CASE CARDS

Easton 18 Robert J. Easton [co-chairman of Bionest Partners, a global medical business consultancy serving pharmaceutical, medical device, and diagnostic firms and their investors], 1-22-2018, "Price controls would stifle innovation in the pharmaceutical industry," STAT, https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/ //DF

The global pharmaceutical industry is among the most profitable, driven by its ability to price 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.

Gleason 17 Patrick Gleason [vice president of state affairs at Americans for Tax Reform, and a senior fellow at the Beacon Center of Tennessee], 2-15-2017, "States Consider Imposing Drug Price Controls," Forbes, https://www.forbes.com/sites/patrickgleason/2017/02/21/states-consider-imposing-drug-price-controls/#406cbfc6639b //DF

The problem for drug price control proponents like Gov. Cuomo and Bernie Sanders is that, despite their claims, pharmaceutical manufacturers do not reap excessive profits. In fact, profits for the pharmaceutical manufacturing industry, among the most research-intensive sectors, are middle of the road. Additionally, drug makers reinvest tens of billions in profits every year on research and development. **Research and development of one medicine takes an average of more than a decade and $2.6 billion. The prolonged timeline and high research costs** associated with the drug development process **make the pharmaceutical industry a riskier investment than other sectors. As such, a higher rate of return is required to ensure a level of capital that will allow drug makers to continue innovative research and the development of life changing** and saving new **pharmaceuticals**. As those fighting state legislative efforts to impose drug price controls have pointed out, **drug price controls will stifle innovation by limiting the ability of drug makers and investors to recover the excessive costs associated with their work and reinvest profits. This could lead to reduced access to life-saving and improving medications in the future**. Robert Graboyes, a health care scholar and senior research fellow at the Mercatus Center, explains the pitfalls with the drug price control bill currently pending in Oregon, which applies to similar proposals being debated in other state capitals. Lawmakers commanding businesses to sell products at lower costs usually does not have a happy ending," Graboyes said, adding "in the future, people may not get well because it was not economically feasible for the manufacturer to research and market the drug that could have helped." Dr. Joel Zinberg, a practicing surgeon at Mount Sinai Hospital and a visiting fellow at the American Enterprise Institute, explains how Europe's experience with drug price controls demonstrates how they reduce the incentive for investment and innovation: Without temporary high prices in the U.S. market before generic competition, there will be less R&D, fewer new breakthrough drugs, fewer competitor drugs developed, and ultimately no lower priced generics

to follow. European countries' price controls imposed in the 1980s prove the point. In the mid-80s, European drug R&D was 24% higher than in the U.S. After price controls, European pharmaceutical R&D grew at half the U.S. rate and today substantially trails American R&D." The good news is last year proved voters are smart enough to see through the falsehoods and hyperbole put forth by those pushing prescription drug price controls. Though Hillary Clinton beat Donald Trump by 30 points in the bastion of progressivism that is California last November, voters there rejected the aforementioned ballot measure to impose drug price controls, Proposition 61, by a 53.2% to 46.8% margin.

Giacotto, 2005, University of Chicgo, "DRUG PRICES AND RESEARCH AND DEVELOPMENT INVESTMENT BEHAVIOR IN THE PHARMACEUTICAL INDUSTRY' https://sci-hub.tw/https://www.journals.uchicago.edu/doi/full/10.1086/426882 (NK)
This paper argues theoretically and shows empirically that pharmaceutical R&D spending increases with real drug prices, after holding constant other determinants of research and development (R&D). Specifically, an estimated elasticity suggests that a 10 percent increase in the growth of real drug prices is associated with nearly a 6 percent increase in the growth of R&D intensity. Simulations that are based on our multiple-regression model indicate that the capitalized value of pharmaceutical R&D spending would have been about 30 percent lower if the federal government had limited the rate of growth in drug price increases to the rate of growth in the general consumer price index during the period **1980–2001**. Moreover, **the results suggest that a drug price control regime would have resulted in 330–65 fewer new drugs**, representing over one-third of all actual new drug launches brought to the global market during that time period. I. Introduction Benjamin Franklin once remarked, "In this world nothing can be said to be certain, except death and taxes." Spokespersons for the pharmaceutical industry might be inclined to argue that the benefit-generating capability of prescription drugs also belongs in this exclusive category. They could make a compelling case: recent studies suggest that pharmaceutical products increase longevity, improve quality of life, and often result in medical cost savings.1 Moreover, pharmaceutical products have significantly reduced the death rates associated with such diseases as tuberculosis, kidney infection, and hypertension.

Gigi Moreno [Precision Health Economics], 2017, "The Long-Term Impact of Price Controls in Medicare Part D," Forum Health Policy, DOI 10.1515/fhep-2016-0011 //DF
Price controls for prescription drugs are once again at the forefront of policy discussions in the United States. Much of the focus has been on the poten- tial short-term savings – in terms of lower spending – although evidence suggests price controls can dampen innovation and adversely affect long-term population health. This paper applies the Health Economics Medical Innovation Simula- tion, a microsimulation of older Americans, to estimate the long-term impacts of government price setting in Medicare Part D, using pricing in the Federal Vet- erans Health Administration program as a proxy. We find that VA-style pricing policies would save between $0.1 trillion and $0.3 trillion (US$2015) in lifetime drug spending for people born in 1949–2005. However, such savings come with social costs. After accounting for innovation spillovers, we find that price setting in Part D reduces the number of new drug introductions by as much as 25% rela- tive to the status quo. As a result, life expectancy for the cohort born in 1991–1995 is reduced by almost 2 years relative to the status quo. Overall, we find that **price controls would reduce lifetime welfare by $5.7 to $13.3 trillion** (US$2015) **for the US population** born in 1949–2005.

Dana Goldman and Darius Lakdawalla, 1-30-2018, "The global burden of medical innovation," Brookings, https://www.brookings.edu/research/the-global-burden-of-medical-innovation/ (NK)

What we pay for medicines today affects the number and kinds of drugs discovered tomorrow. Empirical research has established that **drug development activity is sensitive to expected future revenues in the market for those drugs.** The most recent evidence suggests that it takes $2.5 billion in additional drug revenue to spur one new drug approval, based on data from 1997 to 2007.[3]Another study assesses **the Orphan Drug Act**, passed in 1982 to stimulate development of treatments for rare diseases. Its key feature was the granting of market exclusivity that would restrict entry by competitors — in other words, **allow for higher prices. The result was a dramatic increase in the number of compounds brought into development to treat rare diseases** (figure 3).[4] This linkage may not help patients with tuberculosis today in Nigeria and Indonesia — two poor countries hardest hit by tuberculosis — but **it is currently benefiting patients in the same countries who have HIV. Decades ago, demand for HIV treatment in wealthy countries spurred medical breakthroughs that have since found their way — albeit more slowly than we would like — into the poorest corners of the globe. As of July 2017, 20.9 million people living with HIV were accessing antiretroviral therapy globally; 60 percent of them live in eastern and southern Africa.**[5] American consumers may feel some philanthropic pride about the benefits they have spurred for the world's poorest HIV patients. But similar benefits are also enjoyed by German, British, and French HIV patients, and were financed by the same revenues generated, in large part, by high American drug prices. Whether one sees this as philanthropy on the part of American drug buyers, or free-riding on the part of other wealthy countries who pay much less for the same drugs, **America clearly contributes more to pharmaceutical revenue, and hence incentives for new drug development, than its income and population size would suggest.**

Darren Filson [Associate Professor of Economics, Claremont Graduate University], 2-27-2007, "The Impacts of Price Controls on the Performance of the Pharmaceutical Industry," Semantic Scholar, https://pdfs.semanticscholar.org/3de2/38ebdddc816716041badffa405ce03a991a5.pdf //DF

