R2R

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

Our sole contention is reducing drug prices.

Americans pay unreasonably high prices for their medicines, much higher than citizens in other countries. Across a variety of different healthcare systems, Hirschler of Reuter's reports in 2014: U.S. prices for the world's 20 top-selling medicines are, on average, three times higher than in Britain, six times higher than in Brazil and 16 times higher than in India.

Baker of the New York Times Furthers in 2016:
We pay roughly twice as much for our drugs as the average for other wealthy countries. This additional cost is not associated with better care; we are just paying more for the same drugs.

This trend is only getting worse. Amin of CNBC writes this July that while drug prices have tripled in the US in the past decade, analysts predict they will double again in the next ten years.

Conventional solutions to high prices are also failing now. Beyer at UC Hastings College writes in 2017: when drug patents expire after 20 years, drug manufacturers should be able to produce generic drugs at a lower cost. However, the number of drugs coming off patent is decreasing at a rapid rate – 41% lower than in 2016. This is because companies are using more measures to prevent losing their patents, including paying generic companies not to copy their drugs, and securing dozens of patents for their drugs so they won't expire.

While Americans need to use the same drugs as the rest of the world, the US government has no way of keeping the cost of those drugs in check. Hirschler furthers: the United States, which leaves pricing to market competition, has higher drug prices than other countries where governments directly or indirectly control medical costs.

The simple solution would be to impose price controls on prescription drugs, just like how other countries do. This would ensure that every citizen has access to proper medication. Cliff of Vox explains in 2018: other countries regulate the price of drugs because they see them as a public utility. Countries like Australia, Canada, and Britain don't regulate the price of other things that consumers buy, like computers or clothing. But they have made the decision to regulate the price of drugs to ensure that medical treatment remains affordable for all citizens, regardless of their income.

Lowering drug prices will help combat two serious issues that Americans face.

First, the opioid epidemic.

Gibson at CBS News reports in 2018: as the opioid epidemic continues to kill tens of thousands of Americans each year, the drug naloxone, which reverses the effects of an overdose, has proved invaluable in preventing overdose-related deaths. However, prices have risen more than 50 percent, and driving that is a surge in overdoses that's boosting demand for naloxone, and a dearth of federal rules that could limit price increases.

As a result, consumers cannot afford and are not buying the drug. Wood at Harvard Medical School estimates in 2018: In the midst of the epidemic, sales of Naloxone increased from 2.8 million annually, to only 3.2 million from 2009 to 2015, showing that those most at risk can't afford this life saving drug.

Lack of access to naloxone has deadly consequences, as Gibson writes that drug overdoses killed a record 72,000 Americans in 2017, up 10 percent from the previous year.

Naloxone is crucial, as overdoses often act far to quickly for a hospital. In the case of Heroin, De Addiction centers reports:
the body quite literally forgets to breathe and deprives itself of oxygen eventually killing the user within a matter of 5 minutes.

Second, the nonadherence epidemic.

High drug prices have made life saving medications inaccessible for many Americans. Bornstein 15 reports in the New York Times: one in four American adults — perhaps 50 million people — failed to fill a prescription they needed because of the cost.

Even when they do take the drug, patients take less than the prescribed dosage, which renders them less effective. This has disastrous effects on public health.

Brody at the New York Times writes in 2018: there is an out-of-control epidemic in the United States that affects more people than any disease. This crisis, nonadherence to prescribed medications largely because of cost, is estimated to cause approximately 125,000 deaths per year.

In Fact, Bresnik of Health Analytics reports last year
The high cost of prescription drugs is what drives 67 percent of patients into medication non-adherence

Lower prices are also empirically shown to increase drug adherence and reduce preventable deaths. According to Brody, when Aetna offered free medications to patients who survived a heart attack, adherence improved by 6 percent and there were 11 percent fewer heart attacks and strokes.

Bring prices down, end the epidemic, and affirm the resolution.

