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

Contention 1 is Innovation.

Freeman 17 of the Hill explains that government interference on drug prices isn't needed, the private sector is already coming up with ways to lower prices.

Technological advancements, competition, and diagnostics improvements ensure that they are stable.

Winegarden 17 of Forbes furthers that because price controls limit business revenues, decreasing the return to investors, investment into these companies will decrease.

This is incredibly damaging to small biotech firms as Grabowski 17 of Health Affairs finds that many medical startups become large firms because they have a unique incentive to develop lucrative new treatments to grow their business. Start-ups don't begin with any money of their own since they don't have revenue yet, so they can only fund research with venture capital and early investment. However, the decreased return on investment resulting from decreased revenue makes external investors too nervous to invest in startups.

As a result, Easton of STAT News corresponds that investment would flow into different sectors, such as technology, with the implementation of price controls.

Small biotech is the foundation of innovation as Alsever 16 of Fortune explains that Big Pharma rarely conducts early scientific research anymore. Increasingly, the big players leave that to startups, then later cut deals to acquire or license the drugs.

Unfortunately, Yeoh '17 of the University of Nottingham explains that small businesses, because they lack this political power, feel the brunt of price controls.

Commented [1]: https://www.cnbc.com/2018/03/26/big-pharmas-scramble-to-invest-in-start-ups-to-fuel-innovation.html

Commented [2]: 64% of new medicine in the past 5 years are from small companies

Overall, Lichtenberg 16 of the MEI ultimately concludes that a 10% decline in drug prices would cause at least a 6% decline in pharmaceutical innovation. Declining private R&D is dangerous, as Stossel 17 of the American Enterprise Institute contextualizes that 85% of approved drugs since 1988 arose from the private sector.

Even if new drugs are developed, Cockburn 14 of the National Bureau of Economics Research furthers that price controls more than doubles the delay in launching new drugs.

The Impact is twofold.

First, US Medical Costs

Paranacis of the HINJ in 2014 finds that spending $1 on innovation, reduces other healthcare expenditure by $7.20.

Second, Developing Nations

Hooper of the The Library of Economics finds that high prices in America justify R&D spending allowing other underdeveloped nations in Africa and Latin America to charge significantly less for new pharmaceuticals.

Overall, the National Bureau of Economic Research 14 reports that American creation new therapies through R&D has accounted for a 73% increase life expectancy across the world.

Specifically, Bezerow of the American Council on Science and Health quantifies that since 2000 the American Pharmaceutical Industry has saved over 20 million lives.

Contention 2 is Humanitarian Aid.

Ford of the University of Geneva explains that 2 billion people around the world do not have access to life saving drugs that could greatly increase their quality of life.

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Thankfully, Gray of DEVEX 16 reports that in the status quo companies donate medicines preemptively to humanitarian crisis areas. However, Gray furthers that because the medical assistance needs to be quickly, and reliably prepared the cost is very high.

Burns of Pacific Standard quantifies that pharmaceutical companies donated more than 6.1 billion dollars' worth of medicine.

Unfortunately, there are three reasons affirming undermines this.

First, Positive Public Relations

Hale of Health Affairs finds that drug donations are not profitable for pharmaceutical companies.

Although it is not profitable, Hamblin of the Atlantic 16 writes that the PR pressure of keeping prices high for some is the reason that pharmaceutical companies donate to others like the poor in developing countries.

Third, Cutting Losses

Baer of the University of Georgia finds that, reducing the cost of drugs in the US would "push pharmaceutical companies to stop supplying pharmaceutical drugs to poorer, and developing countries." This is because Baer finds that they would be unable to recoup the fixed costs of research for the drugs.

The impact is Lives

The Global Alliance for Patient Access 17' reports that millions of low-income people around the world depend upon the donated drugs from pharmaceutical companies.

Gorney 17 of National Geographic explains that vaccines are crucial to saving lives in many developing countries, but unfortunately the largest obstacle to this is price.

Thankfully, through programs like drug donations The Gavi Vaccine Alliance 17' was able to donate more than 300 million vaccines across 73 countries, saving the lives of 20 million.

Thus, we negate.

Weighing Overview

Frontlinz

Innovation

AT Innovation Slowing Down RN

1. **The reason why innovation is slowing down rn, according to Sullivan 18 is that the cost of R&D and the approval of new drugs is skyrocketing such as to the point where it is $2.6 billion dollars to get one new drug approved. If the root cause and reason why innovation is slowing down is cost, you cant implement price controls and lower the cost efficiency even more.**

Sullivan Policy & Medicine 18, 5-6-**2018**, "A Tough Road: Cost To Develop One New Drug Is $2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less Than 12%," https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html//ZS

