R2R 2.0

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, and Vernon and Golec explain:

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.

Case

Healthcare:

Drug prices are rising faster than any other healthcare cost (Fielding - US News)
Jonathan Fielding, December 2017, "The High Cost of Rising Drug Prices," US News & World Report, https://www.usnews.com/opinion/policy-dose/articles/2017-12-21/the-high-cost-of-rising-drug-prices (NK)

Pharmaceutical Research and Manufacturers of America, known as PhRMA, raised $271 million in 2016, a $50 million increase over 2015, according to IRS filings. The group gave millions to presidential, congressional and state candidates and spent $57 million on lobbying efforts, a two-thirds increase over 2015. "Does that surprise you?" former PhRMA CEO Billy Tauzin told NPR. When government responds to voters' cry for lower drug prices, Tauzin stated, "PhRMA has always responded by increasing its resources." **Lowering drug prices is long overdue, but this report shows what patients are up against. Right now, spending on prescription drugs rises at a rate faster than any other health care cost.** Growing numbers of Americans can't afford their medications, forcing too many to skip them altogether. Alex Azar, President Donald Trump's pick for health and human services secretary, told a Senate Committee last month that bringing drug prices down would be his top priority, confirming this is the president's priority as well. Encouraging words, but choosing Azar as a change agent is ironic

High prescription drug costs are driving an overall increase in healthcare costs (Goozner - Modern Healthcare)

Goozner, Modern Healthcare, January 2018, "Editorial: Rising drug prices are the root cause of healthcare's cost problem", [professor of journalism at New York University. author of The $800 Million Pill: The Truth Behind the Cost of New Drugs,, and has contributed articles to numerous publications. Goozner earned a master's degree in journalism from Columbia University]
https://www.modernhealthcare.com/article/20180113/NEWS/180119961 (NK)

I've always counted myself among those who see the problem of rising healthcare costs as a "Pogo" issue. "We have met the enemy and he is us," as the newspaper cartoon character used to say. High hospital prices, overpaid doctors, overutilization, disparate regional care patterns all have come in for a share of the blame in recent years. There is a modicum of truth in each of those claims. But, after closely examining the latest CMS expenditures report, **the indisputable fact is that rising drug and medical-device prices remain the most serious contemporary cost problem the healthcare industry has. Indeed, it threatens to overwhelm all other efforts at cost control, many of which are showing signs of progress.** Let's do a quick tour through the math. When the Affordable Care Act passed in 2010, healthcare's share of the national economy stood at 17.4%. It fell to 17.2% by 2013, but by 2016 was back up to 17.9%. The small but noticeable increases in recent years are raising fears we're re-entering a period of uncontrolled spending. However, **not all sectors are increasing at the same rate.** Total personal healthcare consumption, not adjusted for inflation, rose 16.7% between 2013 and 2016. But its hospital spending component rose at a slower pace-15.5%. Professional services, which is mostly physician office-based care, also rose more slowly-16%. On the other hand, **drug spending, whether purchased through pharmacies, mail order or online, rose by 23.9% over the past three years. That led to the drug industry gaining nearly a full-percentage-point share of the overall healthcare economy since 2013. In an economic sector where change is glacial, an increase of 1 percentage point is huge. And the share grab is actually much worse. Retail drug sales don't include the most expensive drugs-those delivered in hospital outpatient and physician offices**. The CMS doesn't track that data separately, but one can get a glimpse of what's happening by examining the latest financial reports from major hospital systems. Ascension, for instance, saw its margins collapse in its most recent quarter. Total operating expenses at the nation's largest not-for-profit hospital system rose 12.9% over its last three full fiscal years, an average of 4.3% a year.

Innovation

Easton writes in StatNews in 2018:

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.

Companies need profits to make drugs

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

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. In addition, for many drugs the costs of imitation are low. It is simple and low cost for a firm that did not develop the drug to produce a copy of a new drug. This means that if free competition were permitted, firms spending hundreds of millions of dollars to bring a new drug to market would be unlikely to recoup those investments, as competition would drive prices down to production costs ("pennies a pill"). It is these features of the economics of new drug development that make the establishment of intellectual property rights through the patent

system and regulation of marketing exclusivity so important to promoting innovation in prescription drugs. Establishing temporary monopoly power for makers of new prescription drug products enables innovator companies to raise prices above the level of production costs and realize economic profits to compensate for the investment in pharmaceutical R&D.