CASE CARDS

¼ Americans don't fill their prescription because of cost (Bornstein - NYT)

David Bornstein, 3-20-2015, "Recycling Unused Medicines to Save Money and Lives," NYT, https://opinionator.blogs.nytimes.com/2015/03/20/recycling-unused-medicines-to-save-money-and-lives/ (NK)

It always troubled Deane Kirchner to throw away good medicine. When residents of the Lincoln Glen long-term facility in San Jose, Calif., where she is the director of nursing, changed dosages, had adverse reactions, or died, she did what health professionals regularly do: sent their unused medicines to be destroyed. "Throughout my entire nursing career, it's something I've done," said Kirchner, who has been a nurse for 21 years. "And each time I would think: 'It's such a waste. There are people out there who have to choose whether to buy medications or buy groceries.'" Lots of people, in fact. In 2012, studies indicate, about **one in four American adults — perhaps 50 million people — failed to fill a prescription they needed because of the cost**. Among adults who were uninsured, the figure was 43 percent. (PDF, p. 28). For older adults, who take four to five medicines on average per week, this is a crisis. Sadly, one in five seniors reports cutting back on basics like food or heat to afford prescription drugs. This is dangerous. Those with cardiovascular disease who said they took less medicine than directed due to cost were 50 percent more likely to experience angina, strokes or non-fatal heart attacks. For many others, cutting back on medicine led to faster health declines, increased hospitalizations and premature death. (PDF, pp. 7-8). And yet, each year, hospitals, pharmacies, manufacturers and nursing homes send billions of dollars worth of medicines to be destroyed.

De Addiction Center, Drugs that Can Kill You in 5 Minutes https://deaddictioncentres.in/news/drugs-kill-5-minutes/ (NK)

Overdoses of heroin kill more people than any other single drug on the market. The initial high given by the drug causes mental confusion, slowed breathing, nausea, and sedation. But when used in excess, the immediate effects of heroin build up and often result in respiratory failure. This means **the body quite literally forgets to breathe and deprives itself of oxygen eventually killing the user within a matter of 5 minutes.** Alcohol The effect of alcoholic beverages is directly related to the amount consumed. Through a process called "metabolizing," your liver does its best to eliminate the toxic alcohol from your blood, but it can only handle so much. The excess alcohol is left to circulate throughout the body. The more alcohol circulating, the more intense its effect; and the more intense the effect, the slower the user breathes. A lack of oxygen reaching the brain can cause coma, which can lead to death.

Costs

UQ – US Prices Highest

The high cost of prescription drugs is what drives 67 percent of patients into medication non-adherence

Bresnik, 9-11-2017, "Cost is a Primary Driver of Medication Non-Adherence Rates," HealthITAnalytics, https://healthitanalytics.com/news/cost-is-a-primary-driver-of-medication-non-adherence-rates (NK)

September 11, 2017 - **The high cost of prescription drugs is what drives 67 percent of patients into medication non-adherence**, according to the latest Truven Health Analytics-NPR Health Poll, contributing to a multi-billion-dollar issue that is of particular concern for population health management initiatives. Ninety-four percent of patients with incomes under $25,000 per year stated that they did not fill or pick up their prescriptions due to the expenses involved, and more than 12 percent said that costs had led them to stop taking a medication before a provider recommended ending the treatment. Despite the fact that cost is a major factor in adherence, just 16 percent of low-income individuals had used drug company rebates or coupons to help reduce the prices of their medications.

US Drug prices far higher than anywhere else - 3x higher than Britain. It's even worse in other places, 16x higher than in India (Hirschler - Reuters)

Ben Hirschler, 2014, "How the U.S. Pays 3 Times More for Drugs," Reuters, https://www.scientificamerican.com/article/how-the-u-s-pays-3-times-more-for-drugs/ (NK)

LONDON (Reuters) - **U.S. prices for the world's 20 top-selling medicines are, on average, three times higher than in Britain, according to an analysis carried out for Reuters**. The finding underscores a transatlantic gulf between the price of treatments for a range of diseases and follows demands for lower drug costs in America from industry critics such as Democratic presidential candidate Hillary Clinton. The 20 medicines, which together accounted for 15% of global pharmaceuticals spending in 2014, are a major source of profits for companies including AbbVie, AstraZeneca , Merck, Pfizer and Roche. **Researchers from Britain's University of Liverpool also found U.S. prices were consistently higher than in other European markets. Elsewhere, U.S. prices were six times higher than in Brazil and 16 times higher than the average in the lowest-price country, which was usually India. The United States, which leaves pricing to market competition, has higher drug prices than other countries where governments directly or indirectly control medicine costs**. That makes it by far the most profitable market for pharmaceutical companies, leading to complaints that Americans are effectively subsidizing health systems elsewhere.