What happens if the U.S. adopts price controls like those in the rest of the world? Firms reduce research substantially, and in the long run, the flow of new drugs falls by approximately 75%. Industry firm value falls approximately 80%. The full impact takes over a decade to occur, because most late-stage candidates in the pipeline remain profitable under the policy change. The option to pursue a late-stage candidate is usually well "in the money" because many hurdles have been overcome, many R&D costs are sunk, and the prospect of obtaining profits is more near. Consumer welfare in the U.S. rises for the first twelve years and falls thereafter. Lower prices yield short run benefits, but the harmful effect of the reduced flow of new drugs outweighs the price effect in the long run. The net present value (NPV) of consumer welfare falls in the U.S. and in the rest of the world by over $13 trillion year 2000 dollars. In the current environment, the prospect of high U.S. profits encourages innovation that consumers everywhere benefit from. The model explains why non-U.S. countries resist abandoning price controls even though it is optimal for the U.S. to resist adopting price controls. I show that if one or more non-U.S. countries abandon price controls, R&D, the flow of new products, firm value, and consumer welfare in the world as a whole all rise. However, consumer welfare falls in the countries that abandon controls. This last result helps explain why non-U.S. countries resist abandoning price controls. The result might also explain why particular U.S. states have attempted to circumvent U.S. federal government policies on pricing and importation, while the federal government has tended to be more of a supporter of market-based prices. Essentially, small subgroups in the population can benefit by free riding on the U.S. states willing to support market prices, but the U.S. as a whole benefits from maintaining market pricing everywhere. Interestingly, the result that global consumer welfare rises when non-U.S. countries adopt market pricing suggests that, in principle, other countries could compensate their consumers for the welfare losses they would incur from market prices. The lack of global institutions to accomplish such transfers, along with the intrinsic difficulties associated with committing to policies and wealth transfers that involve generations of consumers far in the future, ensure that countries other than the U.S. benefit by maintaining their interventionist policies. Thus, the world as a whole remains in a political equilibrium in which non-U.S. countries free ride on the U.S.

Link – Investors

Price controls empirically reduce investment in pharma companies; just the threat of price controls have been enough to scare off investors

Giacotto 05 Carmelo Giaccotto [Professor of Finance, University of Connecticut], 4-2005, "Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry," The Journal of Law & Economics, https://www.jstor.org/stable/10.1086/426882 //DF

Because of the important benefits promised by new-drug innovations and the sizeable costs associated with the innovation process, a number of researchers have explored the determinants of pharmaceutical R&D. Not surprisingly, a major aspect of these studies concerns how various types of public policies, such as drug price regulations, might affect pharmaceutical R&D. The notion is that public policies should foster, or at least not inhibit, R&D investment, particularly investments that offer societal benefits in ex- cess of costs. For example, less than 10 years ago **the Health Care Reform Act of 1993 proposed various types of price controls on the pharmaceutical industry. While Congress did not pass this act, the mere threat that it would pass appeared to have a large negative effect on the market value of many** 45 **pharmaceutical firms**. Had the act actually been passed, Henry Grabowski hypothesizes that a substantial decline in R&D expenditures and innovative activity would have occurred. Although empirical insights have been realized through previous research on the determinants of firm R&D expenditures in the pharmaceutical in- 6 dustry, only F. M. Scherer has conducted an analysis at the industry level. His study, however, was not an analysis of the determinants of pharmaceutical R&D per se; rather, it was an examination of the dynamic rela- tionship between gross profitability and pharmaceutical R&D. To be certain, there is a major advantage to an industry-level analysis: only at the industry level are data available on pharmaceutical R&D expenditures, as opposed to total R&D expenditures. Because most major pharmaceutical firms are di- versified across multiple industries, total-firm R&D often includes expen- ditures on such nonpharmaceutical products as industrial chemicals, medical 8 supplies,andconsumerproducts. Asaresult,allpreviousfirm-levelstudies 9 have been hampered by the quality of the R&D data. For this reason, we believe that an industry-level study provides the most promising context for conducting an empirical investigation of the determinants of pharmaceutical R&D and for considering how, for example, the regulation of pharmaceutical prices in the United States might affect R&D.

Link – Delays

Price controls reduce the exclusivity period and reduce the incentive to invest

Costa-Font 15 Joan Costa-Font [Dr Joan Costa-Font, London School of Economics], 2015, "Regulation Effects on the Adoption of New Medicines," Journal of Empirical Economics http://eprints.lse.ac.uk/60229/1/__lse.ac.uk_storage_LIBRARY_Secondary_libfile_shared_repository_Content_Costa-Font_Regulation%20effects_Costa-Font_Regulation%20effects_2015.pdf //DF

Nonetheless, we observe significant firm and molecule heterogeneity in the speed of launch. In particular, firm economies of scale and a molecule's therapeutic importance grant substantial advantages for launch times internationally. Contrary to findings in the literature, we find no significant advantage to domestic launch. Findings in this paper suggest several policy implications. First, price regulations appear to result in a decrease in timely pharmaceutical adoption on a global scale, especially if there are price interdependencies. This may impose welfare losses, particularly when the innovations that are delayed are cost-effective therapies from a societal perspective. From a public health perspective, lack of access to new drugs may lead to compromises in health outcomes (Schoffski, 2002), shift volume to older molecules of lower therapeutic value (Danzon and Ketcham, 2004) and compromise the quality of health care (Kessler, 2004; Wertheimer and Santella, 2004). Innovative medications offer economic benefits by avoiding expenditures on other forms of medical care (such as hospitalization) as well as reducing missed work days (Hassett, 2004; Lichtenberg, 1996; Lichtenberg, 2003; Lichtenberg, 2005). **Delays in adoption** also **reduce the** net present **value of R&D investments by delaying cash flows and shortening the exclusivity period, which could reduce future R&D and innovation** (Giaccotto et al., 2005). Although **price controls** may therefore increase static efficiency in the short term by driving prices and marginal costs closer, they **could** also **result in potential longer-term losses in dynamic efficiency due to the**

reduced incentives associated with market entry. This study therefore highlights the importance of ensuring price and reimbursement regulation is efficient in this sector, not least as the regulation itself can have important spillover effects across countries. Our analysis also confirms greater concentration leads to longer launch times. To the extent that extensive price controls may reduce incentives to entry, they may play a further role in delaying pharmaceutical product market launch. Finally, due to scale advantages in international rollout strategies, price controls may have helped increase the incentives for mergers and acquisitions, further increasing concentration levels and barriers to entry (LaMattina, 2011).

Impact– Innovation Reduces Deaths

Innovation reduces death rates from deadly diseases, and increase the quality of life

Giacotto 05 Carmelo Giaccotto [Professor of Finance, University of Connecticut], 4-2005, "Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry," The Journal of Law & Economics, https://www.jstor.org/stable/10.1086/426882 //DF
Benjamin Franklin once remarked, "In this world nothing can be said to be certain, except death and taxes." Spokespersons for the pharmaceutical industry might be inclined to argue that the benefit-generating capability of prescription drugs also belongs in this exclusive category. They could make a compelling case: recent studies suggest that **pharmaceutical products in- crease longevity, improve quality of life, and often result in medical cost 1 savings.** Moreover, pharmaceutical products have significantly reduced the death rates associated with such diseases as tuberculosis, kidney infection, and hypertension. Industry analysts are quick to point out that these benefits come at a significant cost: on average, firms invest hundreds of millions of dollars over many years into research and development (R&D) to bring a single new chemical entity (NCE) to market. In fact, recent estimates suggest it takes 2,3 approximately 16 years and costs $802 million to bring a NCE to market. These R&D activities involve discovery research, preclinical testing, and successive and time-consuming clinical trials. The latter are needed to dem- onstrate safety, efficacy, and quality before the U.S. Food and Drug Admin- istration (FDA) will approve a new drug for marketing.

