. But I feel like I do, because I’ve been to Kakuma, I’ve been in Kenya; I’ve been to Lalibela, in Ethiopia. I have gotten to see the little medicine that we produce all the way in Puerto Rico make it to the most remote locations. It’s profound. And it restores your soul on a fundamental level. DUBNER: So let me ask you this: Why is there a department of corporate responsibility that needs a vice president like yourself? Isn’t everyone in a corporation responsible somehow? ROAN: I think, Stephen, that’s a great point. We think of corporate responsibility very simply as the how of how we do business. And it’s very much grounded in the mission of the company. That said, **in order for us to achieve that mission of discovering and developing these great medicines and vaccines, we have to ensure that we’re doing our part to get those medicines and vaccines to the patients who need them.** DUBNER: The economist [Milton Friedman](https://en.wikipedia.org/wiki/Milton_Friedman) famously argued that corporate social responsibility is a — as he called it — a “fundamentally subversive doctrine,” and that quote, “There is one and only one responsibility of business, to use its resources and engage in activities designed to increase its profits.” So, what are the inherent conflicts between profit-seeking and corporate social responsibility?ROAN: Well, I’m very familiar with the business of business is business. But we don’t make lipstick. **We make medicines and vaccines**. And so, I do think, Stephen, you’ll see a vast difference in how industries approach this work. But for Pfizer, **in order for us to discover and develop those medicines and vaccines, they have to get to the people that need them.** **We have to have functioning healthcare systems.** And we’ve got to be more creative and address those needs in a very meaningful way.I mean, **we’re living in a time of vast income inequality around the world**. We know that **the poorest of the poor no longer live in the most remote villages**. They don’t live in low-income countries — **they** actually **live in middle-income countries**, they live in **urban centers, and governments are failing to provide a very basic set of services.** And so, what does that mean for a big multinational company that’s in the business of health? We’ve got to adjust and do our part to prove to those patients and those communities that **we** will **help them get access to quality healthcare, medicines, and vaccines.** And that’s what we do.DUBNER: So give me an example of where you’re having huge success with that — whether it’s life expectancy, alleviation of suffering, prevention of death, etc.ROAN: So, a perfect example of that is our work in addressing trachoma. It’s the number-one cause of preventable blindness. And what happens is that you get a repeated infection and over time your eyelashes turn inward. It’s quite painful, and you go blind. And interestingly, people who came into Ellis Island were checked for trachoma. You might remember seeing pictures of the eyelids being turned.DUBNER: There was also this terrible story of unintended consequences, where they used this tool to check people for it, without realizing that it was a bacterial cause, and that they were actually spreading it as much as they were alleviating it.ROAN: Exactly. And it’s a disease of poverty. It’s a disease that affects the folks that are living literally at the end of the road. Now, **Pfizer discovered that Zithromax**, our antibiotic, **was effective in treating the active infection that causes this disease.** Well, **we doubled down on our efforts to eliminate it**. We have our eyes on the prize of actually **eliminating this disease by the year 2020**. So, in order to do that, we had to conduct the largest global public-health mapping project that has ever occurred. And when we did that, we discovered these pockets of trachoma. And we realized in order to achieve the global elimination goals with the World Health Organization, we were going to have to increase the donation of Zithromax. We were also going to have to support a comprehensive public health strategy. And we are literally changing, one community at a time, the ability for young children and moms to avoid this infection and to avoid blindness. It’s one of the most powerful programs I’ve ever seen in the field, and one that I think I’m most proud about. DUBNER: And I assume you’re giving all that medicine away. Correct? ROAN: Yes. In fact, Stephen, interestingly, **half of the production of Pfizer’s commercial supply of Zithromax — more than half — is donated to support this program**. DUBNER: Let me backup for just a second, because the industry that you’re in is an inherently interesting one. I don’t know about inherently controversial, but it is controversial. So your sector is, we know, not so beloved by the general public, which is interesting, because you make medicine that helps people. But **it is,** according to the latest data I’ve seen, **the least-popular business sector in America**. Worse than the legal field, worse than oil and gas. So, why do you think such a firm and the industry is not better regarded ROAN: I will confess, we don’t have a lot of wind at our back. Those statistics are right. And it’s confounding to us. What I wish the public would understand is Pfizer’s literally deep and abiding commitment to patients. We put patients first in everything that we do. And we believe if we can deliver for patients, we’ll deliver for shareholders and we’ll deliver for society. And unfortunately, Stephen, we’re in a world where bad actors and headlines grab people and the complex story of drug development is hard to give you in a sound bite or in a tweet. And we do our best to tell that story of commitment to patients and commitment to science. But it is hard to break through.DUBNER: **Pfizer is hugely successful.** Annual revenues in the neighborhood of $54, $55 billion, with **profits around $21 or $22 billion**. It’s smart. It’s a strategic firm. But often that strategy isn’t what most people would think of as quite kosher. So let me give you a couple examples, then ask you how C.S.R. fits into that. So, a couple of years ago, Pfizer was planning on an inversion merger with an Irish firm but that was spiked by the Treasury Department. It was considered a method of avoiding taxes by merging with the foreign company. Pfizer has also paid the second-largest settlement claim ever by a pharmaceutical company, more than $2 billion, for violating the False Claims Act with infractions that included kickbacks on several drugs.When we — the non-pharma community — learn about that as a company, and we also know how much pharmaceutical firms spend on lobbying and so on, why wouldn’t we be wise to be skeptical of something like corporate social responsibility as practiced by Pfizer? Why wouldn’t we be wise to see it as little more than a form of P.R. or some kind of white-washing?ROAN: There is a fair amount of skepticism out there for big business overall. For Pfizer, the reason I believe that people should take another look is that we have four clearly defined strategic priorities, and I think it has set the path for us in terms of responsible business growth. And the first is around our science. **We are working every single day to get the necessary resources to innovate to create the next generation of important medicines.** Second, we are looking at the allocation of the resources for the long-term results for our shareholders. We would be remiss if we didn’t do that. The third and fourth imperative are critically important. We’re trying to create a culture where we work as a team, where we win the right way, where we are compliant and consistently delivering the business growth that we want to, in the right way. And the fourth imperative is being a responsible corporate citizen. So every single person in this company knows that that’s a part of their day job.DUBNER: Part of your corporate-responsibility initiative — well, there are many parts. Among the big ones that I’ve read about are what you called “building healthcare capacity,” which means improving health systems in low- and middle-income countries and improving access to healthcare for the most underserved communities. Also part of the portfolio is “expanding access to medicine.” Now, let me be a total devil’s advocate, or maybe just a devil for a minute. **How much is this about building healthcare infrastructure in order to create a robust long-term delivery system for Pfizer products?** ROAN: **If we don’t have a functioning healthcare system**, you’re right, **we can’t deliver our products and our vaccines. But I see that as net-net, a benefit both for the company and for society.** But as I said, I think that’s a bit different than what you might see in a regular commodity, like lipstick or another type of product, where you could maybe argue more on the side of saying, “Well, that’s just because they want to build a market.” **It is in our best interest to have a functioning healthcare system because patients aren’t going to be able to get the support they need. And we know that if patients are healthy and communities are healthy, they’re more likely to have economic success.** DUBNER: Let’s talk about this massive chunk of value that Pfizer gives away as part of its corporate-responsibility initiative. In the most recent year for which you’ve provided the numbers, it’s about $5 billion in total giving, with revenues of about $52 billion. So **roughly 10 percent of revenues are given away.** Now, roughly $4.7 billion dollars of that is product donations. And then the cash represents — if I’m calculating correctly — about 0.004 percent. So if I wanted to be churlish, I would say, “Well okay, Pfizer is giving away not very much money, but giving away a lot of in-kind donation in the form of medicine.” Let’s start with how the value is attached to that medicine that’s given away — what is the actual valuation process to attach a number to the drugs that are given away? ROAN: So I would say the following: that is complicated, and I am not intimately engaged in the valuation process. Look, one of the reasons we give away a lot of product is our product is our most valuable asset, right? When we think about where we can make the biggest difference, what does Pfizer have that’s unique? Well, we have the medicines and the vaccines that we’ve discovered and developed. And people need them. That’s why at any given point, if you were to ask our partners what they’re asking us for, they’re starting with our medicines and our vaccines, right? And in the U.S., for more than 30 years, we’ve had a program in place called Pfizer RxPathways, and that’s designed to help people who are falling through the cracks get access to medicines here in the United States. We offer more than 70 products to patients free or deeply discounted. Last year **we helped 250,000 people get about 1.7 million prescriptions.** DUBNER: Some people say, “Well, it’s wonderful that you and firms like you give away a lot of your drugs to people in need, people in crisis, people who can’t afford it, people who don’t have access to it. But, rather than that model of, ‘Let’s sell our product in some markets and make as much money as we can, which is what firms do, and then give away some of it in other markets,’ why not have a pricing structure that — as difficult as it may be to come up with — makes it affordable for people to buy on a sustained basis everywhere, rather than having communities need to rely on charitable donations?” ROAN: Well, it’s a great point, and increasingly, we are moving in the direction of what we’re calling creative commercial strategies. So **we have tiered pricing globally, which means that countries pay based on an ability to afford the medication. But also, for the poorest of the poor, which is where I focus our efforts, we are looking at strategies that are truly built on public-private partnerships that provide our products at an affordable cost to organizations who are working to serve this population.** A perfect example is our work with [Gavi, the Vaccine Alliance](https://www.gavi.org/). The Gates Foundation really started this effort and deserves credit for it. Gavi makes a whole host of vaccines across companies available to 73 of the poorest countries. And we provide our pneumococcal vaccine, which is one of our most innovative products, at less than $3 a dose. And countries can purchase through the Gavi Alliance, if they so choose to, and I believe it’s a more sustainable approach.DUBNER: And what would that $3 dose cost in the U.S.?ROAN: I actually don’t know what it would cost in the U.S.