Overall, prescription costs are 2-6x higher in the US than anywhere else in the world

Jena 18 Dr. Anupam B. Jena [Ruth L. Newhouse associate professor of health care policy a Harvard Medical School, an internist at Massachusetts General Hospital, and a faculty research fellow at the National Bureau of Economic Research], 1-19-2018, "US drug prices higher than in the rest of the world, here's why," TheHill, https://thehill.com/opinion/healthcare/369727-us-drug-prices-higher-than-in-the-rest-of-the-world-heres-why //DF

Americans pay prices for prescription drugs that are two to six times the rest of the world, despite having personal incomes that are on par with many developed countries. For instance, the average price for Humira — a top-selling drug to treat rheumatoid arthritis — is nearly $2,700 per administration in the U.S., more than twice the price in the U.K. American salaries are not twice as high as British salaries. It's not surprising that in countries with different per capita incomes (e.g., U.S. vs India), the prices of drugs are different. But why is it that in countries with similar per capita income as the U.S., drug prices are so much lower than in the U.S.? One answer is that nearly all countries except the U.S. have policies to lower drug prices, including price controls, regulations that limit the profitability of drugs, reference pricing, and cost-effectiveness thresholds (e.g., in the U.K., the National Health Service is the main purchaser of drugs and frequently does not cover therapies whose cost per "quality-adjusted" life year gained exceeds $50,000 per year). This answer provides a good explanation for how some countries achieve lower drug prices but not why drug prices are higher in the U.S. Perhaps the most common explanation for why drug prices are high in the U.S. is what economists call "free riding." The argument goes like this: because the U.S. is willing to pay higher prices for drugs, other countries don't feel the 'need' to do so and therefore don't. This explanation is overly simplistic and misses the two key economic issues at stake.

More cost for Meds that are no better

Dean Baker, 1-10-2016, "End Patent Monopolies on Drugs," NYT, [*Dean Baker is an economist and the co-director of the Center for Economic and Policy Research.*]

https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/end-patent-monopolies-on-drugs (NK)

The United States stands out among wealthy countries in that we give drug companies patent monopolies on drugs that are essential for people's health or lives and then allows them to charge whatever they want. Every other wealthy country has some system of price controls or negotiated prices where the government limits the extent to which drug companies can exploit the monopoly it has given them. The result is

that **we pay roughly twice as much for our drugs as the average for other wealthy countries. This additional cost is not associated with better care; we are just paying more for the same drugs.** Giving a drug company a monopoly where it charges what it can is like negotiating firefighters' pay when they show up at your burning house. This is not an issue about the free market. The free market doesn't have patent monopolies. The monopoly power provided by a patent is a government policy to promote innovation. There are problems with patent monopolies in many areas, but nowhere is the issue worse than with prescription drugs. Patent protected drugs are often essential for people's health or even their lives. Allowing a drug company to have a monopoly where it can charge whatever it can force the individual, or more typically the insurer or the government, to pay makes little sense. This is like negotiating the pay of firefighters at the point where they show up at your burning house with your family inside. This would give us much worse fire service and many very wealthy firefighters.

UQ – US Prices Rising

Prices only going up (Amin - CNBC)

Tahir Amin, 6-27-2018, "The problem with high drug prices isn't 'foreign freeloading,' it's the patent system," CNBC, [Co-Founder Of Nonprofit I-Mak.Org] https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html (NK)

Americans continue to suffer the highest prescription drug costs of anyone in the world. One in four are unable to fill prescriptions due to high prices, according to a recent poll. **And even though drug prices tripled over the last decade, analysts predict they will double again in the next ten years**. We have a runaway problem on our hands, and while new proposals from Congress and the president seek to improve the drug pricing system, we will fail to reach lasting solutions unless we address a root factor in this national crisis: patents. Contrary to the Trump administration's recent claims, the source of our prescription drug problems is not "foreign freeloading" governments creating unfair pricing schemes—it's the unfair pricing systems created right here in the U.S. Today's drug patent monopolies are deeper, longer and stronger than at any point in the last century—and it's costing Americans and people around the world. Before a prescription drug even enters the market—before pricing negotiations occur between payers, government agencies, insurers, and so on—the U.S. patent office awards exclusivity to drug makers for intellectual property claims that have a huge impact on the market.