Michael Rosenblatt [Chief Medical Officer at Merck & Co. from 2009 to 2016, Dr. Rosenblatt's views also have been informed by a long career in academic medicine, holding leadership positions at Tufts University School of Medicine, Harvard Medical School, and Beth Israel Deaconess Medical Center], 11-20-2017, "Reframing the Conversation on Drug Pricing," NEJM Catalyst, https://catalyst.nejm.org/reframing-conversation-drug-pricing/ //DF
Our society today faces a tsunami of health care costs from Alzheimer's disease. One in nine Baby Boomers will develop Alzheimer's disease. The U.S. will spend $259 billion in 2017 on Alzheimer's costs, and that figure will balloon to $1 trillion by 2050 if current trends continue. Our society can't afford for current trends to continue. There is only one solution, and it isn't building more efficient hospitals, health care delivery systems, and nursing homes. It is discovering new drugs that arrest, delay, prevent, or cure the disease. So far, these attempts have largely failed. More than 400 clinical trials of more than 200 agents yielded only one approved drug for Alzheimer's disease in the period 2002–2012. The failure rate at the clinical trial stage has been a staggering 99%, and that number doesn't include agents that didn't make it out of the lab. There are only five approved drugs; they treat some symptoms of the disease and slow its progression somewhat, but none has major impact on the disease. Recently, two promising Alzheimer's drugs from two research-driven pharmaceutical companies (Eli Lilly and Merck) experienced setbacks in major clinical trials, after 10 to 20 years of research involving hundreds of scientists (some of whom devoted decades of their careers to the effort) and thousands of patients. Abandoning the search is not an option unless the patients who suffer from this dreaded disease are also abandoned. Each failure advances our knowledge and increases our chances for eventual success. But it will be a costly search. The U.S. government spends between $500 million and $1 billion a year on all Alzheimer's-related research. Industry's investment dwarfs that amount: the industry group PhRMA lists more than 80 Alzheimer's medications currently in development. In general, the average cost to develop a drug tops $2.5 billion, according to a Tufts University study published last year. These figures are for just one disease: multiply them by the number of conditions where care could be transformed by one or two pharmaceutical breakthroughs, and the magnitude is stunning. For companies to justify risking billions on finding a breakthrough drug,

they need to be able to anticipate a corresponding return on their investment. But at the same time, the patients who can benefit from a drug need to have access to it without facing bankruptcy, and health insurers need to feel confident that they will reap a return on their investment.

Impact – Innovation Reduces Healthcare Costs

Innovation reduces medical costs

Giacotto 05 Carmelo Giaccotto [Professor of Finance, University of Connecticut], 4-2005, "Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry," The Journal of Law & Economics, https://www.jstor.org/stable/10.1086/426882 //DF

Benjamin Franklin once remarked, "In this world nothing can be said to be certain, except death and taxes." Spokespersons for the pharmaceutical industry might be inclined to argue that the benefit-generating capability of prescription drugs also belongs in this exclusive category. They could make a compelling case: recent studies suggest that **pharmaceutical products in- crease longevity, improve quality of life, and often result in medical cost 1 savings.** Moreover, pharmaceutical products have significantly reduced the death rates associated with such diseases as tuberculosis, kidney infection, and hypertension. Industry analysts are quick to point out that these benefits come at a significant cost: on average, firms invest hundreds of millions of dollars over many years into research and development (R&D) to bring a single new chemical entity (NCE) to market. In fact, recent estimates suggest it takes 2,3 approximately 16 years and costs $802 million to bring a NCE to market. These R&D activities involve discovery research, preclinical testing, and successive and time-consuming clinical trials. The latter are needed to dem- onstrate safety, efficacy, and quality before the U.S. Food and Drug Admin- istration (FDA) will approve a new drug for marketing.

Taking medications can reduce the net healthcare costs paid by some patients

Sokol 05 Michael C. Sokol [MD, Medco Health Solutions], 2005 "Impact of medication adherence on hospitalization risk and healthcare cost," Journal of Medical Care, https://www.jstor.org/stable/pdf/3768169.pdf //DF

For diabetes and hypercholesterolemia, high levels of medication adherence are generally associated with a net economic benefit in disease-related costs. **Higher drug costs are more than offset by reductions in medical costs, yielding a net reduction in overall healthcare costs. This** pattern is observed at all adherence levels for diabetes and at most adherence levels for hypercholesterolemia. These results are consistent with earlier studies that have reported linkages between medication adherence and health outcomes for these conditions.21'34-37 For hypertension, medical costs tended to be lowest at high levels of medication adherence, but offsets in total healthcare costs were generally not found. The cost impacts of adherence may be less salient for conditions hypertension, for which a large fraction of the treated popu- lation has a relatively low risk of near-term complications.14 No significant associations between cost and adherence were observed for CHF. Adherence-related differences in hospital- ization risk were relatively small for these patients, and cost variability in the CHF study sample was exceptionally high. To our knowledge, the current study is the first to demonstrate this pattern of cost offsets for diabetes and hypercholesterolemia in a large benefit plan population. Given the chronic nature of these conditions, it is likely that most patients in these study samples had been receiving medication treatment for an extended period before the anal- ysis period began. The observed savings probably reflect the cumulative effects of adherence levels sustained over several years. Adherence rates in this study were typical of the rates often reported for chronic conditions. 1516'34'38 Observed ad- herence rates (defined as the proportion of patients with 80-100% adherence) ranged between 55% and 73% for the 4 conditions in this study. Although a formal cost-benefit analysis is not possible in an observational study of this type, the return on invest- ment (ROI) can be estimated by comparing costs across adherence ranges (quintiles) in the disease-related analyses. **For diabetes, the average** incremental **drug cost** for a 20% increase in drug utilization **is $177 and the associated disease- related medical cost reduction is $1251, for a net savings of $1074 per patient** (an average ROI of 7.1:1). For cardiovas- cular conditions, the average ROI for a 20% increase in drug utilization is 4.0:1 (hypertension) and 5.1:1 (hypercholester- olemia). The results for diabetes (Fig. 1) suggest that there may be an inverse linear relationship between adherence and cost for some conditions; this should be tested systematically in future research. Adherence-based savings in medical costs appear to be driven primarily by reductions in hospitalization rates at higher levels of medication adherence. For all of the condi- tions studied here, hospitalization rates were lowest for pa- tients who had high levels of adherence. Hospitalization is the largest component of medical costs in these study samples, so it is

likely that the changes in hospitalization risk are the primary driver of the cost savings observed at higher levels of adherence. This is consistent with results reported elsewhere on the impact of pharmacotherapy on hospitalization rates.8,12,43,44

R2R

We negate, resolved: the United States federal government should impose price controls on the pharmaceutical industry.

Our sole point of contention is that drug price controls would be a healthcare disaster.

Over the past forty years, pharmaceutical innovation has saved countless lives and improved the quality of life for millions of people.

Easton writes in StatNews in 2018: Cardiovascular mortality in the U.S. has declined more than 50 percent since the introduction of propranolol. Many cancers, such as childhood leukemia, have almost been cured. AIDS 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

Although these benefits are enormous, the costs of developing breakthrough medicines are staggering. According to Gleason of Forbes in 2017: the research and development of one medicine takes an average of more than a decade and $2.6 billion.

But the process isn't just expensive, it's risky, because most drugs aren't commercial successes. In his 2008 book, "Pharmaceutical Price Regulation," Vernon writes that: only three out of ten drugs earn back their marketed investments.

Pharma companies, and their investors, only take these great risks to create new drugs because they expect that their profits will be recuperated over time. Gleason explains: the prolonged timeline and high research costs make the pharmaceutical industry a riskier investment than other sectors. As such, a higher rate of return is required to ensure a level of capital that will allow drug makers to continue innovative research and the development of life changing pharmaceuticals.

Drug price controls destroy this business model, leading to less risks and fewer innovations. Gleason writes: drug price controls will stifle innovation by limiting the ability of drug makers and investors to recover the excessive costs associated with their work and reinvest profits.

Thus, Giacotto of the University of Chicago finds empirically that between 1981-2001:
a drug price control regime would have resulted in 330–365 fewer new drugs in the US.