#### And, Drug donations are critical to the healthcare systems of developing countries and millions rely on them.

**GAFPA 17** (Global Alliance for Patient Access, 08-2017, GAFPA, THE ROLE OF DRUG DONATIONS IN EXPANDING ACCESS TO MEDICINES, <http://gafpa.org/wp-content/uploads/GAFPA_Drug_Donations_August-2017.pdf>) CC

**Millions of low-income people in countries and communities around the world depend** up**on** the generosity of **donated drugs.** **Over the past two decades, the appropriateness of donations—that is, how well donor offerings reflect actual need—has improved dramatically**.1,2,3 **Whether donated from surplus stock, through philanthropic contributions, as part of disaster responses, or through longer-term development programs,** **drug donations are critical to global health**. While many drug donation programs succeed, certain challenges persist. The importance of these donations begs the question: How can we improve donation processes to make vital drugs available to more people? This paper reflects conversations with experts and a review of articles and policies on the topic of drug donations. It goes on to lay out recommendations for policymaker. **Drug donations** can **make treatment accessible for patients and communities in need**. They also have a more far-reaching impact, such as **strengthen**ing **health systems**, **secur**ing **sustainable supply chains**, **and foster**ing **markets and public services that promote patient access.** Drug donations **to low- and middle-income countries in particular** can free up funds that would otherwise have been spent purchasing drugs through third-party or local vendors at a higher price. These funds can instead support critical resources such as infrastructure, human resources, and capacity for health systems. **Donations can also indirectly enhance governance and accountability. Accepting donations requires, for example, additional reporting by receiving governments and institutions**. In many instances, donation programs can encourage improvements in technology, management, and monitoring and evaluation. In short, **donation programs may directly help patients while also providing wide-ranging benefit to local programs and systems.** Though **drug donations** **are often seen as part of development aid or post-disasters response**, they can also **meet a specialized need**, even **in developed countries.** A unique program in **the U**nited **S**tates, for example, accepts donated drugs from the public, and **focuses on specialized, often costly, medications**. **Medicines to treat HIV/AIDS or cancer are typically donated** through this program from patients or family members of patients who have succumbed to their illness. A major concern and possible disincentive in the United States is the issue of liability, though The Cancer Drug Donation Program Act indemnifies all parties when individuals, hospitals, and other entities donate prescription cancer drugs to qualifying patients. **These donations can have a powerful impact on patient access to** certain specialized **drugs**. HOW DRUG DONATIONS WORK Drug donations entail more than a patient community in need and a pharmaceutical company or entity willing to give. Health facilities receiving drug donations often rely on intermediate organizations, typically non-governmental organizations (NGOs), which have expertise in receiving and disbursing drug donations. These organizations may get the drugs directly as offers from pharmaceutical companies, or through collections and contributions from clinical facilities and health systems in donor countries. NGOs serve as the critical interface to understand and represent recipient need, and to assess the appropriateness of donor contribution. Furthermore, these NGOs understand which donations are feasible, based on factors such as: Experts acknowledge the key role that NGOs play, particularly international NGOs with local offices or those collaborating with local NGOs. These serve as an important bridge between the groups donating drugs and the groups delivering services, and ultimately, the end recipient, the patients.

#### That means that any cut in revenues is a direct cut to drug donations because the donation budget comes from revenues, which puts the millions who rely on donations at risk.

#### Thus, we are proud to negate.

# Frontlines

## Overviews

### Global Altruism

The resolution asks what the United States SHOULD do which implies a moral obligation. Look back to the Mello Evidence in case which tells you that global justice holds that wealthy countries and policymakers have a moral obligation to ensure access to medicines in poorer countries. Thus, the standard for the round is who creates a better healthcare system for poorer countries.

Prefer preserving global medicine for two reasons:

1. The Socioeconomic difference ; The WHO 07 evidence is very clear in saying that 150 million people in the developing world go through financial catastrophe due to the high costs of medicine, which is why they rely on international donors for their medicine. This is because there is such a huge income difference. Phelps 13 finds that the median income of the top ten wealthiest countries in the world is 50 TIMES that of the poorest 10 countries.
2. The Insurance difference ; The WHO 07 evidence in case also tells you that 90% of the people in the developing world don’t have insurance to cover medicine costs, whereas CNBC finds that only 10% of Americans don’t have insurance, but even then there are a ton of patient outreach programs that lower costs. It’s A LOT harder to pay for medicine when you have to shoulder literally all of the cost

Phelps 13:

https://news.gallup.com/poll/166211/worldwide-median-household-income-000.aspx

CNBC:

<https://www.cnbc.com/2017/09/12/maps-show-obamacares-big-on-americans-health-insurance-coverage.html>

### Uniqueness Weighing

1. Prefer our uniqueness of high prices in the US being acceptable for three reasons. First, scope. Their impacts are all specific to Americans, whereas we tell you that we affect literally the whole world. Second, Magnitude. Every single one of our impacts outweighs on magnitude because we affect more people across the globe. Third, moral altruism. Look back to the weighing overview, the standard of the round is helping poorer countries. I’d argue that at the point where the WHO evidence says that people in poor countries are 6 times more likely to pay out of pocket for medicine than wealthy countries, the United States is well enough off already to survive marginally high drug prices.

## AT: Access

#### cFirst, Delink it because:

#### Price Controls will have ZERO effect on the majority of Americans because it doesn’t change what insured people pay for drugs – that still gives us offense because our case specifically talks about how people in developing countries don’t have insurance.