Between 2016 and 2017, R&D investment shifted away from the US and towards Europe (Dunn - Biopharma Drive)

Andrew Dunn, 8-13-2018, "Drugmakers say R&D spending hit record in 2017," BioPharma Dive, https://www.biopharmadive.com/news/phrma-research-development-spending-industry-report/529943/ (NK)

PhRMA changed membership criteria in May 2017 requiring member companies to invest a minimum of 10% of global sales in R&D, resulting in seven companies leaving at the time. That move could have also artificially boosted the figures in this report by removing the lowest-spending companies from the membership pool. The 8-page report found increases in **R&D spending in a variety of measurements for 2017 compared to 2016.** Total R&D increased nearly 9% from $65.5 billion to $71.4 billion. As a percentage of total sales, R&D spending modestly increase from 20.4% to 21.4%. T**he report also showed a slight trend of R&D dollars shifting from the U.S. and toward western Europe from 2016 to 2017, with the geographic concentration of dollars decreasing by 1.9% in the U.S. and increasing 1.1% in western Europe**. **The report did show a slight decrease in the concentration of R&D dollars in the U.S. While domestic spending went up in absolute term**s by roughly $5 billion, **it decreased as a global percentage from 80% to 78.1% from 2016 to 2017**, when compared to last year's report. **Western Europe grew over that same time period in R&D dollars from $9.1 billion to $10.8 billion, an 18.5% increase.** As a geographic share, western Europe grew from 14% to 15.1%. The most expensive area was Phase 3 testing, which accounted for nearly 30% of total R&D spending. Overall, the industry group's findings fit BioPharma Dive's own analysis from last year, which showed an average R&D expenditure increase of about 10% year over year for the first quarter of 2017.

Price Controls → 300 less drugs (Giacotto - UChicago)

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.

Delay Warrants (Danzon - 08)

Danzon, 2008, "EFFECTS OF REGULATION ON DRUG LAUNCH AND PRICING IN INTERDEPENDENT MARKETS" NBER, https://www.nber.org/papers/w14041.pdf (NK)

By contrast, price regulation has become more complex and potentially contributes both direct (domestic) effects on launch lags in the regulating country and indirect (spillover) effects on launch in other countries. **Price regulation may delay launch directly through three mechanisms**. First, **regulation that reduces the manufacturer's expected price and NPV reduces incentives for launch,** especially in small countries and for drugs with low expected sales volume, assuming some fixed costs of launch. Second, **negotiation strategies may lead to strategic delay by firms or regulators to influence**

the ultimate price.2 Third, **regulatory processes may entail pure bureaucratic delay. The welfare consequences of these direct/domestic effects of a country's regulation on its citizens are ambiguous a priori, because any foregone health benefit due to fewer/later launches may be offset by savings from lower drug prices and better prelaunch information about a drug's relative safety and effectiveness.**3 More problematic from a social welfare perspective are the indirect/spillover effects that arise when one country regulates its drug price by reference to the price of the same drug in other countries ("external referencing"). For example, Canada caps the price of innovative new drugs at the median price in seven countries, and some EU countries use the mean or minimum price in a group of referenced countries. By undermining market segmentation and price discrimination, external referencing by high-price countries creates spillover incentives for a firm to not launch in lower-price referenced countries or delay until a higher price is achieved. The welfare consequences in the referenced low-price countries are clearly negative, since they suffer reduced access to new drugs and possibly higher prices due to external referencing by other countries, with no offsetting benefits.

Lower Prices mean more delays in launch (Danzon - Institute of Health Economics)

Danzon, 2005, Institute of Health Economics, "The impact of price regulation on the launch delay of new drugs}evidence from twenty-¢ve major markets in the1990s" [UPENN Professor as well] https://sci-hub.tw/https://www.ncbi.nlm.nih.gov/pubmed/15386651 (NK)

Large variation also exists within the European Union and even for products that are approved through the centralized procedure, which receive market authorization simultaneously in all countries. Of the 29 EMEA-approved NCEs since 1996, 23 were launched in Sweden, compared to only 5 in Portugal, 8 in Italy and 12 in Greece and Spain during our study period. **Countries that have lower expected prices tend to have fewer products launched and longer delays for those products that are launched**, after controlling for per capita income. **This finding tends to confirm the hypothesis that price regulation negatively affects the timing and occurrence of launch**. The magnitude of the expected price effect is similar in the EMEA sample and the full sample. Since all launch variation in the EMEA sample can be attributed to delays associated with pricereimbursement regulation, it seems safe to infer that the expected price effect that we observe in the full sample does in fact reflect launch delays that are due to price/reimbursement regulation rather than market authorization. The exception to this conclusion is Japan, which experienced extremes of delay and non-launch despite relatively high prices. Thus in Japan manufacturer reluctance to launch appears to be less important than regulatory delays in market authorization and price approval.