These drugs would most likely be the life saving drugs, as Vernon explains:
Price controls could have greater impact on R&D investment decisions for life saving drugs, because those drugs typically cost more to produce.

The decline of medical innovation will be bad in two places.

First, the US.
Moreno at Precision Health Economics finds in 2017: price controls will lower the cost of drugs for Americans. However, these gains come at a cost. As the pace of innovation slows, future generations of older Americans will have lower life expectancy as there will be less treatment options. When health benefits are valued appropriately, society experiences a significant loss of $5.7 trillion.

The Second is stunting global research.

Foreign companies make most of their profits in the US because the lack of price controls allows them to recoup their costs. Goldman of USC finds this year that: United States market accounts for up to 78 percent of worldwide pharmaceutical profits. These profits drive drug innovation that ultimately benefits patients around the globe.

Price controls in the US would decimate the profits of these companies as well, leading to less global innovation. For example, Goodman of Brookings writes in 2018 that high prices:

Result in a dramatic increase in the number of compounds brought into development to treat rare diseases. It is currently benefiting patients around the world who have HIV. Decades ago, demand for HIV treatment in wealthy countries spurred medical breakthroughs that have since found their way into the poorest corners of the globe. As of July 2017, 20.9 million people living with HIV were accessing antiretroviral therapy globally; 60 percent of them live in eastern and southern Africa.

Overall, Filson at Claremont University finds that with price controls, consumer welfare will fall in the rest of the world by over $13 trillion.

FRONTLINES

R/T Conservative price controls

We would index to Europe (Pearl - New York Times)
Robert Pear, 10-25-2018, "Trump Proposes to Lower Drug Prices by Basing Them on Other Countries' Costs," New York Times, https://www.nytimes.com/2018/10/25/us/politics/medicare-prescription-drug-costs-trump.html (NK)
WASHINGTON — **President Trump proposed on Thursday that Medicare pay for certain prescription drugs based on the prices paid in other advanced industrial countries** — a huge change that could save money for the

government and for millions of Medicare beneficiaries. As part of a demonstration project covering half the country, **Medicare would establish an "international pricing index" and use it as a benchmark in deciding how much to pay for drugs covered by Part B of Medicare**. "This is a revolutionary change," Mr. Trump said in a speech on Thursday at the Department of Health and Human Services. "Nobody's had the courage to do it, or they just didn't want to do it."

R/T Generics Not Accessible

R/T Evergreening

Generics are chosen over brand-name medication basically all the time

Sarah Lee, 10-15-2018, "New Generic Drug Report Shows Promising Savings," Heartland Institute, https://www.heartland.org/news-opinion/news/new-generic-drug-report-shows-promising-savings //DF
The report from the Association for Accessible Medicines, an industry trade group, states generic drugs saved Medicare and Medicaid $82.7 billion and $40.6 billion, respectively, in 2017. These savings for taxpayers translate to an average of $1,952 for every Medicare enrollee and $568 for every Medicaid enrollee, the report states. Other results of the study show brand-name drugs represent 10 percent of prescriptions filled and 77 percent of all prescription spending. In 2017, **nine out of every 10 prescriptions in the United States were generics, and the generic version was chosen 97 percent of the time over a brand-name medication when both were available**, the report states. Free-Market Success Matthew Glans, a senior policy analyst for The Heartland Institute, which publishes Health Care News, says the study shows the free market works when given a chance.

Prices are going down (Koons - Bloomberg)

Cynthia Koons, 4-11-2018, "Why We May Lose Generic Drugs," Bloomberg, https://www.bloomberg.com/news/articles/2018-04-11/are-drug-prices-too-low (NK)
That flies in the face of the public perception that all medical costs are spiraling upward. While many health-care products, including branded drugs—those still under patent—routinely command big price hikes, that's not the case with most generics. A deflation tracker developed by researchers at Evercore ISI Research shows **generic drug prices are falling about 11 percent a year, while brand-name drugs are rising about 8 percent a year**. About five years ago middlemen in the drug-delivery supply chain started to form buying consortia to gain more leverage over drugmakers. The consolidation has since become so extreme that just four groups now control 90 percent of drug buying in the U.S. And two of those four are joining forces to purchase generics, which likely will lower prices further.

R/T Health Affairs Study

FDA is revising the system that resulted in generic backlogs which is the warrant for why there are shortages in their evidence (FDA)

Office of Generic Drugs, December 2017, "Prioritization of the Review of Original ANDAs, Amendments, and Supplements" https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf (NK)

This MAPP describes how the review of original abbreviated new drug applications (ANDAs), ANDA amendments, and **ANDA supplements will be prioritized for review within the Office of Generic Drugs** (OGD) and the Office of Pharmaceutical Quality (OPQ). 1 This MAPP is a revision of MAPP 5240.3 Rev. 3 **Prioritization of the Review of Original ANDAs, Amendments, and Supplements (June 27, 2017**). BACKGROUND On October 18, 2006, OGD issued MAPP 5240.3 Review Order of Original ANDAs, Amendments, and Supplements. **That MAPP set forth certain modifications to OGD's earlier "first-in, first-reviewed" approach to the review of ANDAs, amendments, and supplements**. The Food and Drug Administration (**FDA) continued to revise that MAPP to reflect approaches to the review of ANDAs, amendments, and supplements designed to prioritize submissions that would have a meaningful impact on generic drug access**. These approaches stem from a variety of legislative and regulatory initiatives including the Food and Drug Administration Safety and

US not inventing

We Are tho
https://xconomy.com/seattle/2014/09/02/which-countries-excel-in-creating-new-drugs-its-complicated/ (cite in screenshot)

Table 2: New chemical entities
By headquarter country of inventing firm

	1971-1980		1981-1990		1991-2000		2001-2010	
Country	**NCEs**	**% total**	**NCEs**	**% total**	**NCEs**	**% total**	**NCEs**	**% total**
U.S.	157	31	145	32	75	42	111	57
France	98	19	37	8	10	6	11	6
Germany	96	20	67	15	24	13	12	6
Japan	75	15	130	29	16	9	18	9
Switzerland	53	10	48	11	26	14	26	13
U.K.	29	6	29	6	29	16	16	8
Total NCEs	508		456		180		194	

Sources: Arthur Daemmrich, "Where Is the Pharmacy to the World? International Variation and Pharmaceutical Industry Location," Harvard Business School Working Paper, 2009; Milken Institute.

R/T Profits ≠ R&D

High profits are needed now as the industry moves into researching more complex medications

Chressanthis 18 George A. Chressanthis [Principal Scientist at Axtria, USA. This article was co-published with Axtria, a big data and analytics company.], 8-16-2018, "The Potential Pitfalls of Price Controls," Medicine Maker, https://themedicinemaker.com/issues/1016/the-potential-pitfalls-of-price-controls/ //DF

Given that drug pricing has been a big topic during the US elections, it is possible that the country will see some form of direct drug price controls in the future. Instituting drug price controls would be a policy approach consistent with a populist-oriented Trump presidency. Whether the Republicans in Congress – who now control both chambers and have traditionally voted against such controls – would go along with it remains to be seen. Pressure will be exerted by the progressive wing of the Democratic party, which has gained in influence during this election cycle from the Bernie Sanders run, and will most certainly push for direct government-imposed drug price controls. Yet, the US government already has a number of powerful mechanisms to help control prices. For example, the federal government establishes Medicaid drug pricing based on significant discounts from the best commercial price being offered. It is important to remember that significant market forces affect pricing, from increased branded drug competition and competition from generic entry post-patent expiration (including early patent challenges), to bioequivalent and therapeutic drug substitutions. Concentrated market power is shown to affect drug pricing and utilization by drug wholesalers, large health payers, and dominant pharmacy benefit managers. What those advocating for drug price controls often fail to recognize is that **the pharma industry is undergoing rapid and fundamental changes. The easy disease targets that can be addressed with small-molecule drugs are rapidly vanishing and more incentives, not less, are needed for pharma companies to unlock the solutions to the most challenging unmet medical needs**. Complicating the challenge facing drug companies is the fact that both improvements in health outcomes and costs of care will be measuring sticks to determine future rewards from drug innovation. This will be an expensive endeavor, and questions exist as to whether society is willing and able to pay for increases in drug innovation needed to solve these medical challenges – the future is

admittedly uncertain. Various groups have traditionally banded together to advocate against direct drug price controls in the US and to date their efforts have been successful (29). However, the dramatic increases in prices necessary to support drug innovation are straining the coalition. Increasingly, new drugs are being priced beyond the means of both payers and patients. Even for drugs that deliver both extraordinary health outcomes and cost-effectiveness – such as new treatments that cure Hepatitis C and so prevent costly complications – patient access is limited because widespread use would quickly bankrupt healthcare reimbursement systems. At the same time, the current commercial model that companies are using to maintain profitability (mainly through price increases) is clearly unsustainable in the long run (30), (31).