Jim **Greenwood 18** (Jim Greenwood, 11-29-2018, The Hill, Think the drug-pricing debate addresses patient costs? Think again., https://thehill.com/blogs/congress-blog/healthcare/418750-think-the-drug-pricing-debate-addresses-patient-costs-think, accessed 12-7-2018) CC

**Drug pricing** **is now inching to the top of Congress’s agenda as that unimaginable issue upon which**[**President Trump**](https://thehill.com/people/donald-trump)**and**[**Nancy Pelosi**](https://thehill.com/people/nancy-pelosi)**actually agree.** But even if bipartisanship does break out on this issue, it **won’t do a thing to relieve pain at the pharmacy counter**. Without explicit requirements to pass along savings to patients, none will be. **Health-care voters did not cast their ballots for price controls that would lower drug costs for insurance companies, drug middlemen like pharmacy benefit managers, and the government  — certainly not at the expense of investment in new cures.** Patients want their costs lowered, and rightfully so. No one should be denied the medicine they need because they can’t afford their treatments. A week before the election, Trump [announced his plan](https://www.nytimes.com/2018/10/25/us/politics/medicare-prescription-drug-costs-trump.html) to lower drug prices in Medicare by tying what our government pays for injectable drugs to what European countries pay under single-payer health-care systems. One of the benchmark countries being used to calculate U.S. drug costs is Greece, which is literally bankrupt. The biotech markets [reacted](https://www.biocentury.com/bc-extra/financial-news/2018-10-24/nbi-drops-6-and-red-2018) to the president’s plan with their worst day in seven years, losing $100 billion in an especially bleak day for the genomic medicine revolution. Importing foreign price controls will take a wrecking ball to our global leadership in drug innovation. It may save some money for Uncle Sam, but it’s going to make it harder for your uncle Sam to access new medical breakthroughs. The president and Speaker-in-waiting are both conflating a drug’s list price with a patient’s out-of-pocket costs. Health plans historically have used flat co-pays to make a patient contribute nominally to their drug costs. But over the last decade, insurers have shifted their approach, forcing patients to pay much higher up-front costs. Half of all patient cost-sharing is now through high up-front deductibles, according to a [recent Peterson-Kaiser study.](https://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth/#item-start) **Government price controls help insurers, not patients. If an insurance company requires a $3,000 deductible, it doesn’t matter if the government cuts the price of a $10,000 drug down to** the $**5,000** paid by Greece**. Patients will still have to cough up $3,000 at the pharmacy counter before they get a dime of help.**Yes, newer medicines are expensive before they go generic and prices plunge. Only [10 percent of medicines in development ever see the pharmacy shelf](https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf). Investors require a return commensurate with those long odds or they won’t invest. Arbitrarily capping prices on the few dozen new drugs that make it to market each year will squeeze investment out of the life sciences like a wrung cloth and slow medical progress. If the government wants to assert its power in this space, it should control the costs borne by patients.Holding insurers accountable for tactics that pad their bottom lines at the expense of patients will require the attention of policy makers, state regulators and the judicial system. However, Congress alone has power to restructure Medicare so [43 million seniors in the Part D program](https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/) can afford their medication.

Second,

#### pharmaceuticals are comparatively not expensive healthcare.

Wayne Winegarden of Forbes in 2018 (Wayne Winegarden, xx-xx-xxxx, Forbes, Pharmaceutical Price Controls Will Not Improve Health Care Outcomes in Illinois, https://www.forbes.com/sites/econostats/2018/05/17/pharmaceutical-price-controls-will-not-improve-health-care-outcomes-in-illinois/#2ed9f8b70d59, accessed 10-5-2018) NC

De facto price controls will not solve the health care affordability problem. Despite the headlines about high-priced drugs, pharmaceuticals represent a small portion of overall medical costs. According to the [Centers for Disease Control and Prevention](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html), about 10 percent of all health spending goes toward prescription drugs nationally; that's roughly the same share as in 1960. Further, pharmaceutical expenditures are not growing faster than overall health care expenditures. According to the latest [national health expenditure data](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf), retail prescription drug expenditures rose 1.3 percent in 2016, less than one-half the growth in overall health care expenditures of 4.3 percent. Generic medicines play an invaluable role creating these positive outcomes. The purpose of generic medicines is to enable a competitive market that drives down prices and creates significant budgetary savings. According to the [Association for Accessible Medicines](https://www.accessiblemeds.org/), generic medicines in 2016 (the latest data available) have enabled $9.6 billion in savings for Medicare, Medicaid, commercially insured, and uninsured patients in Illinois alone.

That means that not only are they not benefitting Americans directly through lowering pharmaceutical prices, they harm Americans in the long-term because decreasing innovation gets rid of medicines that prevent other healthcare spending which is what makes up the majority of spending.

## AT: Defense

### AT: Profit Maximizing

Even if that’s true, I’d say that profit maximizing in the NEG is better than in the AFF ; in the aff world, companies NEED to do whatever they can to make up for lost profits which we tell you would be cutting things beneficial for the rest of the world ; even if they are profit maximizing now, at least they are helping developing countries

### AT: Approval low so should just lower prices

Companies only have the capability to focus on PR when they aren’t in a Price Controlled environment, that’s why when companies have to shift their focus to the domestic market they won’t go easy on the developing world.

### AT: The Patent Cliff is coming = revenues NU

#### 1 --- mitigate it. That doesn’t mean that we should just keep on cutting revenues ; if a decrease in revenues is coming from the patent cliff then adding onto the financial burden through cutting revenues is still a net negative.

#### 2 --- Innovation outpaces profit loss from innovation – a small profit squeeze from patents expiring is different from NO expectation of profits in the future and government PRICE controls

#### 3 --- Vitrano 17 finds that the Patent Cliff is still not an issue and wont be until the middle of the next decade because innovation is high in the squo – that means when you cut off innovation you EXPEDIATE the patent cliff, that gives us another link into revenue loss.

**[extra]**

#### 4 ---Budwell 17 finds that big pharma companies aren’t even the ones affected by the patent cliff strictly because of their bulky innovation pipelines

#### 3 --- No impact to patent cliff — innovation is key.

Vitrano and Wu 17 — Margret Vitrano, Portfolio manager for Clearbidge Investment, and Nicholas Wu, Senior Healthcare Analyst at Clearbridge Investments, 2017 (“Differentiated Growth: Biotech Well Positioned to Outperform,” *Clearbridge Investments,* June 19th, Accessible Online at <https://www.clearbridge.com/news/blogs/2017/differentiated-growth--biotech.html>, Accessed On 10-15-2017)

Despite recent weakness, three of the four trends that powered the biopharmaceutical bull market remain in place today. The patent cliff is still not an issue, with no major patent expirations expected until the middle of the next decade. Regulators remain supportive of new drug treatments (Exhibit 1), and we are optimistic that the regulatory environment will continue to be favorable for innovative new drugs under the Trump administration. Exhibit 1: The Rate of Drug Approvals is Expected to Increase [Chart Omitted] While new drug approvals by the U.S. Food and Drug Administration (FDA) dipped in 2016, we view this as an aberration and a function of timing, with multiple approvals coming at the end of 2015 and start of 2017. 2. 2017 figures are year-to-date through May 31, 2017. Source: FDA. Perhaps most importantly, innovation is alive and well. Based on our fundamental research and active management approach, we continue to invest in biotechnology companies that are developing innovative treatments for rare diseases and inflammatory conditions with high unmet need. Treatments in these areas face less competition and should be less vulnerable to pricing pressure.