Drug prices will keep rising because of America's aging population

Madhavan 17 Guru Madhavan [biomedical engineer and senior policy adviser. He conductsresearch at the National Academy of Sciencesand has been named a distinguishedyoung scientist by the World EconomicForum] 11-2017, "Making Medicines Affordable: A National Imperative," The National Academies of Science, Engineering, Medicine, https://www.nap.edu/resource/24946/11302017AffordableDrugsHighlights.pdf //DF

The trend of increasing spending on health care, including on biopharmaceuticals, is projected to con- tinue for the foreseeable future as the Baby Boomer generation ages. No other nation in the world approaches the level of U.S. health care expenditure, yet various studies indicate that many nations have healthier populations. The United States now ranks 25th in the world in life expectancy at birth, yet among the 10 nations with the largest gross domestic product (GDP), the United States spends about twice as much on health care as a fraction of GDP as the average of the other nine. Annual expenditures on biopharma- ceuticals in the United States now exceed a half trillion dollars, and prescription drugs are among the fastest- growing segments of health care spending. Research and development of new drugs, the lifeblood of the pharmaceutical industry and its contribution to health care, is also extremely costly. The canonical statement about the cost of a new drug—"The first pill can cost over a billion dollars while the second costs only a dime"—captures an important truth: New drugs are exceptionally expensive to develop, and failures are commonplace.

Prices are rising at an "alarming" rate

Beyer 17 Katie Beyer [currently in her second year at UC Hastings College of the Law and has a concentration in Law and Health Sciences. She has received two CALI Awards for Academic Excellence and is a member of the Hastings Law Journal],, 8-3-2017, "Drug Money Part 2: A Look at 2017 State Legislative Efforts to Reduce Prescription Drug Prices," The Source on Healthcare Price & Competition, A

project of the UC Hastings College of Law
http://sourceonhealthcare.org/drug-money-part-2-a-look-at-2017-state-legislative-efforts-to-reduce-prescription-drug-prices/ //DF

It is no secret that drug prices have been rising at an alarming rate. In fact, spending on prescription drugs rose 12.4% in 2014 and 9% in 2015.[1] In 2015, the U.S. spent $457 billion on prescription drugs, which accounted for 16.7% of overall healthcare services.[2] In 2016, Americans filled 4.4 billion drug prescriptions, at a total cost of approximately $400 billion.[3] On average, Americans spend $1,370 out of pocket on prescription drugs per year.[4] With an average annual price increase of approximately 10% over the past three years, drug price increases continue to outpace inflation, which is growing at a rate of 2.3%.[5] These high drug costs affect nearly half of all Americans, with 49% of Americans reporting that they used at least one drug in the past 30 days. These prescription drug users experienced a 208% rise in the prices of the most popular brand name drugs from 2008-2016.[6] The rising cost of life-saving medications is particularly alarming. Bavencio (a cancer drug) costs about $156,000 a year per patient.[7] A new muscular dystrophy drug introduced last year costs $300,000 per year.[8] Daraprim, a popular drug used by AIDS patients spiked from $13.50 to $750 per prescription.[9] The cost of insulin, now more than $700 per patient, tripled between 2002 and 2013 and the cost of an EpiPen spiked 500% since 2007.[10] So what can be done? With little assistance from the federal government, states are taking matters into their own hands. In 2017, 43 states introduced legislation aiming to combat high drug prices. Arkansas, Delaware, Idaho, Kentucky, North Dakota, Ohio, and South Dakota were the only states that stayed silent. As of July 2017, seventeen states passed bills and five states still have bills pending, which is a great improvement from 2016 state efforts. Last year, only ten states introduced legislation requiring pharmaceutical companies to disclose research and development costs.[11] Vermont was the sole state to enact its legislation.[12] In 2017, the Massachusetts legislature lead the charge and introduced ten bills with the purpose of lowering drugs costs. California, Maine, Maryland, New York, and Oregon followed closely behind.

Link – Reference Pricing Solves

Reference-based pricing solves the drug cost issue without stifling innovation

Laszewiski 18 Robert Laszewski [President Of Health Policy and Strategy Associates, He has 20 years of experience in the insurance industry, serving as a chief operating officer for nine of those years, before beginning his Washington, D.C. policy- and market-consulting business], 5-11-2018, "Here's the most obvious way to reduce drug prices that the US is missing," CNBC, https://www.cnbc.com/2018/05/11/the-obvious-way-to-reduce-drug-prices-that-the-us-is-missing.html //DF