Most generic turns

In an analysis isolating for healthcare spending, using infant mortality as a proxy, Cremieux finds empirically that More pharmaceutical spending leads to better health outcomes (Cremieux - U Hong Kong)

Pierre-Yves Cremieux, 2015, University of Hong Kong, "Pharmaceutical spending and health outcomes in the united states", https://sci-hub.se/https://www.emeraldinsight.com/doi/abs/10.1016/S0194-3960%2801%2914004-7 (NK)

Table 4 summarizes the results of the regression model. The overall predictability is high (R-squared = 0.87) and, in almost all cases, the direction of the relationship between infant mortality and the explanatory variables (i.e. as indicated by the sign of the coefficients) is consistent with hypothesized values based on the correlation statistics as well as existing literature. To understand the implications of these findings, the discussion below also incorporates reference to the impact of 10% changes in various of the independent measures.

Pharmaceutical Expenditures Our results show that **an increase in pharmaceutical spending is associated with a significantly reduced infant mortality rate** ($p < 0.001$). In fact, **a 10% increase in pharmaceutical spending would decrease infant mortality by close to 1%** (341 lives saved). As noted earlier, this result must be understood as a conservative estimate of the value of pharmaceuticals generally, since much of this category of spending is not targeted to health outcomes that are likely to affect infant mortality at all (e.g. palliative care, care for the elderly).

if spending on pharmaceutical products had been equal to the level observed for the 10th (lowest) percentile in the sample each year; and (3) if spending on pharmaceutical products had been equal to the level observed for the 90th (highest) percentile in the sample each year. In all three cases, the impact of pharmaceutical spending on the infant mortality rate is surprisingly large. **Even when limiting the health outcome measure to infant mortality, the results clearly indicate that higher spending on pharmaceutical products could have significant effects on health outcome. The number of infant lives potentially saved by an increase in pharmaceutical spending is significant**. In 1997 alone, if spending in each state on pharmaceutical products had been equal to that of the state at the 90th (highest) percentile in that category, more than 0.275 infant lives per 1,000 live births may have been saved. This corresponds to over 1,000 infant lives or more than 3% of infants who died that year. In contrast, maintaining pharmaceutical spending at their 1981 levels would have led to an additional 3,500 infant lives lost in 1997 alone. As the public policy debate continues to take shape over the optimal level and composition of both public as well as private health expenditures, various forms of health care investment must be understood as conferring different types of value on society. As basic health care needs are met, and as the population ages, individuals may be eager to pay higher prices for increased effectiveness, comfort and convenience. This analysis suggests that, at least where pharmaceutical products are concerned over the last 20 years, the increase in spending observed in the United States has been accompanied by a measurable increase in effectiveness that translates into lower infant mortality.

High spending, better outcomes (Frank - Brookings)

Richard Frank and Paul Ginsburg, 11-17-2017, "Pharmaceutical industry profits and research and development," Brookings, https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2017/11/17/pharmaceutical-industry-profits-and-research-and-development/ (NK)

A central tenet of economics is the law of diminishing returns. In this case, additional resources going into innovation inevitably yield fewer important breakthroughs. At some point, perhaps already reached, the yield from additional resources going into R&D no longer justifies what society is paying in the form of higher prices to support this. BASIC ECONOMICS OF PATENT PROTECTION AND PHARMACEUTICAL R&D

Pharmaceutical innovation has produced an enormous amount of social value. The evidence on this point is strong and comes from multiple sources. **Studies of disease-specific spending on prescription drugs,**

macro-comparisons in the United States, and international comparisons have all pointed to high social returns with respect to longevity and functional health outcomes.[1] Those benefits from pharmaceutical innovation stem in great measure from patent policy and the granting of marketing exclusivity to new drug products. The pharmaceutical industry is what economists call a high-fixed low-cost marginal cost industry. This means that the cost of bringing a new drug to market is very high and the process is risky, while the cost of producing an extra unit of a product that is on the market is frequently "pennies a pill". There is energetic disagreement about the exact cost of bringing a new drug to market, but there is widespread recognition that the costs run into at least many hundreds of millions of dollars per new drug product.

R/T European Companies Are Profitable

Revenues from the US subsidize pharma companies worldwide (Mcardle - The Atlantic)

Megan Mcardle, 2009, "Does the US Really Account for So Much Pharma Profit?," Atlantic, https://www.theatlantic.com/business/archive/2009/09/does-the-us-really-account-for-so-much-pharma-profit/24465/ (NK)

For example, GlaxoSmithKline, which Waldman mentions as a counterargument to my estimate, just had a catastrophic collapse in its US revenues due to the expiration of important patents like Wellbutrin XL, Paxil CR, Imitrex, and Lamictal. Waldman would have known this had he, like, Googled it. But there are other ways that we can back into the question of which markets are the most important. Sadly, there are no definitive numbers on the topic that I am aware of. And I've asked a lot of researchers, left and right. We can, first of all, look at financial statements longitudinally. W**e can examine what happens to profits of pharmas when sales in the US decline, while sales in Europe (and overall revenues) rise. The answer, for GlaxoSmithKline, was that profits fell 13%. The US is punching massively out of its weight class on their balance sheet**. Next, we can look at where the revenues come from. According to the OECD's invaluable *Pharmaceutical Pricing Policies in a Global Market*, which really is a bargain at the price, **45% of global sales come from the United States,** 30% from Europe, and 9% from Japan, meaning that **the US accounts for the lion's share of profit--sales in other countries are too low margin to be currently important markets**, though they're undoubtedly nice gravy, and serve an investment function. The OECD also says that the United States accounts for more than half the growth in pharmaceutical revenue. And it singles out the United States as the "important exception" to the otherwise iron rule that no country's prices much affect the level of R&D spending. We can look at per-capita pharma spending. The United States spends about twice the OECD average, and as aforementioned, does more than half of the OECD spending on pharmaceuticals.

Implementing price controls in the United States would have adverse effects on European consumers, by depressing rates of innovation. These global linkages create major policy problems in an international marketplace, because a given country does not fully realize the benefits (or costs) of its own policies. **European price controls**, for example, **have smaller effects on innovation, because of the presence of a large U.S. market, which acts as a counterweight to policies that reduce European revenues**. Moreover, some of the costs that do accrue end up being borne by U.S. consumers, further dampening Europe's incentives for higher prices. Any single scenario may be incorrect, since many of the needed parameters are difficult to estimate. Our more general finding is that from a long-run global perspective, reducing copayments tends to be a robust and welfare-improving policy, while imposing price controls risks large costs in the hope of a relatively modest benefit. Policymakers facing uncertainty about the structure of pharmaceutical markets may find copay reduction to be a safer strategy than price controls, and one that is extremely likely to improve welfare over the status quo.