Developing a new prescription medicine that gains marketing approval is estimated to cost drugmakers $2.6 billion according to a recent study by Tufts Center for the Study of Drug Development. This is up from $802 million in 2003—equal to approximately $1 billion in 2013 dollars, **and thus a 145 percent increase in the ten year study gap**. Furthermore, while the average time it takes to bring a drug through clinical trials has decreased, the rate of success has gone down by almost half, to just 12 percent. Tufts breaks down its $2.558 billion figure per approved compound to include approximate average out-of-pocket cost of $1.4 billion and time costs (the expected returns that investors forego while a drug is in development) of $1.2 billion. Furthermore, the estimated cost of post-approval research and development of $312 million "boosts the full product lifecycle cost per approved drug" to close to $3 billion. R&D costs include studies to test new indications, new formulations, new dosage strength and regimens, and to monitor safety and long-term side effects in patients" as required by the FDA as a condition of approval. Tuft's analysis was developed from information provided by 10 pharmaceutical companies on 106 randomly selected drugs that were first tested in human subjects anywhere in the world from 1995 to 2007. "Drug development remains a costly undertaking despite ongoing efforts across the full spectrum of pharmaceutical and biotech companies to rein in growing R&D costs," stated Joseph A. DiMasi, director of economic analysis at Tufts CSDD and principal investigator for the study. "Because **the R&D process is marked by substantial technical risks, with expenditures incurred for many development projects that fail to result in a marketed product, our estimate links the costs of unsuccessful projects to those that are successful in obtaining marketing approval from regulatory authorities."**

AT “Me Too drugs”

1. **It is big medicine not the small biotech companies like we talk about that are doing me too drugs, this is because they need to be new in order to make it on the market. Their response is not responsive.**

AT Public> Private

1. **Stoessel 17 of AEI finds that 85% of all new drugs approved came from the private sector.**
2. **Labrie 14 of the IEDM finds that the public sector only does really basic research, and is not the truly new and innovative research like what we talk about.**

Thomas Peter 17, 1-4-2017, "Removing barriers to medical innovation," AEI, http://www.aei.org/publication/912939///ZS

Truth be told, however, in this era private industry, rather than the GABC, has progressively become the dominant source of new medical products. By 1990, corporate investment in medical research had exceeded that of the NIH, and it is now over twice as large. Three separate analyses concluded **that 85% of the drugs approved by the FDA since 1988 arose solely from research and development performed within the industry**. An important fact to remember about medical innovation is that, unlike engineering advances informed by physics and chemistry, it relies on the far more uncertain underpinning of biology. Although insufficient information is one reason for this uncertainty, the dominant problem is the biological variability that evolution has programmed into us. Highly mutable micro-organisms dominate our world and use the components of our bodies to colonize and sicken us. If our responses were static and predictable, these invaders would have eliminated our species eons ago. The liability of this unpredictability is that drugs that seem promising in the laboratory or in inbred animals more often than not fail in clinical trials. As a result, the basic science discoveries championed by Vannevar Bush, though extremely valuable in some ways, are not reliable or straightforward guarantees of medical innovation. Regardless, the GABC continues to pour money into the pursuit of basic science, often in the name of medical innovation, for a number of cultural and economic reasons.

Yanick **Labrie** 14, 9-3-2014, "What Role Do the Public and Private Sectors Play in Pharmaceutical Innovation?," IEDM, https://www.iedm.org/50137-what-role-do-the-public-and-private-sectors-play-in-pharmaceutical-innovation//ZS

More recently, economists from Tufts University in Massachusetts traced the history of the development of the 35 most important drugs and drug classes. While **the public sector plays a prominent role in basic research, the private sector was nonetheless responsible for major advances in basic science** in 20% of these drug classes. Moreover, it deserves credit for major progress in applied science in 97% of the drug classes, and in 80% of them when it comes to improvements in the clinical applications of drugs or their manufacturing protocols.13 Drugs belonging to the class of beta blockers, used to treat various cardiovascular diseases, are a clear example of the importance of the role of the private sector in pharmaceutical innovation. After some major breakthroughs in the field of cell biology at the University of Georgia in the 1940s, R&D efforts were pursued for a number of years in private sector companies, in particular at Imperial Chemical Industries (now part of AstraZeneca) and at Eli Lilly. This extensive work culminated in the creation of a new therapeutic class starting in the early 1960s.

AT ^ Generic Competition

1. **Junoy of the NCBI found that because generic drugs are made by small businesses, and price controls decrease the profitability of drugs, small businesses can't afford to enter their drugs to the market, this is crucial since Junoy empirically found that generics where higher prices in European countries that implemented price controls.**

Puig-**Junoy** J xx, xx-xx-xxxx, "Impact of European pharmaceutical price regulation on generic price competition: a review.," No Publication, https://www.ncbi.nlm.nih.gov/pubmed/20515079//ZS