#### 4 --- big pharma companies aren’t affected by it

Budwell 17 (Motley Fool, 9/27/2017, George, “3 High-Yield Stocks to Own in a Market Crash” 3 High-Yield Stocks to Own in a Market Crash” https://www.fool.com/investing/2017/09/27/3-high-yield-stocks-to-own-in-a-market-crash.aspx)

Even after a six year bull run, the broader markets don't appear to be showing any signs of slowing down. Even so, income-seeking investors who have been riding this market to new all-time highs may want to start to rotate into a handful of defensive stocks that can withstand any unexpected downturns moving forward. With this theme in mind, we asked three of our Motley Fool investors which stocks they think can act as both strong income generators and defensive plays right now. They suggested Pfizer (NYSE:PFE), Proctor & Gamble (NYSE:PG), and AT&T (NYSE:T). Read on to find out more. The power of cash George Budwell (Pfizer): Stocks that can withstand market lulls tend to be tied to companies with exceptional free cash flows and above-average cash positions. The pharma giant Pfizer has both of these traits in spades. Despite experiencing an avalanche of patent expirations for top products like Lipitor over the past seven years, Pfizer was still able to generate over $15 billion in free cash flows in the past 12 months, thanks to its growing anti-inflammatory, oncology, and cardiovascular-care franchises. The drugmaker also sports a cash position in excess of $14 billion -- even though it doled out over $35 billion to acquire Anacor Pharmaceuticals, Hospira, and Medivation in just the past two years. Pfizer's unique ability to generate cash has allowed it to plow a whopping $56 billion into share buybacks and another $50 billion into dividends since 2010. While this company hasn't been able to produce particularly enticing levels of top-line growth lately, Pfizer's shares have still marched higher at a respectable clip because of its top-notch shareholder-rewards program. In a nutshell, Pfizer's stock has performed admirably during, perhaps, its worst stretch of time in terms of losing key products to the so-called patent cliff -- up 150% on a total return basis since 2010. And now that the company is passing through the eye of the needle, so to speak, from a patent-expiration standpoint, and its immense pipeline is on track to produce a number of new blockbuster products, this titan of the pharma industry appears capable of shrugging off even a marked decline in the broader markets. Perhaps best of all, though, Pfizer offers a dividend yield of 3.61% that's close to the top of its big pharma peer group.

### AT: Won’t cut good programs, will just cut marketing

No… when faced with financial challenges, a companies money-makers will be the last things cut ; the reason they would stop giving price concessions and stop donating drugs is in order to keep the company’s revenues afloat.

## AT: Innovation Defense

### AT: Price Controls Pre-Req Access to R&D Drugs

#### Before anyone can decide the price of a drug, it has to be created first. Thus, innovation pre-reqs affordability because the drug can’t have a price if it doesn’t exist.

#### Innovation slashes overall healthcare costs. Without it, healthcare will become more unaffordable than it is right now.

(Dean J. Paranicas is President and CEO of the Healthcare Institute of New Jersey, “The Value of Medical Innovation: Saving Lives, Saving Money”, December 18, 2014, http://hinj.org/the-value-of-medical-innovation-saving-lives-saving-money/)//RS

Collectively, new therapies are the greatest contributors to increased life expectancy. According to the National Bureau of Economic Research (NBER), between 1960 and 1997, new therapies accounted for 45 percent of the increase in life expectancy in 30 developing and high-income countries. Between 2000 and 2009, new therapies accounted for 73 percent of the increased life expectancy for these countries. Despite the dramatic life-saving advancements that the life sciences sector has made, our work is far from done. Diabetes, Alzheimer’s, Ebola, different types of cancers, and other formidable medical conditions demonstrate the compelling need for America’s medical innovation community to build upon its tremendous achievements to continue saving lives around the world. Toward that goal, every day, teams of scientists from New Jersey companies go to work to research and discover the next generation of medicines, therapies, devices, technologies and diagnostic tools that will alleviate even more of these life-threatening and life-altering diseases. Medical Innovation’s Overlooked Benefit With these medical innovations, past and future, comes an often-overlooked benefit: the incalculable billions of dollars in savings to patients, their families, insurers, employers, governments and hospitals in avoided medical expenses associated with keeping people healthy or curing them of a life-long, chronic condition. Certainly, these medicines, therapies, medical technologies, devices and diagnostic tools keep people healthier. They limit the need for frequent visits to the doctor. They help to avoid costly hospital stays. They [and] help patients avoid expensive surgeries. **Unfortunately, these tremendous cost savings often go unrecognized.** Instead, we hear frequent reports about the high cost of medicine or about new technologies or diagnostic tools being deemed “too expensive” or “unnecessary.” We hear that medical innovation is a cost-driver, not a cost-saver. The reality is quite to the contrary. **Medications, therapies and medical technologies and devices not only save lives — they save money.** **By eradicating a disease, people no longer need to seek or spend money on treatment**. By better managing and preventing more serious complications from an existing disease, people avoid more costly medical care. **By discovering a new treatment or cure, the costs that would have been incurred in addressing a patient’s ongoing medical issues can be avoided entirely**. Therefore, developing new treatments, cures and health technologies is one of the most important steps we can take — not only to save lives and improve the quality of life, but also to avoid the expenditure of enormous amounts of health care dollars. How much savings does medical innovation produce? **There is not one, simple answer to that question. However, there are numerous academic and government statistics that point to the economic benefits of innovation in the health-care marketplace. In a paper published by the Journal of Political Economy in 2006, it was estimated that over the preceding 50 years, medical innovation had been the source of nearly half of all economic growth in the United States.** **Impressively, for every dollar spent on innovative medicines, total healthcare spending is reduced by $7.20, according to an NBER pape**r. As for the price of medicine in America, only 9 cents of every health care dollar spent in America goes to medicines, according to the Centers for Medicare & Medicaid Services (CMS) in 2013. The other 91 cents goes to hospitals, physicians, clinics, long-term care facilities, and government administration and net cost of health insurance.

### AT: R&D Done By NIH

#### Publicly funded R&D is only basic and relies on further development by the private sector.

David Hogberg of The National Center for Public Policy Research in 2007, Ph.D. is senior policy analyst at The National Center for Public Policy Research in Washington, D.C., Letting Medicare "Negotiate" Drug Prices: Myths vs. Reality, <https://www.nationalcenter.org/NPA550MedicareDrugPrices.html>, DOA: 8-10-17, Y2K

Myth: Medicare price controls will have no effect on pharmaceutical industry research and development, especially as most drug research is conducted by the National Institute of Health. Reality: The National Institute of Health plays an important but limited role in drug research. Furthermore, price controls in OECD countries have already caused a decline in pharmaceutical industry research and development and, thus, the development of new drugs. Jonathan Cohn provides a typical disparagement of the importance of pharmaceutical industry research and design (R&D): ...the most important basic medical and scientific research that leads to major medical breakthroughs usually takes place under government auspices - typically, through grants from the National Institutes of Health. In other words, taxpayers - not drug companies - are the ones financing the most important drug research today. So, even if the pharmaceutical industry did reduce its research and development investment because of declining revenues, what we'd lose probably wouldn't be the next cure for cancer - it would be the next treatment for seasonal allergies, and likely no better than the ones we have already.18 A systematic study conducted by the National Institute of Health (NIH) suggests that the NIH's role is not as large as Cohn suggests it is. The NIH funds a lot of "basic research," and the study noted, "technologies developed in basic research laboratories are nascent, requiring extensive further development."19 It is the pharmaceutical companies that fund that further development. The study also examined pharmaceuticals that had at least $500 million in sales in the U.S. Of the 47 drugs that met that standard, the NIH determined that it had involvement in only four of them. The other 43 included drugs for bacterial infections, diabetes, hypertension, high cholesterol and Hepatitis C - hardly mere "treatments for seasonal allergies."