Low prices leads to less investment (Morton - Cato Institute)

Fiona M. Scott Morton, "The Problems of Price Controls," Cato Institute, [Fiona M. Scott Morton is an associate professor of economics and strategy at Yale University. Her academic interests include global competitive strategy, E-commerce, and strategic management.]https://www.cato.org/publications/commentary/problems-price-controls (NK)

One of the most important issues to Americans is how to manage prescription drug prices, especially for seniors who depend on Medicare coverage. Some policy advocates are urging the federal government to contract directly with drug manufacturers to purchase drugs for seniors - at prices set by the government. Despite the high-minded intentions of these advocates, such price controls could be very harmful to Americans' future health. **When prices are held below natural levels, resources such as talent and investor capital leave an industry to seek a better return elsewhere. This means that there will be less discovery and innovation, and fewer new drugs will become available to consumers.** Often this change happens over the long term ¾ longer than the tenure of any policy-maker. Thus, it is vitally important to remind policy-makers of the effects of price controls whenever they are proposed as government policy. DISRUPTING SUPPLY AND DEMAND

US Spends the most

Kesselheim, 2016, "The High Cost of Prescription Drugs in the United States," JAMA, https://jamanetwork.com/journals/jama/article-abstract/2545691 (NK)

Per capita prescription drug spending in the United States exceeds that in all other countries, largely driven by brand-name drug prices that have been increasing in recent years at rates far beyond the consumer price index. In 2013, **per capita spending on prescription drugs was $858 compared with an average of $400 for 19 other industrialized nations.** In the United States, prescription medications now comprise an estimated 17% of overall personal health care services. **The most important factor that allows manufacturers to set high drug prices is market exclusivity, protected by monopoly rights awarded upon Food and Drug Administration approval and by patents**. The availability of generic drugs after this

exclusivity period is the main means of reducing prices in the United States, but access to them may be delayed by numerous business and legal strategies. The primary counterweight against excessive pricing during market exclusivity is the negotiating power of the payer, which is currently constrained by several factors, including the requirement that most government drug payment plans cover nearly all products. Another key contributor to drug spending is physician prescribing choices when comparable alternatives are available at different costs. Although prices are often justified by the high cost of drug development, there is no evidence of an association between research and development costs and prices; rather, prescription drugs are priced in the United States primarily on the basis of what the market will bear.

US responsible for global innovation (Goldman - Brookings)

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.**

Price controls reduce innovation by reducing the return on investment from costly investments into new drugs – this is empirically proven in Europe

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.

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.

Politics DA

UQ – Price Controls Unpopular

Price controls are not popular – they even lack a majority support in liberal states like California

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

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. Speaker Paul Ryan and Senate Majority Leader Mitch McConnell are in the process of getting their caucuses on the same page with an Obamacare repeal and replacement plan that will increase access to care by reducing costs through a more consumer-oriented system in which states have greater flexibility to innovate. While that's happening, lawmakers toiling away in the 50 laboratories of democracy should reject misguided proposals to impose state-level drug price controls. While Democrats have total control of the legislature in most of the states considering drug price control legislation this year, many of those states fortunately have Republican governors who could serve as a backstop, should this innovation and investment-stifling legislation be approved by state lawmakers.

Trump doesn't seem interested in it, and a bill proposing negotiations hasn't left committee

Tribble 17 Sarah Jane Tribble [Senior Correspondent, reports on pharmaceutical drug development, costs and pricing], 12-12-2017, "Experts Tell Congress How To Cut Drug Prices. We Give You Some Odds," KaiserNews, https://khn.org/news/experts-tell-congress-how-to-cut-drug-prices/ //DF