What is even more frustrating is to see an easy solution that has worked for years in these other industrialized countries. Even though they are single-payer government-run systems, their drug pricing schemes are as American-style free market as they could be. Would any major U.S. corporation spend loads of money on procurement without first going out to bid on both price and performance? Would the Pentagon buy a new ship or aircraft system without going out to bid on both price and capability? Would the U.S. General Services Administration put up a new government office building without first bidding it out to determine which contractor would construct the best facility for the price? So, if we are looking for market-based solutions to the high cost of prescription drugs, we need look no further than the government-run health care systems in France, Canada, Germany, the U.K., and others. Rather than pointing the finger at these other nations that "pay too little" for their drugs and then condemn them for it, we might first recognize that they are out marketeering –the United States. These foreign bureaucrats are making American capitalists look like little leaguers when it comes to keeping drug prices under control. What these other countries have in common is that they use a system called reference-based pricing. While there are differences among them, they generally request bids and use the market to set a reference price for each prescription drug that also takes clinical results into consideration—it could be the lowest price

from a range of alternative drugs in a class (Italy), an average of all of the drugs in a class (Germany), or an average of a group of the lowest priced players (Spain). The health care system then pays no more than the reference price for a drug in the class no matter which pharmaceutical company the consumer and their physician decide to use. In the end, the market sets the price and innovation is still rewarded by paying the price the most competitive player wants to charge. In such a competitive bidding process prices and drug outcome results are completely competitive and fully transparent. If a patient and their doctor want to pay more of an alternative drug, because they think it will do a better job for a particular patient, they know all of the prices and the comparative clinical outcomes upfront. If a drug company is truly able to innovate for an existing class of drug, that drug could be placed in a new class–innovation is still rewarded. The value of reference-based pricing is limited until there is more than one competitor in a class–drug companies are still rewarded for blockbuster breakthroughs. But when more than one player comes to market in the same drug class, they compete based both on price and clinical outcomes.

The US should be able to negotiate drug prices

Engelberg 15 Alfred B. Engelberg [retired intellectual property lawyer and philanthropist. During his legal career, he was a patent examiner at the US Patent Office, a patent trial attorney at the US Department of Justice, and a member of the New York City law firm of Amster, Rothstein and Engelberg. As counsel to the generic drug industry, he played a major role in drafting the Hatch-Waxman Act of 1984, which created the modern generic drug industry], 10-29-2015, "How Government Policy Promotes High Drug Prices," HealthAffairs, https://www.healthaffairs.org/do/10.1377/hblog20151029.051488/full/ //DF

For decades, Congress has simply been transferring wealth from ordinary citizens to the pharmaceutical industry. While claiming to believe in free market capitalism, it has created a web of monopolies which cause the United States to pay the world's highest prices for drugs even though it is the largest purchaser. The US would save $80 billion annually if its per capita drug costs were only 50 percent higher ($750 per capita), rather than 100 percent higher, than those of other developed countries. Investing some of those savings to accelerate the development of cures for our most costly diseases could eventually reduce health care costs and justify a high price for life-saving medicines. Looking Ahead What specific changes to US law could create that virtuous cycle? Here are some specific recommendations: Reduce The Scope And Length Of Monopolies Granting special monopolies to pharmaceutical companies that are not based on the patent law is a costly and inefficient way to induce investment in research. The five year exclusivity for small molecules; 12 year exclusivity for biologics; six-month pediatric exclusivity and all other similar non-patent monopolies are now being granted without any regard for the investment required or value produced. A drug which provides little or no incremental value over existing products gets the same ability to charge a monopoly price for an extended period of time as a life-saving breakthrough that required 10 times the risk and investment to discover. The current system of exclusivities should be repealed and replaced by a system which reasonably rewards research that produces drugs of high therapeutic value and little or no reward to low-risk research that produces "me too" drugs. Paying For Value As the largest payer for prescription drugs, the US government is entitled to the best price. It can achieve that price in one of two ways. It can modify existing law to assure that Medicare, Medicaid, and other public programs utilize the full array of tools for evaluating the value of each new drug and allow government programs to directly negotiate drug prices using those tools, including restricted formularies, reference pricing, and the like, just as it is now done by other developed nations and by pharmacy benefit managers. In the short term, it can modify existing rebate laws so as to base rebates on the lowest price being charged for a drug in one or more OECD countries having a comparable standard of living rather than basing it on the inflated price charged in the US market.