Although economic theory indicates that it should not be necessary to intervene in the generic drug market through price regulation, most EU countries intervene in this market, both by regulating the maximum sale price of generics (price cap) and by setting the maximum reimbursement rate, especially by means of reference pricing systems. We analyse current knowledge of the impact of direct price-cap regulation of generic drugs and the implementation of systems regulating the reimbursement rate, particularly through reference pricing and similar tools, on dynamic price competition between generic competitors in Europe. A literature search was carried out in the EconLit and PubMed databases, and on Google Scholar. The search included papers published in English or Spanish between January 2000 and July 2009. Inclusion criteria included that studies had to present empirical results of a quantitative nature **for EU countries of the impact of price capping and/or regulation of the reimbursement rate (reference pricing or similar systems) on price dynamics, corresponding to pharmacy sales, in the generic drug market. The available evidence indicates that price-cap regulation leads to a levelling off of generic prices at a higher level than would occur in the absence of this regulation.** Reference pricing systems cause an obvious and almost compulsory reduction in the consumer price of all pharmaceuticals subject to this system, to a varying degree in different countries and periods, the reduction being greater for originator-branded drugs than for generics. In several countries with a reference pricing system, it was observed that generics with a consumer price lower than the reference price do not undergo price reductions until the reference price is reduced, even when there are other lower-priced generics on the market (absence of price competition below the reference price). Beyond the price reduction forced by the price-cap and/or reference pricing regulation itself, the entry of new generic competitors is useful for lowering the real transaction price of purchases made by pharmacies (dynamic price competition at ex-factory level), although this effect is weaker or non-significant for official ex-factory prices and consumer prices in some countries. When maximum reimbursement systems such as reference pricing or similar types are applied, pharmacies are seen to receive large discounts on the price they pay for the pharmaceuticals, although these discounts are not transferred to the consumer price. The percentage discount offered to pharmacies in a country that uses a price-cap system combined with reference pricing is positively and significantly related to the number of generic competitors in the market for the pharmaceutical (dynamic price competition at ex-factory level).

Cut Cardz

Contention 1

Freeman

Robert A 17, 5-24-2017, "The myth of sky-high drug prices," TheHill, https://thehill.com/blogs/pundits-blog/healthcare/334937-the-myth-of-sky-high-drug-prices//ZS

Government interference on drug prices isn't needed — **the private sector is already coming up with ways to bring costs down**. Advances in diagnostics and personalized medicine have improved our ability to deliver the right treatment, to the right patient, at the right time. That reduces waste and inefficiency by avoiding treatments that will not work for specific patients. **Insurers are also striking "value-based pricing" agreements with drug companies.** An insurer pays the market price for a drug, but if that drug does not perform as expected, the drug company has to pay back some or all of that price in the form of a rebate. For instance, Harvard Pilgrim, an insurance company, requires Amgen to provide a full refund if one of Harvard Pilgrim's customers suffers a heart attack or stroke while taking Amgen's cholesterol-lowering medicine**. These deals prevent insurers and patients from paying hefty fees for medicines that are only marginally effective.**

Winegarden

Wayne Winegarden xx, xx-xx-xxxx, "Price Controls Will Reduce Innovation and Health Outcomes," Forbes, https://www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduce-innovation-and-health-outcomes/?fbclid=IwAR0zLXnIMWA3_4L_ZGk3hdiLU-C8D3qypFkvrk31K_Z5oCFdSAk_Bpq1lc8#6f4249cf63a6//ZS

While inapplicable to most patients, **the minority of patients** who take innovative medicines that are still on patent (e.g. the medicines at the frontier of the pharmaceutical market) **would be impacted by the proposed price control schemes.** And, just like the example of **price controls** on doctors**, the adverse consequences would be, on net, very costly for the U.S. health care system. The R&D process for innovative drugs is lengthy, requires billions of dollars in outlays** ($2.6 billion as of 2016), and is fraught with large risks. **Price controls make it more difficult for manufacturers to recoup this cost of capital, diminishing the incentives to innovate and bring new medicines to market**. Importantly, **the introduction of new drugs has been essential to improving the quality of health care delivered.**

Garbowski

Henry Grabowski 17, 6-2-2017, "Drug Prices And Medical Innovation: A Response To Yu, Helms, and Bach," No Publication, https://www.healthaffairs.org/do/10.1377/hblog20170602.060369/full///ZS