Tuesday's hearing, which is the third in a series by the Senate Health, Education, Labor and Pensions Committee, comes as Americans across the political spectrum say lowering the price of prescription drugs is a top priority. Nationwide, dozens of cities, counties and school districts have turned to drug importation as a solution to high prices. And legislators from both parties have also supported importation of drugs from countries where list prices are cheaper. While individual states have passed laws for more transparency and price controls and President Donald Trump has publicly called for lower drug prices, Congress has stalled. So, will the committee's recommendations spur action? Kaiser Health News takes the political temperature, talks to experts and rates their chances: Recommendation No. 1: Allow the federal government to negotiate drug prices Current law prohibits the U.S. Health and Human Services secretary from directly negotiating drug prices, and the committee says that's ridiculous. The committee recommends Medicare and other agencies negotiate which drugs are placed on a list of covered drugs and, when necessary, exclude some drugs. This is not a new idea. Some states are already restricting

high-priced drugs in Medicaid, the state-federal insurance program for low-income Americans. But federal efforts to change Medicare are more complicated. Just two months ago, top House Democrats introduced another Medicare negotiation bill. But don't hold your breath, Trump hasn't responded to multiple letters sent from Rep. Elijah Cummings (D-Md.) — including one after the most recent bill was introduced in late October. That bill hasn't moved past the health subcommittee.

UQ – Pharma Industry Influence

Pharma companies have political influence and have stopped other price control bills in the past

Karlin-Smith 18 Sarah Karlin-Smith [health care reporter, specializing in covering the policy and politics that affect the drug industry], 10-25-2018, "Trump to propose sweeping changes to Medicare drug prices," POLITICO, https://www.politico.com/story/2018/10/25/trump-medicare-drug-prices-plan-888607 //DF

The administration is bracing for blowback, said one official, noting that hospitals and doctors — and of course the drug companies — all have reason to be unhappy about a plan that will cost much of the health sector money. The drug industry and its allies have lots of lobbying clout; a less ambitious effort by the Obama administration to address Medicare Part B prices fizzled in late 2016. "Nobody's going to like this," said the official. "It antagonizes too many people." But Trump's proposal could appeal to patients — who stand to benefit from lower prices — and Democrats, who have chastised the Trump administration for not using all of its regulatory power to cut drug prices, which polls have shown are a concern of Republican and Democratic voters alike. Health care has emerged as a hot issue in the midterms, with Democrats making gains by pledging to protect Obamacare protections for people with pre-existing conditions. Those protections would have been undermined in GOP repeal bills and are now threatened by a White House-backed lawsuit brought by conservative states. Trump's pivot to drug prices could help Republican candidates needing a winning message on health.

Congress opposes negotiations because of pharma influence

Kantarjin 16 Hagop Kantarjian [chairman of the Leukemia Department at the University of Texas MD Anderson Cancer Center and a Baker Institute scholar for health policies at Rice University], 12-12-2016, "The Harm of High Drug Prices," US News & World Report, https://www.usnews.com/opinion/policy-dose/articles/2016-12-12/the-harm-of-high-drug-prices-to-americans-a-continuing-saga //DF

While expressing a desire to "be part of the solution," the drug industry has done little. Instead, it funded a $100+ million public relations campaign in 2016 to support the sustenance of high prices. Of interest, some drug industry CEOs favor lowering drug prices, arguing that affordable drugs will have deeper market penetration, keeping more patients alive who continue to purchase and use these drugs, thus generating more long-term profits. Several solutions can be implemented to reduce drug prices: 1) Allow Medicare to negotiate drug prices (this can save $400-800 billion over a decade). 2) Establish a post-FDA mechanism to review the benefits of drugs and define fair prices. 3) Encourage medical organizations to incorporate price into definitions of "treatment value." 4) Prevent strategies that delay the availability of generics (this saved the U.S. health care system $227 billion in 2015 and $1.46 trillion over a decade. 5) Accelerate the process of generics approval and reduce costs of filing. 6) Request that drug companies report transparently the costs of research and development to justify prices. Unfortunately, these measures are opposed in Congress because of the influence of the drug industry lobby. Elected officials seem to represent industry interests rather than interests of American citizens who elected them. Future actions and legislation will show whether the U.S. is still a democracy, or whether it has transformed into a "pharmaceutocracy."