#### No – private pharma is key. Hogberg 7

David Hogberg 7, Ph.D. is senior policy analyst at The National Center for Public Policy Research in Washington, D.C., Letting Medicare "Negotiate" Drug Prices: Myths vs. Reality, <https://www.nationalcenter.org/NPA550MedicareDrugPrices.html>, DOA: 8-10-17, Y2K

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### AT: R&D Drugs Are Public Funded

#### Private biotech efforts dominate biotech innovation – government and university innovation is theory based and doesn’t build on past innovation.

Tom Stossel of Harvard in 2017 (Tom, the Director of the Translational Medicine Division and Senior Physician in Hematology at Brigham & Women's Hospital, Harvard Medical School in Boston, "Don’t Thank Big Government for Medical Breakthroughs," January 5, 2017, WSJ, <https://www.wsj.com/articles/dont-thank-big-government-for-medical-breakthroughs-1483660786?mg=prod/accounts-wsj>)

The assumption seems to be that the root of all medical innovation is university research, primarily funded by federal grants. This is mistaken. The private economy, not the government, actually discovers and develops most of the insights and products that advance health. The history of medical progress supports this conclusion. Few findings in medical science significantly improved health until the late 19th and early 20th centuries. During that period came breakthroughs such as anesthesia and antisepsis, along with vaccines and antibiotics to combat infectious diseases. The discovery of vitamins and hormones made it possible to treat patients with deficiencies in either category. In America, innovation came from physicians in universities and research institutes that were supported by philanthropy. Private industry provided chemicals used in the studies and then manufactured therapies on a mass scale. Things changed after World War II, when Vannevar Bush, who had led the U.S. Office of Scientific Research and Development during the war, persuaded Congress to increase federal subsidies for science. The National Institutes of Health became the major backer of medical research. That changed the incentives. Universities that had previously lacked research operations suddenly developed them, and others expanded existing programs. Over time these institutions grew into what I call the government-academic biomedical complex. Since then, improvements in health have accumulated. Life expectancy has increased. Deaths from heart attack and stroke have radically decreased, and cancer mortality has declined. New drugs and devices have ameliorated the pain and immobility of diseases like arthritis. Yet the question remains: Is the government responsible for these improvements? The answer is largely no. Washington-centric research, rather, might slow progress. Many physicians have never lacked motivation to develop treatments for diseases. But the government-academic biomedical complex has recruited predominantly nonphysician scientists who value elegant solutions to medical puzzles—generally preferring to impress their influential peers rather than solve practical problems. Vannevar Bush believed that basic research, unrelated to specific ends, was the best approach to scientific progress. How something works became more important than whether it works. Aspirin, for example, came into use even though researchers weren’t sure exactly what made it effective. That approach would never work today. Instead of the messy work of studying sick patients, scientists now prefer experimenting with inbred mice and cultured cells. Their results accrue faster and are scientifically cleaner, but they arguably are less germane to health. Practical innovation requires incremental efforts. But the reviewers of grant applications for medical research are obsessed with theory-based science and novelty for novelty’s sake. They find incrementalism mundane. Consistent with that attitude, a 2003 review published in the American Journal of Medicine found that of more than 25,000 publications in prominent biomedical journals, only 100 even mentioned a medically relevant application of the research. Academic administrators, operating under the delusion that government largess would grow forever, have become entitled. But since the 1980s, funding for the National Institutes of Health has lagged far behind the growth of an aging population in need of medical innovation. The extra $4 billion in the 21st Century Cures Act will have little effect on that financial gap. Today, researchers compete for government grants at increasingly shorter intervals and with diminishing chances of success: Less than 1 in 5 grant applications succeeds. This inhibits risk taking. By contrast, private investment in medicine has kept pace with the aging population and is the principal engine for advancement. More than 80% of new drug approvals originate from work solely performed in private companies. Note that such drug approvals come on average 16 years after the beginning of clinical trials, which typically cost $2.5 billion from start to finish. Even if grant-subsidized academics wanted to create a new drug, economic reality prevents it.

### AT: Academic Research Creates R&D

#### Academic research doesn’t work without the private sector

Robert Kneller of the Department of Intellectual Property in 2010 Department of Intellectual Property, Research Center for Advanced Science and Technology, University of Tokyo, The importance of new companies for drug discovery: origins of a decade of new drugs, Nature Reviews Drug Discovery 9, 867-882 (November 2010), DOA: 8-11-17

The data also show that biotechnology companies rather than pharmaceutical companies tended to undertake early development of innovative university drugs. A comparison of the entries in Table 1 for Uright arrowB drugs with those for Uright arrowP drugs shows that biotechnology companies undertook the initial development of the majority of university-discovered drugs that were scientifically novel (74%) or offered substantial benefit over existing drugs (70%). By contrast, pharmaceutical companies and biotechnology companies shared approximately equally in the initial development of university-discovered drugs that were not priority reviewed, and scientific follow-ons. Small, established pharmaceutical companies contributed to the discovery of seven of the 252 drugs (five of which are for neurology indications). Of these seven, the majority are follow-ons and only one was granted priority review. This suggests that small, established pharmaceutical companies are no more likely than pharmaceutical companies as a whole to discover innovative drugs. The same applies to drug discovery by companies whose main area of business is not pharmaceuticals, nine of whose drugs are included in this analysis (see Supplementary information S3 (box), note 3). Regional trends. The cross-tabulations in Supplementary information S2 (table) summarize the WDE attributions by type of drug, inventing organization and country of origin. Key findings are highlighted in Figs 1,2,3. Interestingly, the overall discovery shares are close to each country's share of the 2005 world pharmaceutical market, except for the UK and Switzerland, which substantially exceed their market shares (see Supplementary information S4 (box), note 1). In all but a few countries, pharmaceutical companies discovered the overwhelming majority of drugs (Fig. 1). The most notable exception is the United States, which accounted for the discovery of nearly half (117.6 WDEs) of the 252 drugs studied. Here, over 60% of the attributed WDEs were for drugs discovered in universities or biotechnology companies. In most other countries, the majority of drug discovery occurred in the in-house laboratories of large pharmaceutical companies (Fig. 1). When considering the number of WDEs discovered outside pharmaceutical companies, the only countries in which biotechnology companies and/or universities made a notable contribution (>1 WDE) are the UK (4.8 WDEs; 1.6 from biotechnology companies), Japan (4.3 WDEs; 2 from biotechnology companies), Israel (3.7 WDEs; 3.2 from universities), the Czech Republic (3.1 WDEs from universities), Germany (2.9 WDEs from universities), Canada (2 WDEs from universities), Australia (2.3 WDEs; 2.1 from universities), France (1.9 WDEs from universities) and Sweden (1.75 WDEs from universities). It is also notable that only in Australia, Canada and Israel did the contribution from universities and biotechnology companies outweigh or approach that of pharmaceutical companies (see Supplementary information S3 (box), note 4). It is probably not a coincidence that in these three countries, and of course also the United States, the proportion of drugs discovered in universities is higher than in other countries. Nearly 80% of drugs discovered in US, Australian and Canadian universities were transferred to biotechnology companies. Biotechnology companies (mainly in the United States) developed about half of the university drugs from outside these three countries, but they tended to develop the more innovative of these products (see Supplementary information S3 (box), note 5). The regional analysis suggests that countries where biotechnology companies and universities transferring to biotechnology companies are active in drug discovery are also countries with high proportions of scientifically or medically innovative drugs. Figure 2 shows that, in the United States, most of the scientifically innovative drugs (Box 1) were discovered in biotechnology companies or in universities transferring to biotechnology companies. The same trend was seen, although on a much smaller overall scale, in Australia and Canada. Elsewhere, only in Switzerland and France did the number of scientifically innovative drugs exceed the number of follow-ons. In every major pharmaceutical country, most follow-on drugs were discovered in pharmaceutical company laboratories. A similar pattern emerges when comparing standard new molecular entities (sNMEs), priority-reviewed new molecular entities (pNMEs) and new therapeutic biologics (NTBs) (Fig. 3).