In Fact, US consumers make up for up to 78% of global pharmaceutical profits (Goldman - USC)

Dana Goldman, USC, 2018, "The Global Burden of Medical innovation", [Dana Goldman is the Leonard D. Schaeffer Chair and a Distinguished Professor of Pharmacy, Public Policy, and Economics at the University of Southern California}
https://healthpolicy.usc.edu/research/global-burden-of-medical-innovation/ (NK)
U.S. consumers spend roughly three times as much on drugs as their European counterparts, and 90 percent more as a share of income. Calculations using publicly available aggregate data suggest that the **United States market accounts for 64 to 78 percent of worldwide pharmaceutical profits. These profits drive drug innovation that ultimately benefits patients around the globe**. While American subsidies to innovation provide much-needed philanthropy to poor countries, patients in richer countries outside the United States would benefit longer-term if they financed a greater share of drug discovery. Using a previously published economic-demographic microsimulation, we estimate that if European prices were 20 percent higher, the resulting increased innovation would generate $10 trillion in welfare gains for Americans, and $7.5 trillion for Europeans over the next 50 years. Encouraging other wealthy countries to shoulder more of the burden of drug discovery — including higher prices for innovative treatments — would ultimately benefit patients in the United States and the rest of the world. Download the full paper here.

US makes a lot more return than EU (vernon and Golec)

Vernon and Golec, American Enterprise Institute, "Pharmaceutical Price Regulation" 2008.
32 PHARMACEUTICAL PRICE REGULATION example, Dowdell, Govindaraj, and Jain (1992) and Dranove and Olsen (1994) show that the introduction of more stringent production, testing, and compliance regulations significantly decreased pharmaceutical firms' stock prices. Although current profits were not affected, investors expected future costs to rise, making pharmaceutical stocks worth less. Perhaps this is not so surprising, given our understanding of the effects of profit margins and stock prices on R&D spending. Golec and Vernon (2006) show that U.S. firms' profit margins exceeded those of EU firms by an average of five percentage points from 1906 through 2004. **And from 1993 to 2004, the percentage return on U.S. pharmaceutical stocks exceeded the return on EU pharmaceutical stocks by 100 percentage points. Relatively high US stock prices have allowed US biotech firms to raise significant amount of equity capital to fund R&D spending.** In the previous section, we noted that because US firms sell more of their medicines at US prices, they have higher profit margins and their investors recieve higher returns compared to European firms.

R/T Pharma more profitable than other industries

Pharma is moderately profitable, and their profits are actually decreasing

John Lamattina, 1-23-2018, "About Those Soaring Pharma Profits," Forbes, https://www.forbes.com/sites/johnlamattina/2018/01/23/about-those-soaring-pharma-profits/#7a06c0e43f9d //DF
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%). **Another measure, Internal Rate of Return** (IRR) is even more telling. IRR **calculates the sales/cash flows resulting from R&D investments**, ties R&D and the returns it generates together, and is **a more appropriate metric for biopharma productivity**. Deloitte reports that the IRR for biopharma R&D **has been steadily falling from 10.1% in 2010 to 3.2% in 2017**. Even Wall Street hasn't bought into the "pharma soaring profits" view. Since February 1, 2014, while the Dow has risen 63%, the stock prices of a number of major pharma companies have been muted with Pfizer and Bristol-Myers each growing by about 15%, and Merck and AstraZeneca by roughly 6.5%. Even Lilly's growth of 43% still lags the Dow.

R/T Pharma not profitable

Still the most profitable industry (Forbes - 2015)

Liyan Chen, 2015, "The Most Profitable Industries In 2016," Forbes, https://www.forbes.com/sites/liyanchen/2015/12/21/the-most-profitable-industries-in-2016/#432dcabd5716 (NK)

Earlier this year, we examined the profitability of different sectors in 2015 based on estimates from Factset. As 2015 will soon come to an end, we are taking a look at the forecasted net profit margins for 19 major U.S. sectors next year. As shown in the interactive chart below, almost all sectors -- with the exception of transportation -- will see an increase in profitability, according to Factset. **Health technology is projected to be the most profitable sector in 2016 again with a 21.6% net profit margin.** With 17.2% net margin, technology services will edge out finance (17.1%) to take the second place. Interestingly, the Federal Reserve's first interest rate hike since 2006 did not cause any significant changes to the earnings estimates for companies in the finance sector in 2016. Electronic technology and consumer non-durables still trail at fourth and fifth place.

Profits have increased the past 10 years, and R&D has gone up as well (US GOV - 2017)

2017, US GOVERNMENT ACCOUNTABILITY OFFICE, "DRUG INDUSTRY Profits, Research and Development Spending, and Merger and Acquisition Deals" https://www.gao.gov/assets/690/688472.pdf

The amount of money people spend on prescription drugs has nearly doubled since the 1990s. Much of this increase is due to expensive brand-name drugs, but the prices of some generics have also gone up. We looked into changes in **the drug industry and found that pharmaceutical and biotechnology sales revenue increased from $534 billion to $775 billion between 2006 and 2015. Additionally, 67% of drug companies increased their annual profit margins during the same perio**d—with margins up to 20 percent for some companies in certain years. **Drug industry spending for research and development increased from $82 billion in 2008 to $89 billion in 2014.**

R/T R&D won't be cut

It will, because its so profitable. Each dollar spend in advertising gives companies up to $4 in revenue (Ventola - NCBI)

Ventola, NCBI, 2011, "Direct to Consumer Advertising, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/ (NK)

Prior to 2005, the Government Accountability Office (GAO) had estimated that DTCPA was growing at approximately 20% per year, or twice as fast as spending on pharmaceutical direct-to-physician (DTP) advertising or on drug research and development.23 Th**e growth in DTC advertising expenditures was not without reason, being that it was estimated that every dollar spent on DTCPA would increase sales of the advertised drug by an estimated $2.20 to $4.20.24–26 Still,** in 2005, DTCPA accounted for only 14% of industry expenditures, whereas DTP advertising totaled 24%.6,26 Although the relaxation of FDA rules in 1997 might not have been totally responsible for the rapid growth of DTC drug advertising, it did have an impact on the most preferred media for DTCPA.15,17 Most of the budget for DTCPA is now spent on television commercials.26,27 The average American television viewer watches as many as nine drug ads a day, totaling 16 hours per year, which far exceeds the amount of time the average individual spends with a primary care physician.5,23,27 In recent years, drug marketers have also increased their expenditures for marketing efforts on the Internet, as searching for health-related information has become the third most common activity for online users.22,26 In 2003, the pharmaceutical industry spent $59 million on DTC promotion on the Internet, and spending is now estimated to have grown to $1 billion.15,26 This channel of promotion also promises to be lucrative; data show a 5:1 return on investment for online DTCPA, which is much better targeted than print or television ads in reaching the intended audience.22

R/T Increasing Access increases pharma profits

1. This isn't true because most consumers have maximum prices that they can pay under insurance. If the price of the drug goes over the maximum, they will still only pay the maximum, so demand won't go down

Richard Frank [Margaret T. Morris Professor of Health Economics in the Department of Health Care Policy - Harvard Medical School] and Paul Ginsburg [Director - Center for Health Policy, USC-Brookings Schaeffer Initiative for Health Policy Leonard D. Schaeffer Chair in Health Policy Studies Senior Fellow - Economic Studies], 11-17-2017, "Pharmaceutical industry profits and research and development," Brookings, https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2017/11/17/pharmaceutical-industry-profits-and-research-and-development/ //DF