Link – Tethered Pricing Solves

Tethered prices would work best to show that the US won't pay higher prices than other countries

Mohammed 15 Rafi Mohammed [founder of Culture of Profit, a consultancy that helps companies develop and improve their pricing strategies, and the author of The Art of Pricing: How to Find the Hidden Profits to Grow Your Business (Crown Business, 2005) and The 1% Windfall: How Successful Companies Use Price to Profit and Grow (HarperBusiness, 2010)], 9-22-2015, "It's Time to Rein in Exorbitant Pharmaceutical Prices," Harvard Business Review, https://hbr.org/2015/09/its-time-to-rein-in-exorbitant-pharmaceutical-prices //DF

I believe in the free market and rarely advocate any type of price regulation. There are compelling reasons, however, to consider doing so for pharmaceuticals. The biggest expense of a new drug is R&D; once developed, the cost of producing pills is relatively trivial. Most important, everyone in the world can – and should – benefit from pharmaceutical advancements, especially since the variable costs are so low. In other words, the R&D behind new drugs is a common good. Typical solutions to the dilemma of high drug prices include single payer (e.g., U.S. government negotiates "take it or leave it" prices for its territory) and price regulation (e.g., the government simply specifies prices). These tactics will lower prices but don't address the issue of paying for new pharmaceutical developments. How can we make sure that the cost of developing new drugs is equitably split among the various beneficiaries around the world? That high-price-paying Americans are not essentially subsidizing R&D for pharma multinationals? A tethered price regulation is the answer. Regulators could pass a law that says neither American insurers nor government agencies would pay more than a set percentage above (or below) what other developed countries pay for drugs. In other words, our prices are tethered to theirs. This accomplishes two goals. First, drug prices will be lowered for Americans. Second and just as importantly, pharma companies and other countries will be on notice that sick Americans are no longer going to shoulder a disproportionate share of drug development costs. Tethered regulation should apply only to new drugs, not existing drugs, which were developed with the understanding that U.S. prices will be as high as the market can bear. We made a bad deal, but we should keep our word. A common reaction to any whiff of price regulation is concern that pharma R&D will be reduced. This is a fair concern, but it's not a given that R&D will decrease. Pharma companies may opt to cut sales and marketing costs (which 9 out the top 10 pharma companies spend more on than R&D), executive compensation, or dividends instead, keeping R&D budgets healthy. That said, it is very possible R&D may decrease as a result of regulation. In utopia, it'd be wonderful for pharma companies to have unlimited R&D budgets. But back here in reality, tradeoffs are made. Even today, R&D budgets are not infinite. And if budgets are cut by 20%, instead of funding 100 initiatives, it may be that only the top 80 with the highest potential will be greenlit.

IL + Impact – Overdoses

The inability of the government to regulate the price of naloxone has led to massive price increases

Kate Gibson, 9-11-2018, "As opioid crisis rages, cost of overdose antidote spikes," No Publication, https://www.cbsnews.com/news/as-opioids-kill-more-americans-cost-of-overdose-antidote-spikes/ //DF

As the opioid epidemic continues to kill tens of thousands of Americans each year, the drug naloxone has proved invaluable in preventing overdose-related deaths. Yet a spike in its cost in recent years has constrained access to naloxone, potentially depriving health care professionals, emergency responders and families of a critical treatment than can save lives. Driving that price spike, experts say: An ongoing surge in overdoses that's boosting demand for naloxone; a dearth of federal rules that could limit price increases; a lack of drug industry competition; and pharmaceutical firms' lack of transparency in setting prices for drugs to counter the effects of opioids. The rising price of naloxone comes at a time that drug overdoses have become the leading cause of accidental death in the U.S. for those aged 25 to 64 -- opioids are involved in nearly two-thirds of those fatalities, according to federal health data. The U.S. Centers for Disease Control and Prevention estimates drug overdoes killed a record 72,000 Americans in 2017, up roughly 10 percent from the previous year. Most of those fatalities involved prescription opioids, including OxyContin or Vicodin. Since 2013, an estimated 170,000 people have died from overdosing on both prescription and illegal opioids. That's roughly three times the number of U.S. military personnel killed during the Vietnam war. As a result, demand for naloxone -- a synthetic drug akin to morphine that reverses the effects of an overdose by blocking opiate receptors in the nervous system -- has never been higher, researchers with the Food and Drug Administration's Center for Drug Evaluation and Research note in an upcoming report. Rising demand has helped drive the price of naloxone up more than 50 percent in recent years, the FDA researchers write in a study set to be published in the journal Addictive Behaviors. They estimate that the cost of one injectable form of naloxone has tripled since 2012, while another single-dose formulation rose 244 percent. "We don't have any mechanisms to stop manufacturers from raising prices," Leigh Purvis, director of health services research in AARP's Public Policy Institute, told CBS MoneyWatch. The cost of of naloxone -- which has been around in generic form for more than 30 years -- varies depending on whether it comes packaged as an injection device, auto-injector or nasal spray. Products also come in different dosages, which can affect pricing, while individual manufacturers may offer discounts and rebates to some buyers.