Essentially**, the authors imply that the US price 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. **The Particular Danger To Start-Ups If The United States Moves Toward International Prices It is also important to recognize that over the past several decades, hundreds of start-ups have emerged in the biopharmaceutical industry, backed by venture capital firms and other early investors that are concentrated in the United States**. A few of these start-up companies have evolved into significant entities based on the development of important new therapies, while many others have disappeared given the high failure rate of new drug candidates. A number of the companies on Yu, Helms, and Bach's list are relatively young companies that illustrate this phenomenon; for example, Amgen, Biogen, Celgene, Gilead Sciences, and Cephalon (now a division of Teva) were start-ups in the recent past. **Obviously, a new start-up company has no revenues to use for research and development spending, so it must entice investors to support its research and development efforts. US policies designed to decrease prices toward those that prevail abroad would have particularly adverse consequences for young start-ups that invest in uncertain early-stage research.** Venture capital firms do not restrict their activities to investments in new drugs and medical technologies, but also invest in web-based applications, new and improved energy sources, advanced scientific instruments, and many other competing opportunities. If expected returns in start-up biopharmaceutical companies are reduced, early-stage investors will look elsewhere for returns. **Established companies also respond to these same pressures. If the return to pharmaceutical research and development is reduced, they will be led to seek other investments by reducing pharmaceutical research and development spending or will return money to shareholders (through higher dividends or share repurchases) so that the shareholders can invest their money elsewhere.** In summary, the authors fail to address the dynamic nature of research and development investments and the expected consequences for future global drug innovation that would occur from downward pressures on US drug prices to levels prevalent abroad. Rather, the authors look at the geographic distribution of revenue from products already on the market and ask whether the domestic revenues from the US price premiums exceed global research and development investments. This is a meaningless exercise from the perspective of assessing policy issues relating to drug prices, research and development investments, and future global biopharmaceutical innovation.

EaStOn

Robert J. Easton 18, 1-22-2018, "Price controls would stifle innovation in the pharmaceutical industry," STAT, https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry///ZS

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.

Alsevor

Jennifer Alsever 16, 5-13-2016, "Big Pharma Innovation in Small Places," Fortune, http://fortune.com/2016/05/13/big-pharma-biotech-startups///ZS

Giants like Pfizer (PFE, +1.31%) have tried to become more entrepreneurial, and some behemoths have beefed up R&D. **Yet rarely do they conduct early scientific research anymore.** Increasingly, the big players leave that to startups, then later cut deals to acquire or license the drugs. "**Biotech is becoming more important than ever to Big Pharma and becoming the fuel source for their drug pipelines,"** says Nicholson, who once scouted for such acquisitions at Merck. Small companies received $5.6 billion in upfront licensing payments in 2014, double the prior year, according to the trade group BIO. Small companies offer the classic high-risk, high--reward dichotomy: a lot of the former, and handsome payouts in the case of the latter. Tony Coles, who spent 22 years at Bristol-Myers Squibb (BMY, -1.49%) and Merck, walked away with $62 million after serving as CEO of Onyx Pharmaceuticals, which was acquired by Amgen (AMGN, +1.37%) in 2013 for $9.7 billion. (Coles has since launched another startup.) Former Amgen executive Terry Rosen started Flexus Biosciences and sold it 17 months later for $1.3 billion. (His share was undisclosed.)

Barret

No Author xx, xx-xx-xxxx, "," No Publication, https://www.ipi.org/docLib/PR-184-DrugReImport-3.pdf-OpenElement.pdf//ZS

To evaluate the full effect of the proposed policy, we need to compare the difference between the number of drugs in the pipeline in a given year under the baseline assumption versus the number of drugs in the pipeline under the price control policy.17 This is accomplished by calculating the total number of lost drug years of R&D spending. Under the baseline assumption, a drug that successfully completes clinical trials represents eight years of R&D expenditures. A drug abandoned for economic reasons due to the price control policy in the fourth year of clinical trials represents a loss of four drug years of R&D spending. Table 4 illustrates this difference by year and the associated difference in R&D spending. The key result of this exercise is that lost R&D spending, while moderate in the first year of a price control or reimportation policy, becomes substantial very quickly, as the cumulative effect of abandoned drug years grows with each new cohort entering development. The results illustrate that in 2005 the U.S.-wide losses in R&D spending amount to $310.9 million (in 2000 dollars), but grow quickly as new cohorts of drugs enter development and reach $2.6 billion by **2013. In the 12 years following the implementation of a price control policy, R&D spending by pharmaceutical and biotechnology firms would fall by $14.8 billion, in net present value terms.**

Yeoh

Tricia Yeoh 18, 10-29-2018, "Column," No Publication, http://www.thesundaily.my/node/427968//ZS

Policies like these hit the small businesses the worst, because they do not have the resources, infrastructure or economies of scale to adapt as quickly as big businesses. They do not have the same connections needed either to voice out these concerns to policymakers, whether it is to big law firms, business chambers or politicians. **Thousands of stories like these mean that the country loses as much as US$12 billion a year on cumbersome business regulations, economic opportunities that we would have otherwise gained. The poorest of the poor are affected, and worse, it stifles their spirit of enterprise and efforts to get themselves out of poverty.** The signs are already showing. The SME growth rate fell by 20% from 2011 to 2015 (7.3% to 6.1%), and worse, the total early-stage entrepreneurial activity rate – or the start-up rate in short – fell by almost 50% from 2010 to 2016 (4.96% to 2.9%).