In a market economy, with government acting only to provide patent protection and exclusivity to allow innovation to be viable, drug prices would be set by supply and demand. Since much of the cost of producing drugs involves the research and development to create them—as opposed to the cost of manufacturing the pills—the price that can be obtained influences the amount that is invested in development of new drugs. However on the demand side, higher prices lead to fewer units of the drug being sold. This demand constraint leads to investment being sensitive to value—what a drug accomplishes medically for patients compared to what it will cost. To the degree that health insurance pays for a substantial portion of the price of drugs, manufacturers can charge higher prices and likely will invest more to develop new drugs. But three important developments in recent years have altered the demand constraint. First, more people have coverage for drugs as a result of the implementation of Medicare Part D and the expansion of insurance coverage under the Affordable Care Act. Second, insurance for drugs has become substantially more comprehensive through the spread of benefit designs that set a maximum on the amount of out-of-pocket spending that the enrollee has to pay. Third, some newer drugs—especially specialty drugs used to treat complex, chronic conditions like cancer, rheumatoid arthritis, and multiple sclerosis—have very high prices, a factor that impacts demand through its interaction with various elements of the insurance benefit design. If a patient is using a $50 drug and a new, perhaps better medication comes along at a price of $100, insurance benefit designs usually allow the patient (with support from a prescribing physician) to use the newer drug, but at an additional cost. While the difference in cost to the patient is usually less than the price difference between the drugs, only patients who perceive better results will switch. But this all changes when prices are $100,000 per year or $200,000 per year. For these drugs, most patients who have to pay a substantial part of the cost will not be able to afford the drug at all. However, out-of-pocket maximums make the drugs affordable and in the process make the patient insensitive to price differences. So the $100,000 drug and $200,000 drug cost the patient the same amount—their out-of-pocket maximum. This means that raising prices at this level does not trigger demand restraint on the part of patients. Thus, the combination of current benefit designs and very expensive drugs means that raising prices even higher may not lead to fewer units. The likely result is higher revenues and more investment in development of new drugs because they promise to be so profitable.

2. If this were true then companies would charge lower profits

R/T Public Funding

The NIH only funds early stage development - private sector is still necessary (NCBI)

NCBI, 2009, "Breakthrough Business Models: Drug Development for Rare and Neglected Diseases and Individualized Therapies: Workshop" https://www.ncbi.nlm.nih.gov/books/NBK50972/ (NK)

The principal investors in drug development differ at each stage. While basic discovery research is funded primarily by government and by philanthropic organizations, late-stage development is funded mainly by pharmaceutical companies or venture capitalists. The period between discovery and proof of concept, however, is considered extremely risky and therefore has been difficult to fund. Several initiatives discussed below have been undertaken to overcome this funding gap. Early-and Late-Stage Development Historically, **the largest government investments in basic drug discovery research have been made by the National Institutes of Health (NIH)**. The Defense Advanced Research Projects Agency (DARPA) has also contributed to the discovery stage by taking on some relatively high-risk biologic projects. Moreover, in part as a result of the public's impatience with the slow pace of the discovery process, state governments are increasingly taking the initiative in this area. One such example is the California Institute for Regenerative Medicine, a state agency established in 2005 by the California Stem Cell Research and Cures Initiative, which provides grants and loans for stem cell research and facilities at California's research institutions and universities. Another example is the Texas Cancer Initiative, under which state funds are dedicated to cancer research conducted in Texas. **Beyond these public investments, private foundations are also taking a significant financial interest in the discovery process, facilitating progress by funding research in their particular areas of interest**. At the other end of the continuum is **late-stage development, which is funded primarily by pharmaceutical companies or venture capitalists** with some collaborative support from government sources, such as NIH. Such partnerships are critical in the transition from proof of concept to clinical development.

PHARMA DOES CLINICAL TRIALS - THE EXPENSIVE STUFF (ANGELL 23 - 24)

R/T $600 million R&D Study

This is a pretty bad study because they functionally look at 10 companies who made one successful drug, which is misleading because most of the cost comes from making so many drugs that fail (Herper - Forbes)

Matthew Herper, Oct 2017, "The Cost Of Developing Drugs Is Insane. That Paper That Says Otherwise Is Insanely Bad," Forbes, https://www.forbes.com/sites/matthewherper/2017/10/16/the-cost-of-developing-drugs-is-insane-a-paper-that-argued-otherwise-was-insanely-bad/#2f43edca2d45 (NK)

You probably know this poem, or at least the story it tells. One man likens the elephant to a wall, another to a spear, a third to a snake, a fourth to a tree. The point is that each sees only part of the animal, and is thereby deceived. Well, here's how the same thing happened when it came to a new estimate of the cost of developing a new medicine. For years, the pharmaceutical industry has relied on estimates from the Tufts Center for the Study of Drug Development, the most recent of whichthat puts the cost of bringing a medicine from invention to pharmacy shelves at $2.7 billion. Last month, two cancer researchers grabbed headlines by asserting that estimate is way off. **Their number, published in JAMA Internal Medicine: $648 million**. In an editorial that ran alongside the new study, journalist Merrill Goozner wrote: "Policymakers can safely take steps to rein in drug prices without fear of jeopardizing innovation." There are reasons to think that (more on that later), but this paper does not add to them. **Unfortunately for the authors, pharmaceutical investors, and people fighting to control drug prices, the $648 million estimate doesn't stand up scrutiny**. A closer look at the authors' own data raises problems with their analysis**. A larger data set I published four years ago, when taking into account the study's implicit arguments, yields a figure of about $2 billion.** This study doesn't upset the previous work on drug development costs at all. In fact, the data present a highly consistent picture – if you know whether you're holding a tusk, a trunk, or a tail. A primer: **The amount spent to develop any individual drug depends mostly on what it costs to conduct studies to prove it is safe and effective and secure regulatory approval. That can**

range from $10 million to $2 billion, depending on what the drug is for. But what really drives up costs is the fact that 90% of medicines that start being tested in people don't reach the market because they are unsafe or ineffective. The $2.7 billion figure includes the cost not only of these failures, but also of not putting the money spent on them into something that would give a more reliable return. The authors of the new study, oncologists Vinay Prasad from Oregon Health & Science University and Sham Mailankody from Memorial Sloan Kettering Cancer Center, t**hink that large companies inflate these costs through inefficiency or worse. So they chose to look at the 10 companies that developed only a single cancer drug from 2006 through 2015. The $648 million figure is simply the median R&D spending of these 10 companies.** The number of drugs under development by 10 biotech firms evaluated by Prasad and Mailankody, versus their R&D spending.JAMA INTERNAL MEDICINE **Prasad and Mailankody assert this analysis takes into account the high attrition rates of drug development because each company was developing between 2 and 11 experimental medicines, only one of which reached the market. But this assumes that the companies were developing a large enough number of medicines to capture the high failure rate of drug development. Given that 9 in 10 medicines fail, it seems unlikely that looking at companies that had made 4.3 attempts at creating a drug, on average, would capture this. Conceptually, this is no different from simply looking at companies that had only tried to develop a single drug and happened to succeed. Researchers call this "survivorship bias" – it's like estimating an average lifespan by asking people their ages, but not finding out if anyone already died**.Just graphing the amount spent by each company in Prasad and Mailankody's data set makes it plain that they didn't overcome survivorship bias. Generally speaking, the more drugs a company was developing, the more it spent on R&D per drug. How can you tell how many times you have to try to develop a drug to have good odds of doing so from this? You can't

R/T innovation decreasing

Innovation will remain high for a number of years (Lamattina 18)

John Lamattina [I was the president of Pfizer Global Research and Development in 2007 where I managed more than 13,000 scientists and professionals in the United States, Europe, and Asia. I've received numerous awards including an Honorary Doctor of Science degree from the University of New Hampshire], 6-12-2018, "Pharma R&D Investments Moderating, But Still High," Forbes, https://www.forbes.com/sites/johnlamattina/2018/06/12/pharma-rd-investments-moderating-but-still-high/#484b83216bc2 //DF

A new analysis, "World Preview 2018, Outlook to 2024" newly issued by EvaluatePharma provides guidance on this. Interestingly, EvaluatePharma is predicting accelerating sales for the pharmaceutical industry with annual compound growth of 6% between now and 2024. "The launch of novel therapies, including gene and cell therapies, as well as increased access to medicines globally should help fuel progress in the market. Total prescription sales are expected to be $1.2 trillion in 2024." But, these higher sales are not expected to translate into higher R&D investments. "R&D spend is forecast to grow at a CAGR of 3.1% to 2024 lower than the CAGR of 3.6% between 2010 and 2017 signaling that companies will be improving R&D efficiencies or less revenue will be directed towards replenishing pipelines." While disappointing, it is important to put these numbers into perspective. According to EvaluatePharma, in 2017 the top 20 pharmaceutical companies invested 20.9% of top line revenues into R&D - a very impressive number. This amounted to $97.2 billion in 2017. For comparison purposes, the NIH budget is $37 billion. In 2024, EvaluatePharma is projecting that the top 20 companies will be spending $116.4 billion on R&D, 16.9% of sales – still a very high percentage when compared to other industries. The 2024 leaders will be Roche at $11.7B, Johnson & Johnson at $10.0B and Novartis at $9B. These changes are probably not

enough to allay Stott's concerns. However, it is clear that the pharmaceutical industry is going to continue to invest in R&D at a pretty healthy rate for the foreseeable future. For all of our sakes, it is imperative that their efforts are successful.