### AT: R&D Decreasing

#### Gurjyan 17 at the top of our case tells you that the pipelines is being refreshed, meaning that innovation is going up.

#### Innovation is on the rise

Katarzyna Smeitana of McKinsey & Company in 2016 (Katarzyna Smietana, McKinsey & Company, Nature Reviews Drug Discovery 15, 379–380, 2016)

The R&D transformation efforts seem to have resulted in an improvement in the overall pipeline quality, leading to a gradual increase in Phase II and Phase III success rates. The increasing proportion of failing compounds observed in Phase I could be interpreted as a positive trend, suggesting that companies conduct an increasingly thorough early evaluation in order to prevent costly late-stage failures. The Phase II success rate might be slightly inflated in our analysis owing to a growing share of potentially life-saving products being expedited straight to Phase III trials through adaptive trials and breakthrough mechanisms, which is reported as a Phase II success in our methodology. Such an approach carries a risk of a later-stage failure. However, so far, drugs for treating rare diseases — which have frequently benefited from accelerated development pathways — have had a much higher overall success rate from Phase I to approval (29% compared with 10% for drugs for non-rare diseases in the past 3 years, with 73% and 64% success rates in Phase III, respectively). More products are getting approved. It is noteworthy that this apparent improvement in the attrition profile of the aggregate industry portfolio has not been accompanied by a reduction in the overall size of the portfolio. There was a significant slowdown in portfolio growth between 2008 and 2013, but the size of the overall portfolio has increased by a compound annual growth rate (CAGR) of ~6% over the past 10 years from 2,271 novel clinical-stage compounds in 2006 to 3,823 compounds in 2015. This observation led to the prediction in 2012 (Nat. Rev. Drug Discov. 11, 435–436; 2012) that the average number of approved new molecular entities (NMEs) would be around 35 per year in the 5 years to 2016, up from 25 per year on average in the period 2001–2012. In fact, the number went even higher: 41 novel molecules were approved by the FDA's Center for Drug Evaluation and Research in 2014 and 45 were approved in 2015. The industry pipeline is growing in successful areas. After 2013, pipeline growth accelerated predominantly in the areas of recent scientific advances, including a wave of immuno-oncology products, and anti-infectives boosted by commercial successes in the antiviral space. The question remains whether the industry could now be overinvesting in those 'hot' areas. However, the fact that hot spots of innovation are emerging in fields that have long been stagnant, such as cardiovascular disease (for example, proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors) and gastrointestinal diseases (for example, microbiome-based approaches), suggests sufficient pipeline breadth to drive medical advances across therapeutic areas.

### AT: R&D Cheap

#### N0 – R&D is super expensive.

Brandon Arnold of the Washington Examiner in 2017 – Brandon Arnold is the Executive Vice President of NTU. (“Letting the government 'negotiate' with drug companies is just window dressing for price controls,” Washington Examiner, <http://www.washingtonexaminer.com/letting-the-government-negotiate-with-drug-companies-is-just-window-dressing-for-price-controls/article/2628548>, August 12, 2017)//RS

History allows us to look back and see that price controls regularly produce negative consequences, but are still believed by some to be a saving grace. To be perfectly clear, price controls in the United States have never worked. Just look at historical examples in different industries: gasoline shortages in the 1970s, rolling electrical blackouts in California in the early 2000's, and fewer benefits for consumers because of debit card transaction fee caps. No matter the industry, the outcome of price controls is always predictable: The seller and the buyer are always worse off. It is foolish to believe that price controls on prescription drugs would bring forth a different result. While some observers enjoy demagoguing pharmaceutical companies for charging high prices, this narrative ignores the costs and risks associated with drug development. In fact, only about 30 percent of drugs actually produce a positive return on investment, which means that nearly 70 percent of drugs are unprofitable for pharmaceutical companies. This is because the research and development process is incredibly costly with both time and capital. The entire process from discovery to market takes an average of 15 years. In addition to the long regulatory process, the cost to develop a drug has more than doubled in the last 10 years to $2.6 billion. These high development costs are driven higher by increasingly stringent Food and Drug Administration regulations, which reduce competition and ultimately lead to higher prices for consumers. If price controls are imposed, it would be even less appealing for drug manufacturers to bring riskier drugs to market since prices will be below equilibrium. Investors will move resources like capital or researchers into other areas which will produce a greater return on investment. Further, economists estimate that a 40 percent price ceiling on drugs will lead to a 30-60 percent reduction in R&D for new drugs. Profits motivate companies to reinvest those earnings back into other areas of R&D for new life-saving medications. More drugs mean a greater opportunity to make money and provide desperate patients with access to medicine. Less money means less discovery, innovation, and fewer new drugs for consumption for those in need.

### AT: Profits aren’t reduced / Don’t matter

That’s not what we’re talking about. Profits and revenues are two different things. Sood 17 explains that a company’s profits are the difference between revenues received and costs of good sold. That means that their argument about profits being unaffected is unresponsive to our whole case bc even if they prove that profits stay the same revenue does not.

Neeraj Sood 17 (Neeraj Sood, 06-2017, USC, https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC\_Flow-of-MoneyWhitePaper\_Final\_Spreads.pdf, accessed 11-29-2018) CC

**A company’s** gross **profits are the difference between revenues received and costs of goods sold**; gross margin is this amount expressed as a percent of revenues. For example, gross profits for wholesalers are revenues received primarily from pharmacies less payments made primarily to manufacturers. Some of these gross profits are spent on other business expenses such as marketing, R&D, depreciation, interest, and taxes. What remains after subtracting these expenses is net profits, which accrue to the shareholder owners of the firm. We estimated gross and net margins as a fraction of net revenues for all companies using information from their 2015 SEC filings (forms 10K and 20F). To the extent that SEC filings allowed, we isolated financial data for US pharmaceutical operations and for the sector of interest. For example, for a company with both specialty pharmacy and PBM divisions that report separate financial results for each, we used PBM division data to estimate margins for the PBM business. In some cases, it was not possible to isolate the results of pharmaceutical business activities—for example, health insurers do not report financial results for their pharmaceutical claims activity separate from medical claims activity. In these cases, our margin estimates include activities of other types of business. When data did not permit a US-specific margin to be calculated, we used the global margin. (See Appendix Section A for more detail.) We also calculated separate gross margins for branded and generic drugs for each sector. For manufacturers, we categorized each company as either a branded or generic producer, and calculated separate gross and net margins for each.13 For pharmacies, we used the National Average Drug Acquisition Cost (NADAC) and the National Average Retail Price (NARP) datasets from the Centers for Medicare and Medicaid Services (CMS) for 2013, and calculated gross margins as described in Appendix Section B, analyzing generic and branded subsamples separately. The SEC filings of wholesalers and insurers do not report results of generic and branded activity separately, so we could not estimate drug-type specific margins for them. Instead, we used other published estimates of gross margins specific to brand and generic drugs.14,15

### AT: Drop in Revenue = Sunk Cost = Doesn’t matter

It definitely does matter ; the Atkinson 18 evidence at the top of the case is very clear = there is a one to one correlation between revenues and RND expenditures, when there is a drop in revenues there’s a drop in RND ; that’s definitely not a sunk cost. But even if it is a sunk cost, companies don’t PERCEIVE it that way and that’s why they cut beneficial things that don’t make profit.