Lichtenberg

No Author xx, xx-xx-xxxx, "," No Publication, https://www.iedm.org/files/cahier0216_en.pdf//ZS

A number of studies have provided evidence for the hypothesis that, in order to sustain a robust rate of pharmaceutical innovation, fi nancial incentives are required. For instance, the amount of pharmaceutical innovation is positively related to the burden of disease in developed countries but not in developing countries. The most plausible explanation is that incentives to develop medicines for diseases primarily affl icting people in developing countries have been weak or nonexistent. Similarly, the 1983 Orphan Drug Act in the United States, which gave fi rms incentives to develop drugs for diseases affl icting fewer than 200,000 people, led to increased development of such drugs. A simple theoretical model of drug development suggests that in the long run, a **10% decline in drug prices from the re-importation of cheaper drugs into the U.S. would likely cause at least a 5-6% decline in pharmaceutical innovation.** Other estimates indicate that there is a sizable, robust, negative relationship between the penetration of generics and early-stage pharmaceutical innovation.

Stoessel

Thomas Peter 17, 1-4-2017, "Removing barriers to medical innovation," AEI, http://www.aei.org/publication/912939///ZS

Truth be told, however, in this era private industry, rather than the GABC, has progressively become the dominant source of new medical products. By 1990, **corporate investment in medical research had exceeded that of the NIH, and it is now over twice as large. Three separate analyses concluded that 85% of the drugs approved by the FDA since 1988 arose solely from research and development performed within the industry**. An important fact to remember about medical innovation is that, unlike engineering advances informed by physics and chemistry, it relies on the far more uncertain underpinning of biology. Although insufficient information is one reason for this uncertainty, the dominant problem is the biological variability that evolution has programmed into us. Highly mutable micro-organisms dominate our world and use the components of our bodies to colonize and sicken us. If our responses were static and predictable, these invaders would have eliminated our species eons ago. The liability of this unpredictability is that drugs that seem promising in the laboratory or in inbred animals more often than not fail in clinical trials. As a result, the basic science discoveries championed by Vannevar Bush, though extremely valuable in some ways, are not reliable or straightforward guarantees of medical innovation. Regardless, the GABC continues to pour money into the pursuit of basic science, often in the name of medical innovation, for a number of cultural and economic reasons.

Cockburn

No Author xx, xx-xx-xxxx, "," No Publication, https://www.nber.org/papers/w20492.pdf//ZS

This paper studies how patent rights and **price regulation** a§ect launch lags for new drugs. **Using new data on launches of 642 new molecules in 76 countries during 1983-2002, we show that, all else equal, longer and more extensive patent protection accelerated di§usion, while price regulation strongly delayed it.** Health policy institutions, and economic factors that make markets more proÖtable, also sped up di§usion. These results hold both for developing countries and high income countries, and the results are robust to using instrumental variables to address the endogeneity of policy regimes. Our Öndings also raise the broader point, not limited to pharmaceuticals, that patent rights can have an important impact on the di§usion of new innovations as well as on the rate at which new innovations are created. Of course, the same policies that promote faster launchóstronger patent rights and the absence of price regulationóare also those that raise prices. This highlights the basic tradeo§ countries face between making new drug therapies available and making them a§ordable. Finding ways to best mitigate the adverse e§ects of this tradeo§ is a major challenge. There are four main empirical Öndings in the paper. First, we show that new drugs become available in many countries only after long lags (often more than 10 years) between the date when a product in Örst launched commercially anywhere in the world (typically in the US, Europe, or Japan) and its launch in other countries. Many new drugs are never launched outside a handful of

wealthier countries. Second, we demonstrate that the patent policies governments adopt strongly a§ect how quickly new drug therapies are launched in their countries. Longer duration, and stronger, patent rights substantially speed up di§usion. These impacts are large and robust to a variety of empirical speciÖcations. Third, we show that **countries that adopt** strong **pharmaceutical price regulation experience** signiÖcantly longer launch lags for new drugs. We estimate that introducing price regulation decreases the per-period hazard of launch by about 15 percent, which is equivalent to increasing launch lags by about 25 percent (when instrumented, 49 to 60 percent reduction in the hazard rate, **equivalent to about a 80 percent to 100 percent increase in launch lags**.) Fourth, we Önd that new drugs are launched much faster in countries that have health policy institutions that promote availability and distribution of drugsóin particular, adopting the Essential Drug List of the World Health Organization and having a National Formularyóand these institutions do not appear to be simply a proxy for unobserved institutional quality.

Impact-1

Paranacis

American Life 14, 12-18-2014, "The Value of Medical Innovation: Saving Lives, Saving Money," No Publication, http://hinj.org/the-value-of-medical-innovation-saving-lives-saving-money///ZS

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 paper.