Companies have jacked up the price of lifesaving opioid overdose medicine, putting them out of reach of those who most need it

Wood 18 Stephen P. Wood [fellow in the Center for Bioethics at Harvard Medical School; practicing nurse practitioner in the department of emergency medicine at the Winchester Hospital in Winchester, MA. He has nine years of clinical experience in hospital-based emergency medicine as well as over 25 years of clinical experience in pre-hospital medicine], 6-4-2018, "As opioid overdose numbers rise, so does the cost of naloxone," Bill of Health, Petrie-Flom Center at Harvard Law School http://blogs.harvard.edu/billofhealth/2018/06/04/as-opioid-overdose-numbers-rise-so-does-the-cost-of-naloxone/ //DF

Currently there are seven patents that protect naloxone in its branded formulations, primarily marketed as Narcan and Ezvio. These patent protections extend to the year 2035. However, the protections are not for the drug, whose patent expired long ago, but for the "novel" delivery devices for naloxone, such as nasal actuators and auto-injectors. Naloxone has been historically inexpensive and pharmaceutical companies really didn't care much about it. Only six pharmaceutical companies even made the drug prior to 2014. It wasn't until the onset of the opioid epidemic, and public health initiatives that allowed public access to this drug, that prices began to soar. Naloxone's wholesale, generic cost is around $20.00 for a single dose. By comparison, the cost of a two-injector kit under the brand name Evzio is $4,000.00. This represents a stunning 680 percent increase from the drug's original price in 2014. Meanwhile, the numbers of deaths from opioid overdose continued to rise. Narcan brand nasal spray is slightly cheaper, coming in around $140.00 per dose. However, overdose reversal may require several doses,

adding to its cost. Speaking of novel, how novel is a nasal actuator anyways? Access to these drugs is mostly limited to those with health insurance, and even then, most require a co-pay. The data substantiates that consumers cannot afford and are not buying the drug. In the midst of the epidemic, sales increased from 2.8 million annually, to only 3.2 million from 2009 to 2015. Simply put, those most at risk can't afford this lifesaving drug. These price increases came when the opioid epidemic was at its peak, and they came without any explanation. There have been actions in several states to limit these increases, but little in the way of federal regulation to enforce them, despite recommendations by the CDC to expand access. Many states have tried to meet that challenge, through pharmacy standing orders, pharmacist prescriptive authority or community distribution. These are novel means to increase access, but until the cost is contained, they are not likely to make an impact in increasing access and use. Considering the success of community-based naloxone programs, access is an imperative.

Overdose deaths are increasing now and raising the mortality rate

Lamagna 18 Maria Lamagna [Reporter], 8-16-2018, "More evidence that the opioid epidemic is only getting worse ," MarketWatch, https://www.marketwatch.com/story/how-much-the-opioid-epidemic-costs-the-us-2017-10-27 //DF

The opioid epidemic just keeps getting worse. Approximately 71,568 predicted drug overdose deaths were reported for the 12-month period to January, a jump from 67,114 predicted deaths from drugs in January 2017, according to newly released data from the Centers for Disease Control and Prevention. There are even more suspected deaths, which are still being investigated. The predicted number of deaths from drug overdoses rose 33% in Nebraska and 24% in New Jersey over the same period. Nebraska had the largest increase, but it is also one of the states with the fewer numbers of drug overdoses: Only 152 reported deaths occurred for the 12-month period to January in that state, compared to 2,585 in North Carolina. Twelve states have seen a drop in overdose deaths year over year, most of which are in the Midwest and Rocky Mountain regions. Wyoming saw the greatest drop, at 33% for the 12-month period to January, and has one of the fewest numbers of predicted cases at 61 for the 12 months to January, down from 91 for the same period in 2017. White Americans seem to be at the greatest risk for death by opioid, according to a study published in the American Journal of Preventive Medicine last year. The rise in fatal drug overdoses is almost entirely responsible for the growth in mortality rates for white, non-Hispanic people between the ages of 22 and 56 in recent years, according to a new study published in the American Journal of Preventive Medicine. Mortality rates for that population rose by 21.2 deaths per 100,000 people between 1999 and 2015, the study found. If drug mortality rates had stayed at 1999 levels, mortality rates would have actually declined for men in that population considerably and risen only slightly for women. Recent analysis by the Centers for Disease Control and Prevention found that recent increases in drug overdose deaths "are driven by continued sharp increases in deaths involving synthetic opioids other than methadone, such as illicitly manufactured fentanyl."