### AT: Other countries do it better

If that was true, the US wouldn’t make up 74% of the worlds innovation and the top 10 most charitable organizations in the world wouldn’t all be US pharma companies. And, the AFF uniquely harms other countries abilities to appropriate profits ; Ubel 14 finds that pharmaceutical products are cheaper abroad because companies know that they can make money in the US market and are thus willing to tolerate smaller profit margins in other countries. But even if you don’t believe that, the EPR finds in 2017 that the reason that European R&D is coming back is because of meaningful R&D incentives which my opponents can’t prove will happen.

#### [1]The plan would cause changes in how pharma negotiates abroad---limits access.

Peter Ubel 14, physician and behavioral scientist at Duke University., 4-18-2014, "People In The US Are Footing The Bill For Switzerland's Medical Care," Forbes, https://www.forbes.com/sites/peterubel/2014/04/18/the-real-health-care-subsidy-problem/#7fa6c9622881

People have criticized The Affordable Care Act for amounting to a large transfer of wealth, from wealthy Americans to those not as well off. But the real transfer of wealth has been from United States to other developed nations, whose healthcare costs we have subsidized for many years by paying so generously for many of our healthcare services. No better example of this comes to mind than the price we pay for pharmaceuticals in the US versus elsewhere. Below is a picture of what we pay for brand-name drugs here compared to peer nations. Pharmaceutical products are cheaper abroad in part because companies know they can make money in the US market, and thus are willing to tolerate smaller profit margins in other countries. In effect, therefore, we are subsidizing the cost of healthcare in those other countries. And not just any old countries. Some of the richest countries in the world – like Switzerland and Germany. If we negotiated pharmaceutical prices more aggressively here in the US, the pharmaceutical industry might be more reluctant to accept lower prices elsewhere. More likely, lower prices in the US would mean lower profits for the industry. This would undoubtedly have an effect on the willingness of pharmaceutical companies to invest in new products. Nothing promotes research spending better than the promise of future profits. It is worries about such research incentives that have caused some people to argue against negotiating lower prices with pharmaceutical companies. To lower profit margins, they contend, would be to slow down medical progress.

#### [2]That’s because their governments have federal R&D incentives which the Aff can’t fiat.

European Pharmaceutical Review in 2017 (European Federation Of Pharmaceutical Industries and Associations (Efpia), xx-xx-xxxx, European Pharmaceutical Review, A strong EU IP framework guarantees future innovation for patients, https://www.europeanpharmaceuticalreview.com/news/51548/strong-eu-ip-innovation/, accessed 11-18-2018) ED

Thanks to this meaningful incentives regime, the pharmaceutical industry has invested more than €30 billion in Europe every year since 2012, leading to the development of many important advances in medical treatment. This is why it is critical that as the [European Commission](https://ec.europa.eu/commission/index_en) conducts its review of pharmaceutical rewards and incentives, it prioritises continuing to foster and protect innovation and to drive investment in medical research in areas of unmet medical need. With IP-intensive industries accounting for around one third of all jobs in Europe, Member States and citizens, as well as the life science industry, share a strong interest in fostering an IP system that supports innovation both domestically and globally. The incentives and rewards system also strengthens the EU’s competitiveness in global trade and defines it as an attractive investment location for the most innovative industries. This is a framework that has placed the EU at the forefront of pharmaceutical innovation and among the top knowledge-based economies, whilst simultaneously creating wealth and jobs.

### AT: Mergers

#### Mergers *increase* innovation

Ringel 17 (Michael S, Boston-based senior partner of The Boston Consulting Group and global leader of its research and product development topic, 7-24-2017, "A new wave of pharma mergers could put innovative drugs in the pipeline," STAT, https://www.statnews.com/2017/07/24/mergers-pharma-drug-development/)

A new wave of pharmaceutical industry mergers may be on the horizon, driven in part by the $1.3 trillion in overseas cash that U.S. corporations currently hold. If policymakers provide a tax holiday on repatriation of these funds, some experts say that U.S. pharmaceutical companies would be flush with cash and could likely spend a meaningful portion of this windfall on mergers. While big mergers could have many impacts — on employment at home and abroad, competition, and drug prices, to name a few — one of the most important would be the effect on research and development productivity and innovation. Analysts have tackled this topic before. Their work has been of mixed quality and, perhaps not surprisingly, has yielded mixed results. Pundits at the Institute for Competition Economics in Dusseldorf, Germany, for example, claimed last year in a Harvard Business Review article that previous drug company mergers had “substantially” reduced R&D and innovation, not only at the merging firms but at the merging firms’ competitors as well. Another team, this one from Duke University, the University of Toronto, and Baruch College/CUNY, reached a different conclusion with its data-driven approach. The team’s review of hundreds of mergers and acquisitions from 1985 to 2009, published in Loyola University Chicago Law Journal, indicated that the correlation between merger and acquisition activity and FDA approvals of new drugs is “moderately positive,” both at an industry level and individual firm level. Who’s right? Are those in need of new lifesaving drugs harmed by consolidation in the pharmaceutical industry, or are they helped? We believe that one of the main problems with much of the previous research in this area has been an over-reliance on anecdotal reporting rather than employing systematic data analysis. Even when such analysis has been done, researchers have sometimes focused on research and development spending or patent activity as benchmarks of success, as if these metrics are indicators of — or even synonymous with — actual product innovation. But they aren’t necessarily the same. Spending is just an input, measured in dollars or some other currency. The same is true with patents. There is a long distance between the laboratory where new compounds are discovered and the corner drugstore where medicines are purchased. We sought to address this uncertainty by focusing on research and development productivity: the amount of innovation created as measured by the value of new FDA-approved compounds reaching the pharmacy, relative to input. After all, what matters to patients is the creation of quality medicines, not how much a company spends on research and development or the number of patent applications it files. To determine whether mega-mergers benefit patients, we looked at what happened to research and development productivity in all of the major mergers going back to 2001, including the last big wave in 2009 that brought together Merck & Co. and Schering-Plough, Pfizer and Wyeth, and Roche and Genentech. As expected, the results varied from year to year and company to company. But our report in Drug Discovery Today showed that 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.

### AT: Drugs are already Developed, need to focus on America

That’s just blatantly false ; the Wolf 14 evidence in case is very clear when it says that 36% of the innovation pipeline is making drugs to combat neglected diseases right now, which is why we need to sustain innovation ; that’s literally why the Hansman evidence says that consistent innovation can save 10 million lives every year.

### AT: Me-Too Drugs

#### Turn: Me-Too drugs are essential for effective and affordable healthcare and R&D for a laundry list of reasons.

Wertheimer 09 (Albert I. Wertheimer, Ph.D., MBA, is a professor of pharmacoeconomics and the director of the Center for Pharmaceutical Health Services Research at the Temple University School of Pharmacy in Philadelphia, and Thomas M. Santella is an assistant to the President and CEO at Lannett Company, a manufacturer and distributor of generic pharmaceuticals. He previously served as the research coordinator for the Center for Pharmaceutical Health Services Research at the Temple University School of Pharmacy in Philadelphia, “Pharmaceutical Evolution: The Advantages of Incremental Innovation in Drug Development,” April 2009, https://cei.org/sites/default/files/Wertheimer%20and%20Santella%20-%20Pharmaceutical%20Evolution.pdf)

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

### AT: R&D Moves to China

#### The world without price controls is comparatively better because its profitable to invest in BOTH US and Chinese markets. Two markets for innovation is better than one.