Impact- 2

Hooper

About The xx, xx-xx-xxxx, "Pharmaceuticals: Economics and Regulation," Econlib, https://www.econlib.org/library/Enc/PharmaceuticalsEconomicsandRegulation.html//ZS

Why are drugs so expensive to develop? The main reason for the high cost is the aforementioned high level of proof required by the Food and Drug Administration. Before it will approve a new drug, the FDA requires pharmaceutical companies to carefully test it in animals and then humans in the standard phases 0, I, II, and III process. The path through the FDA's review process is slow and expensive. The ten to fifteen years required to get a drug through the testing and approval process leaves little remaining time on a twenty-year patent. Although new medicines are hugely expensive to bring to market, they are cheap to manufacture. In this sense, they are like DVD movies and computer software. This means that a drug company, to be profitable or simply to break even, must price its drugs well above its production costs. The company that wishes to maximize profits will set high prices for those **who are willing to pay a lot and low prices that at least cover production costs for those willing to pay a little. That is why, for example, Merck priced its anti-AIDS drug, Crixivan, to poor countries in Africa and Latin America at $600 while charging relatively affluent Americans $6,099 for a year's supply.** This type of customer segmentation—similar to that of airlines—is part of the profit-maximizing strategy for medicines. In general, good customer segmentation is difficult to accomplish. Therefore, the most common type of pharmaceutical segmentation is charging a lower price in poorer countries and giving the product free to poor people in the United States through patient assistance programs.

NBER

American Life 14, 12-18-2014, "The Value of Medical Innovation: Saving Lives, Saving Money," No Publication, http://hinj.org/the-value-of-medical-innovation-saving-lives-saving-money///ZS

Medical innovations produced by **American life sciences companies have vastly improved the human condition**. Our pharmaceutical, biotech, medical technology, device and diagnostics companies have helped people live longer, with less pain and greater quality of life. Over the past century, the life sciences has eradicated some of the world's most dreaded diseases such as polio and smallpox. More recently, the industry has made other diseases such as breast cancer, HIV/AIDS, heart disease and lung cancer no longer the death sentences that they once were. 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.**

Berezow

Alex Berezow 16, 11-11-2016, "Measles: Thank WHO, Big Pharma for Saving 20 Million Lives Since 2000," No Publication, https://www.acsh.org/news/2016/11/11/measles-thank-who-big-pharma-saving-20-million-lives-2000-10432//ZS

The bolded line near the bottom of the chart shows how many people in the world died of measles in each year from 2000 to 2015. Despite the fact that we had a global public health campaign underway, approximately 651,600 people died of measles in 2000. But notice how that number has steadily declined to the current estimate of 134,200 people in 2015. What would happen if there was no measles vaccine? That's what the upper bolded line depicts. As shown, the CDC estimates that roughly 1.5 million people would die of the disease every single year. **That means, from 2000 to 2015, vaccination has saved the lives of 20.3 million people from measles alone.** That

is a truly breathtaking statistic. Obviously, we have public health officials, such as the WHO, to thank. But thanks must also be given to pharmaceutical companies, such as Merck, without which we would not have mass-produced vaccines. This public health triumph represents the very best of government and the private sector working for the greater benefit of mankind. One day, like smallpox, measles will be relegated to the dustbin of history.

Contention 2

Ford

Carmen 2, 1-13-2002, "Pricing of drugs and donations: options for sustainable equity pricing," No Publication, https://onlinelibrary.wiley.com/doi/full/10.1046/j.1365-3156.2001.00801.x//ZS

Two billion people do not have regular access **to life-saving drugs or to those drugs which could vastly improve their living conditions.** For diseases affecting the rich and the poor alike, prevalent in both developing and developed countries, there is ongoing research, development and production of effective drugs by the research-based pharmaceutical industry This article summarizes recent price studies for drugs used in the therapy of four diseases that predominate in the developing world, and examines the possibilities available to achieve greater drug access. The price differences among the various manufacturers, in some cases, the **effect drug donations have or could have on these populations is presented.**

Malnick

Edward Malnick, Whitehall Editor xx, xx-xx-xxxx, "2018 will be the 'worst for humanitarian crises' since the Second World War," Telegraph, https://www.telegraph.co.uk/news/2017/12/31/2018-will-worst-humanitarian-crises-since-second-world-war///ZS

Next year could herald one of the worst humanitarian crises since the end of the Second World War, the new International Development Secretary has warned. Penny Mordaunt described 2017 as a year of "harrowing humanitarian crises", adding that "2018 could be even bleaker". The warning came as Ms Mordaunt's Department for International Development announced an additional £21 million package of support for a United Nations fund enabling agencies to respond to emergencies around the world. The department cited ongoing famines and conflicts in Yemen, South Sudan and Burma as significant concerns. In early 2017 the United Nations said the world faced the largest humanitarian crisis since 1945, with more than 20 million people in four countries facing starvation and famine. But Ms Mordaunt believes next year "could be even worse". “While 2017 was a year of harrowing humanitarian crises, the truth is 2018 could be even bleaker," she said.