UQ – Pharma Doesn't Like Criticism

The pharma industry has deflected criticism over high prices by shifting the blame to PBMs

Johnson 18 Carolyn Y. Johnson [She previously covered the business of health, the pharmaceutical industry and the affordability of health care to consumers], 1-2-2018 "Pharma, under attack for drug prices, started an industry war," Washington Post, https://www.washingtonpost.com/business/economy/pharma-under-attack-for-drug-prices-started-an-industry-war/2017/12/29/800a3de8-e5bc-11e7-a65d-1ac0fd7f097e_story.html?noredirect=on&utm_term=.89e0b902fe2c //DF

The intra-industry conflict has meant that 2017 — a year when it seemed as if concerns about the affordability of drugs might translate into action — was consumed with an effort to try to unravel what is happening in the supply chain. The federal government has moved forward on technical policy fixes that largely spare the drug industry. But the kind of sweeping changes people were girding for — importing cheaper drugs from abroad or allowing the government to negotiate drug prices — never came. As the drug-price problem began to look more like a Matryoshka doll with many nested layers, the potential solutions became less clear. "The pharmaceutical industry's efforts to change the discussion to the breadth of the supply chain has, to an extent, seemed to slow down a discussion of pricing," said M. Nielsen Hobbs, executive editor of the Pink Sheet at Informa Pharma Intelligence. "For the past year, they've played fantastic defense." The success of this strategy was on view at a congressional hearing Dec. 13, when 10 witnesses from different industries stretched across a long table — from the drug companies on one end, through to insurers, distributors, doctors, pharmacists, PBMs, hospitals and patients. To make it even more confusing, companies along the supply chain have formed a dizzying array of alliances. Health-insurance plans side with PBMs — to the extent of coming together under one roof, as with the $69 billion deal announced last month for CVS Health to buy Aetna.

Link – Republicans win Midterms

Price controls restores support for Republicans in the healthcare arena where they have been lacking previously

Karlin-Smith 18 Sarah Karlin-Smith [health care reporter, specializing in covering the policy and politics that affect the drug industry], 10-25-2018, "Trump to propose sweeping changes to Medicare drug prices," POLITICO, https://www.politico.com/story/2018/10/25/trump-medicare-drug-prices-plan-888607 //DF

President Donald Trump on Thursday will unveil a plan to overhaul how Medicare pays for certain drugs, attacking "foreign freeloaders" that he says have driven up costs in the U.S. The bold move addresses a Trump campaign pledge to lower drug prices, just days before the tightly contested midterm elections in which health care is playing a pivotal role. Trump is scheduled to outline the details in a speech at HHS at 2 p.m., his first address at the health department. The proposal, described to POLITICO by three individuals with knowledge, still needs to be refined and put through a federal rulemaking process. The proposal, which was sent to the White House earlier this month, would use Medicare's innovation center to test three ways to lower the costs of drugs — including negotiating for some drugs that are directly administered by doctors, in hopes of keeping them in line with the lower prices paid in many other countries. The proposal applies only to drugs administered in doctors' offices and outpatient hospital departments — medicines like cancer treatments and injectable treatments for rheumatoid arthritis or eye conditions. It won't affect most prescriptions purchased by patients at local pharmacies. The Trump administration will say that Medicare could save more than $17 billion over five years, with the cost of some drugs dropping by as much as 30 percent. HHS did not respond to requests for comment Wednesday night. But HHS Secretary Alex Azar alluded to the announcement early Thursday morning as he touted a new report on high U.S. drug prices that bashed "global freeloading" and said that

Medicare often pays nearly twice as much as countries like France and Japan to use the same drugs. "I look forward to hearing from POTUS later today on the administration's efforts to address the high cost of prescription drugs, and our work to put American patients first," Azar tweeted. "Stay tuned." The administration is bracing for blowback, said one official, noting that hospitals and doctors — and of course the drug companies — all have reason to be unhappy about a plan that will cost much of the health sector money. The drug industry and its allies have lots of lobbying clout; a less ambitious effort by the Obama administration to address Medicare Part B prices fizzled in late 2016. "Nobody's going to like this," said the official. "It antagonizes too many people." But Trump's proposal could appeal to patients — who stand to benefit from lower prices — and Democrats, who have chastised the Trump administration for not using all of its regulatory power to cut drug prices, which polls have shown are a concern of Republican and Democratic voters alike. Health care has emerged as a hot issue in the midterms, with Democrats making gains by pledging to protect Obamacare protections for people with pre-existing conditions. Those protections would have been undermined in GOP repeal bills and are now threatened by a White House-backed lawsuit brought by conservative states. Trump's pivot to drug prices could help Republican candidates needing a winning message on health. The administration proposal has several strands, all of which dramatically shake up the industry that right now has vast control over setting Medicare drug prices.

Frontlines

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 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

Angelll 96

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.

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.

Companies don't spend on R&D

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.