#### R&D in a different country without price controls would arguably be worse. Otherwise pharma companies would focus on those countries now instead of the US. This could be for many reasons such as being less economically robust, having a less educated populous on average, etc.

### AT: R&D Moves to Mexico

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### AT: Levy

#### The most likely scenario is that the US will implement a price control much greater than 20%.

Trump wants to implement a price control mimicking other countries, and OECD countries with pharmaceutical price controls have set them around 67%. The part of their statistic our opponents don’t read you says anything above a 20% price control will cause revenues to plummet, and this is happening now as pharma companies in these price-controlled countries lose about $18 billion to $20 billion annually in sales according to the Department of Commerce in 2004. Thus, the most likely price control in the US will be around 67% and cause revenues to plummet by tens of billions of dollars annually.

<https://2016.trade.gov/td/health/DrugPricingStudy.pdf>

https://pdfs.semanticscholar.org/165a/6bd0fe11429735b9f49c7aff5de39023b183.pdf

### AT: Large Profit Margins

#### The pharmaceutical industry actually has a very small profit margin.

John Lamattina of Forbes in 2018 (John Lamattina, xx-xx-xxxx, Forbes, About Those Soaring Pharma Profits, https://www.forbes.com/sites/johnlamattina/2018/01/23/about-those-soaring-pharma-profits/#3c2b80b03f9d, accessed 11-18-2018) ED

That’s a pretty good speech, but in an era of fake news, how accurate are Read’s comments? Actually, available data\* are pretty supportive. The average return on equity for key industries from 2014 – 2016 shows that biopharma’s profits stand at 16.2%, significantly lower than Computer Sciences (31.6%), Beverages (27.4%), Aerospace/Defense (23.0%), and Trucking (19.1%) while modestly higher than Software System/Applications (15.2%) and Healthcare Support Services (14.4%).

### AT: Stocks Went Up After Trump Announcement

#### David Borun finds in May that the reason that stocks went up after they briefly decreased was because Trump’s plan isn’t comprehensive in including the biggest fears of investors, like letting Medicare negotiate.

[1]David Borun May 11, 2018 (May 11, 5-11-2018, NASDAQ, Trump Announces Plan to Reign In Drug Prices and Pharma Stocks Rally., https://www.nasdaq.com/article/trump-announces-plan-to-reign-in-drug-prices-and-pharma-stocks-rally-cm962844, accessed 11-9-2018) ED

As the president began speaking, the stock prices of the biggest drug companies did in fact briefly decline, only to reverse course and ended the day broadly higher. The reason?&nbsp; The plan doesn't seem to be "taking them on" at all. The biggest fear was that the new plan would include provisions for Medicare to negotiate directly with drug companies on price. Roughly 30% of the dollar value of prescriptions filled in the U.S. is paid for by Medicare, making the U.S. government the single biggest customer for pharmaceuticals by a wide margin.&nbsp; Drug companies have been staunchly opposed to the idea of direct negotiation as it would almost certainly damage profits. Once it was clear direct negotiation wasn't on the agenda, investors snapped up shares of the biggest U.S. drug makers, including Abbvie ( [ABBV](https://www.zacks.com/stock/quote/ABBV?q=abbv) ), Amgen ( [AMGN](https://www.zacks.com/stock/quote/AMGN?q=amgn) ) and Merck ( [MRK](https://www.zacks.com/stock/quote/MRK?q=mrk) ), each of which finished the day 2% or more above their mid-speech lows.

## AT: Access Defense

### AT: UCLA// adjust prices due to buying power of customers

The WHO evidence tells you that even small price hikes are deadly because people can barely afford medicines in the developing world. That, in conjunction with cutting off drug donations, means that developing countries are put in a lose-lose scenario.

### AT: just use it to make a foothold = won’t cut

Just because they make a foothold in these countries doesn’t mean it’s a bad thing. We tell you that price concessions help millions afford drugs and drug donations help build local health systems. And, we’re not saying that everything just goes away, we tell you that there would be a substantial rise in prices and a substantial decrease in drug donations, all of which puts millions at risk.

## AT: Drug Donations Defense

### AT: Donations Bad

No, their evidence is super outdated. The World Health Organization only started to heavily regulate drug donations after 2010 ; And, Bero 10 finds that the WHO guidelines have been very successful in the case of drug donations from pharmaceutical companies. The only pitfalls of drug donations come from donations during emergencies, not normal times.

Bero 10:

https://www.who.int/bulletin/volumes/88/12/10-079764/en/

### AT: Used/Expired drugs, easier to donate

1] Better to donate some drugs than none at all

2] The bigger pharma companies don’t do that because they know there will be backlash

3] The WHO regulates drug donations and mitigates this problem (((Bero 10)))

### AT: Tax Deductions

This just means that its beneficial to send drugs, so this defense is barely mitigatory. We tell you no matter what benefits drug donations have to pharma companies, profits and revenues will always come first which is why pharma will cut those programs when they are forced to.

## Miscellaneous

**AT Research and Development Budgets Small**

1. **The** [**BPD**](https://www.biopharmadive.com/news/phrma-research-development-spending-industry-report/529943/) finds that pharmaceutical companies spent 21% of their revenue on R&D, and that number is increasing as they are facing more scrutiny for high prices.

**AT Tax Breaks Lead to R and D**

1. Tax breaks aren’t enough to make up for the billions lost from price controls - Europe had tax breaks yet price controls still destroyed innovation

**AT Public > Private Sector**

1. The private sector is super important
   1. [**Policymed**](https://www.google.com/url?q=https://www.policymed.com/2011/02/nejm-the-private-sector-discoveries-account-for-79-90-of-pharmaceutical-products.html&sa=D&ust=1542410505984000&usg=AFQjCNHcyx31b1qs0-mMQg3yiH2eWfWhig) finds that 79%-90% of discoveries came from the private sector. Their evidence is only about drugs it doesn't take into account if these drugs were new molecular entities.

**AT Companies Lose 50% of Revenue and Still Innovate (Emanuel of UPenn)**

1. Probably true for larger firms but the smaller ones we talk about would be cut out fast
2. This is just an opinion article and he just asserts it, no math behind it at all prefer the empirical examples and research we give.

**AT Europe has more Innovation (Light of Stanford)**

1. [**Lowe of Hendrix College**](https://www.google.com/url?q=https://blogs.sciencemag.org/pipeline/archives/2010/11/09/where_drugs_come_from_by_country&sa=D&ust=1542410505983000&usg=AFQjCNGRbTvNDcXF9XagoGSlGyjkVrImJg) - Europe innovated more because they copied drugs. The US makes newer drugs so you need more $ to innovate compared to copy stuff

**AT Affordability Prerequisites Innovation**

1. Generics are solving what we need is the new drugs to cure
   1. When resistance develops we need something right?
2. [**Jena of Harvard**](https://thehill.com/opinion/healthcare/369727-us-drug-prices-higher-than-in-the-rest-of-the-world-heres-why) - Health rises short-term fall long term. $50,000 to healthcare and decrease in life expectancy by 0.7 years
   1. The US also impacts everyone and does stuff such as change developing nations prices

**AT Me too drugs.**

1. [**Bloom of the American Council on Science and Health**](https://www.acsh.org/news/2012/05/10/me-too-drugs-are-innovative-too) - companies tweak formulas to increase effectiveness.
   1. More replica drugs decrease the cost by 50%

1. 53 NASEM Report, supra note 13, at 34-35. [↑](#footnote-ref-1)
2. 54 For a summary of several countries' approaches, see id. at 82-86. [↑](#footnote-ref-2)