Gray

About The 16, 2-29-2016, "Pharmaceutical companies donating medicines in crisis situations," Devex, https://www.devex.com/news/pharmaceutical-companies-donating-medicines-in-crisis-situations-87797//ZS

While this debate goes on, **many pharmaceutical companies continue to make product donations a common feature of their corporate social responsibility efforts.** In response to the current crisis in **Syria**, for example, several major multinational pharmaceutical companies have **donated medicines and cash to emergency relief organizations**, including the International Committee of the Red Cross, International Health Partners and Project Hope. Other humanitarian organizations, such as Médecins Sans Frontières, generally decline to accept such donations, citing, for example, the impact on efficiency, and the potential for conflicts of interest. Since 2008, the Access to Medicine Index has tracked the policies and practices of pharmaceutical companies in a range of access-related activities in low- and middle-income countries, including medicine donations. We have also worked with a range of stakeholders to build consensus around what the global community can expect from pharmaceutical companies that donate medicines. There must also be **no double standard in quality between medicines that are donated and those that are sold: donations must not be used as an opportunity to dispose of expired, unsafe or otherwise unwanted medicines that place a burden on health systems when they are least able to cope.**

Burns

Melinda Burns xx, xx-xx-xxxx, "Partners in Aid Help the Medicine Go Down," Pacific Standard, https://psmag.com/health-and-behavior/rx-for-humanitarian-relief-14634//ZS

“We made an educated guess and thought, ‘Let’s boost inventories.’ … It avoids the fog of disasters, which is like the fog of war,” said Thomas Tighe, president and CEO of Direct Relief, a nonprofit group that **provides medical assistance in the United States and around the world.** (Tighe is also a member of the editorial advisory board of Miller-McCune.) **Chaos engulfed Haiti** anyway, not in a hurricane, but in January’s catastrophic earthquake. And in those first tumultuous days, the Direct Relief caches provided enough antibiotics, sterile gauze, disinfectant, pain medications and prescription drugs — courtesy of Abbott Laboratories — to treat 3,000 people. **Direct Relief and most of its top corporate donors** belong to the Partnership for Quality Medical Donations, **an alliance of 14 manufacturers of drugs and medical equipment, and 16 nonprofit humanitarian groups working in developing countries. In 2017, the latest year for which figures are available, the corporate partnership members gave $6.1 billion in aid to the developing world,** according to The Index of Global Philanthropy and Remittances. That was out of a total $6.8 billion **from U.S. corporations overall.**

Warrant 1

Kyle

Authors 7, 2-7-2007, "MIT Press Journals," MIT Press Journals, https://www.mitpressjournals.org/doi/pdfplus/10.1162/rest.89.1.88//ZS

Implying that **drugs invented by firms in price- controlled countries reach two fewer markets on average**. One interpretation of this pattern is that the incentives created by price control regimes spur firms in these coun- tries to introduce new products that are slightly different from, but not a huge advance over, their existing products, because the prices of **their existing products are ratcheted down by regulators over time.** This research has two implications for public policy. The costs of deterring innovative products that may result from imposing price controls should be balanced against any short-run savings from lower prices, in addition to concerns about the long-run effects on R&D incentives and the development of future products. Second, the effect of **price controls is not isolated in a single market**, but influences **the global launch decisions of pharmaceutical firms and thus affects the extent and timing of a new drug's launch.** These results have particular salience as individual states in the United States adopt price control measures to control Med- icaid costs, and as the federal government considers similar legislation. The strategic response to changes in links be- tween markets, such as international reference pricing and parallel trade, should also be considered for poorer countries expected to enter the European Union and for developing countries elsewhere. One effect of efforts to keep prices low in such countries could be a reduction in the number of innovative products available.

Warrant 2

Hale

No Author xx, xx-xx-xxxx, "Oxymoron No More: The Potential Of Nonprofit Drug Companies To Deliver On The Promise Of Medicines For The Developing World," No Publication, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.24.4.1057//ZS

Another approach is **drug donation programs, whereby pharmaceutical companies provide needed medicines to people in developing countries.** For example, Merck and Company has donated the drug ivermectin for the treatment of river blindness in western and central Africa for more than two decades and has helped eliminate the disease in these areas. 8 GlaxoSmithKline (GSK) is a partner in the lymphatic filariasis elimination program, along with the World Bank, the WHO, and the United Nations Children's Fund (UNICEF). 9 The Prevention of Mother-to-Child Transmission (PMTCT) Donations Program is a combined effort by Boehringer-Ingelheim and Abbott Laboratories to provide Viramune (nevirapine) and Determine (rapid HIV diagnostic test) **free of charge to PMTCT programs involved** in the prevention of mother-to-child transmission of HIV in Africa and other developing countries. 10 **However, most drug companies, whose shareholders expect a return on investment, cannot be expected, by themselves, to provide drugs on the mass scale required for some diseases.**

Hamblin

James Hamblin 16, 10-14-2016, "Doctors Refused a Million Free Vaccines–to Make a Statement About the Pharmaceutical Industry," Atlantic, https://www.theatlantic.com/health/archive/2016/10/doctors-with-borders/503786///ZSi

And this cost is the fundamental issue to Jason Cone, the executive director of Doctors Without Borders in the United States. He explained that donations from pharmaceutical companies are ineffective against a problem of this scale. While the donation would benefit people under the care of Doctors Without Borders immediately, accepting it could mean problems for others, and problems longer-term. Donations, he writes, are "often used as a way to make others 'pay up.' **By giving the pneumonia vaccine away for free, pharmaceutical corporations can use this as justification for why prices remain high for others,** including other humanitarian organizations and developing countries that also can't afford the vaccine." Which is to say that for a disease of this scale, isolated donations are inadequate. "**I'm not** absolutely **against donations,"** MSF's vaccine pharmacist Alain Alsahani told me by phone from Paris. **In cases of neglected disease where there is little or no market for a product, he explained, "donation becomes a more interesting option for some countries to get access.** But in the case of PCV, that's not a solution at all, in any way."