Low innovation is a result of external factors, such as increased development costs, or higher rates of failure. This trend could change soon with the advent of new technologies like precision medicine (OECD)

OECD, 2015, "Research and development in the pharmaceutical sector"
https://www.oecd-ilibrary.org/docserver/health_glance-2015-70-en.pdf?expires=1540930143&id=id&accname=guest&checksum=3E744B2C2B2D0F770281BA656143314E (NK)

Is this increase in R&D spending associated with a higher output or productivity? In the United States, the world's largest developer of pharmaceuticals, the annual number of approved new drugs, formulations or indications has more than doubled since 1970 (Figure 10.16). **However, when compared with R&D spending over that period (adjusted for inflation), the number of approvals per billion USD spent on R&D has reduced by a factor of 15** (Figure 10.16). The reasons for this observation are likely to be complex. **Growing requirements to obtain regulatory approval have increased development costs. Higher failure rates and an ever-increasing "back catalogue" of effective drugs may also be a factor.** More fundamental problems with the current R&D model and development pipeline have also been suggested (Scannell et al., 2012). Risk-benefit decisions made by industry regarding early R&D targets may also be a function of the regulator, payer and the community response to the eventual product. Of course, **the downward trend may reverse in the coming years due to changes in the R&D model, or the emergence of new technology (e.g. precision medicine).** References Kezselheim, A., Y. Tan and J. Avorn (2015), "The Roles of Academia, Rare Diseases, and Repurposing in the Development of the Most Transformative Drugs", Health Affairs, Vol. 34, pp. 286-293. OECD (2015), Main Science and Technology Indicators Database, online, available at: www.oecd.org/sti/msti.htm [accessed 8 July 2015]. Scannell, J. et al. (2012), "Diagnosing the Decline in Pharmaceutical R&D Efficiency", Nature Reviews Drug Discovery, pp. 191-200. Definition and comparability Business enterprise expenditure on R&D (BERD) covers R&D activities carried out in the private sector by performing firms and institutes, regardless of the origin of funding.

R/T R&D won't decrease

They need investors, and if rates of return go down, they will not get investors to fund the R&D projects

Vernon and Golec, American Enterprise Institute, "Pharmaceutical Price Regulation" 2008.

Firms will undertake the high return projects first (the vertical bars on the left hand side of the chart) and continue to undertake additional investment projects so long as the expected rate of return from the next project exceeds the firm's cost of capital, meaning that few of the projects further to the right will pay off. This is the classic supply and demand framework. **In economic terms, price regulation shifts the marginal internal rate of return schedule down, and fewer R&D projects meet the criterion of earning an internal rate of return that exceeds the cost of capital required to fund the project. Investors will not supply capital to fund the marginal projects whose internal rates of return fall below their required returns. These marginal_projects could be minor medical advances or major breakthrough medicines. If one assumes that breakthrough medicines can command higher market prices, then price regulation is more likely to be applied to them**. Indeed, the Clinton administration's Health Security Act proposed to regulate mostly high-priced breakthrough drugs. After all, there is little cost savings in constraining low-priced, seldom-used drugs. Finally, figure 1-4 excludes the effects that internal cash flows have on capital supply to the firm. Cash flows exert a positive influence on the level of firm investment spending, but price regulation constrains this internal capital supply and thus reduces R&D investment.

R/T Innovation ineffective

Low innovation is a result of external factors, such as increased development costs, or higher rates of failure. This trend could change soon with the advent of new technologies like precision medicine (OECD)

OECD, 2015, "Research and development in the pharmaceutical sector" https://www.oecd-ilibrary.org/docserver/health_glance-2015-70-en.pdf?expires=1540930143&id=id&accname=guest&checksum=3E744B2C2B2D0F770281BA656143314E (NK)

Is this increase in R&D spending associated with a higher output or productivity? In the United States, the world's largest developer of pharmaceuticals, the annual number of approved new drugs, formulations or indications has more than doubled since 1970 (Figure 10.16). **However, when compared with R&D spending over that period (adjusted for inflation), the number of approvals per billion USD spent on R&D has reduced by a factor of 15** (Figure 10.16). The reasons for this observation are likely to be complex. **Growing requirements to obtain regulatory approval have increased development costs. Higher failure rates and an ever-increasing "back catalogue" of effective drugs may also be a factor.** More fundamental problems with the current R&D model and development pipeline have also been suggested (Scannell et al., 2012). Risk-benefit decisions made by industry regarding early R&D targets may also be a function of the regulator, payer and the community response to the eventual product. Of course, **the downward trend may reverse in the coming years due to changes in the R&D model, or the emergence of new technology (e.g. precision medicine).** References Kezselheim, A., Y. Tan and J. Avorn (2015), "The Roles of Academia, Rare Diseases, and Repurposing in the Development of the Most Transformative Drugs", Health Affairs, Vol. 34, pp. 286-293. OECD (2015), Main Science and Technology Indicators Database, online, available at: www.oecd.org/sti/msti.htm [accessed 8 July 2015]. Scannell, J. et al. (2012), "Diagnosing the Decline in Pharmaceutical R&D Efficiency", Nature Reviews Drug Discovery, pp. 191-200. Definition and comparability Business enterprise expenditure on R&D (BERD) covers R&D activities carried out in the private sector by performing firms and institutes, regardless of the origin of funding.

R/T Recycling

R/T TURN Higher Value Drugs

R/T Safer Drugs

R/T invest in AI Etc.

R/T Diminishing Returns

R/T Gov't Funding Solves

The government only funds basic research, but the more expensive part is the clinical testing

Marcia Angell [M.D.], 2005, "The Truth About Drug Companies," Random House Publishers (23) //DF
The development part of R&D is itself divided into two stages–preclinical and clinical. The preclinical stage has to do with finding promising drug candidates and then studying their properties in animals and cell culures. Companies keep vast libraries of drug candidates–molecules that can now be screened very rapidly by computerized methods to see if they will target the Achilles' heel found by the basic research. In addition, new molecules can be synthesized or extracted from animal, plant, or mineral sources. Only the small fraction of drug candidates that make it through preclinical development go on to be tested in humans–the all-important clinical stage (more on that later). According to the pharmaceutical industry, only one in fine thousand candidate drugs make it to market–one in one thousand survive preclinical testing, and of those, one in five make it through clinical testing. Paradoxically, although it is the least creative part of the process, **clinical testing is the most expensive**. The great majority of drug candidates are thus weeded out very early on, before there has been a great deal of money invested in them.

R/T R&D Spending going down

Pharmaceutical companies report spending a record $71.4 billion on research and development in 2017, according to an annual survey of members of PhRMA, the powerful industry lobbying group. The group's annual report found **R&D spending was up in not only absolute terms as total spending, but also in relative terms as percentage of total sales. Proportionally, companies spent 21.4% of total sales on R&D.** The report comes as pharmas are under pressure for escalating drug costs, with President Donald Trump proposing an array of measures to tamp down. Some critics have for years called into question the industry figures, which are a common rationale for steep drug prices.

R/T Per capita Spending is the same

R/T Europe has more per capita

R/T Prioritize short Term

EXTRAS