Collins

No Author xx, xx-xx-xxxx, "," No Publication, http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.823.6887&rep=rep1&type=pdf//ZS

Pharmaceutical companies often argue that, because **there is no market for drugs in developing countries**, programs like the Mectizan **donation program are simply corporate acts of good will**. However, the case of ivermectin **highlights the public relations value of drug donation programs;** In contrast, the Mectizan donation program developed out of Merck's decision to develop a drug without a market, **donate the drug, and assemble public organizations to aid in the distribution of the drug.** However, the development of the Mectizan donation program was not without its obstacles, and the experiences of the program provide insight into future public/private partnerships in public health. This paper will consider the issues Merck faced in the decision to donate ivermectin and in the subsequent development of the Mectizan donation program.

Warrant 3

Baer

No Author xx, xx-xx-xxxx, "," No Publication, https://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1361&context=jipl//ZS

Allowing parallel imports of drugs thwarts the protection provided by U.S. patents. Though proponents argue that the 2000 amendments are in line with free trade principals, price differentials of pharmaceuticals are mostly the result of governmental intervention, not market forces. Consequently, not only are the patented drugs imported into the U.S., but the laws and regulations of the nations from which they come are imported as well. The result is that U.S. patent protection is effectively reduced to that offered in the nation with the least protection and the greatest **price controls.** This result runs contrary to well established patent principals since the late 1800's and **makes it virtually impossible for pharmaceutical companies to recoup their fixed costs. Faced with the possibility of insolvency, pharmaceuticals may stop supplying drugs to poorer nations, harming consumers who most desperately need innovative medicine.** Should pharmaceuticals choose to continue to supply poorer countries, U.S. consumers and consumers worldwide would be harmed, because pharmaceutical companies would have few dollars and little incentive to embark upon research that would lead to improved medicine.

Impact 1 Lives

Global Alliance for Patient Access

No Author xx, xx-xx-xxxx, "," No Publication, http://gafpa.org/wp-content/uploads/GAFPA_Drug_Donations_August-2017.pdf//ZS

Millions of low-income people in countries and communities around the world depend upon 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 longerterm development programs, **drug donations are critical to global health.**

Gorney

Cynthia Gorney xx, xx-xx-xxxx, "Here's Why Vaccines Are So Crucial," Magazine, https://www.nationalgeographic.com/magazine/2017/11/vaccine-health-infection-global-children///ZS

Here's Why **Vaccines Are So Crucial If children in poor countries got the shots that rich countries take for granted, hundreds of thousands of young lives could be saved.** Go see the child, Samir Saha said. Just sit with her. Probably the siblings will be there too, the brother and sister **whose lives are also altered permanently. 'This is why the vaccine is so important**,' Saha said. '**We want to reduce this number to a minimum, if not zero. So no other children will be like this.'** It was a little after dawn in Dhaka, the capital of Bangladesh, and Saha was in the back seat of his car, brooding. A uniformed driver threaded the Toyota through a cacophonous mess of jitneys, motorcycles, rickshaws, trucks, and battered buses with passengers hanging out the doors. "We could save the life, but we could not …" He left the sentence unfinished. "You'll be seeing the scenario," he said. "You'll understand."

Gavi

No Author xx, xx-xx-xxxx, "," No Publication, https://www.pfizer.com/files/health/vaccines/Pfizer_One_Year_Later_Humanitarian_Update_11_6_17.pdf//ZS

Pfizer is providing its new MDV at the lowest prevailing global price, $3.05 per dose**, for both humanitarian emergencies and Gavi countries.** Pfizer also committed to extend the price of $3.05 per dose to Gavi eligible countries even after they graduate based on their improved economic standing through 2025. In the world's poorest countries, Pfizer partners with **Gavi to make its pneumococcal conjugate vaccine available to Gavi-eligible countries, which consist of 73 countries with Gross National Income** (GNI)/capita of $1580 or less. Pfizer is proud of its **significant commitment to the world's poorest countries**. **Today, one out of every two doses of pneumococcal conjugate vaccine** that Pfizer distributes **goes to the world's poorest countries through** its **Gavi** partnership. To date, **Pfizer has delivered more than 300 million doses of its pneumococcal conjugate vaccine helping to protect more than 20 million babies in Gavi countries each year.**