IL + Impact – Non Adherence

8% of Americans don't take their meds because of costs (Cohen - CDC)

Robin Cohen, CDC, 2015, "Strategies Used by Adults to Reduce Their Prescription Drug Costs: United States 2013" https://www.cdc.gov/nchs/data/databriefs/db184.htm (NK)

To save money, almost 8% of U.S. adults (7.8%) did not take their medication as prescribed, 15.1% asked a doctor for a lower-cost medication, 1.6% bought prescription drugs from another country, and 4.2% used alternative therapies. Adults aged 18–64 (8.5%) were nearly twice as likely as adults aged 65 and over (4.4%) to have not taken their medication as prescribed to save money. Among adults aged 18–64, uninsured adults (14.0%) were more likely than those with Medicaid (10.4%) or private coverage (6.1%) to have not taken their medication as prescribed to save money. **The poorest adults—those with incomes below 139% of the federal poverty level—were the most likely to not take medication as prescribed to save money.**

Approximately one-fifth (18%) of the $263 billion spent on retail prescription drugs in the United States in 2012 was paid out of pocket (1). Some adults offset the cost of prescription drugs by reducing the dosage and frequency of the recommended pharmacotherapy (2-3). Other cost-saving strategies include asking providers for less-expensive medications or purchasing medications abroad (4). This report updates previously reported estimates for strategies used by U.S. adults aged 18 and over to reduce their prescription drug costs (5), using data from the 2013 National Health Interview Survey.

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

High drug prices are harmful. Medical costs and out-of-pocket expenses result in high rates of bankruptcies, and 10-25 percent of patients either delay, abandon or compromise treatments because of financial constraints. Survival is also compromised. For example, in chronic myeloid leukemia, the 8-10 year survival rate is 80 percent in Europe (where treatment is universally affordable); in the U.S., where finances may limit access to drugs, the 5-year survival is 60 percent. In surveys, 78 percent of Americans worry most about costs of drugs. Sadly, three years after the issue was raised, there has been little progress. The problem is compounded by 2 additional factors. First is the increasing shift in the cost of care and drugs to patients. Insurers justify this "skin-in-the-game" strategy as effective in reducing costs, but the high out-of-pocket expenses have turned this into "deterrence-in-the-game," discouraging patients from seeking care or purchasing drugs. In a recent survey, one-third of insured Texans delayed or did not pursue care because of high out-of-pocket expenses. Second is the spill-over of high drug prices to generics. Complex regulatory issues and shortages allow companies to increase prices of generics to levels as high as patented drugs. The latest scandals – Turing, Valiant and Mylan – are only the most extreme examples of a common strategy in pricing drugs. Generic Imatinib to treat chronic myeloid leukemia is priced at $5,000-8,000/year in Canada, $400/year in India, but $140,000/year in the U.S. For generic drugs to be priced low, four to five generics have to be available. The average cost of filing for FDA approval of a drug is $5 million in 2016, and the average time to approval is 4 years. There are currently more than 3,800 generic drug applications awaiting FDA action. The FDA should overhaul its procedures to reduce the cost of filing to less than $1 million per drug, reduce the timeline to approval to 6-12 months and monitor for the availability of multiple generics at all times.

Nonadherence to medications causes 125k deaths per year, with costs being a major contributor

Brody 17 Jane E. Brody, 4-17-2017, "The Cost of Not Taking Your Medicine," New York Times, https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html //DF

There is an out-of-control epidemic in the United States that costs more and affects more people than any disease Americans currently worry about. It's called **nonadherence to prescribed medications**, and it is — potentially, at least — 100 percent preventable by the very individuals it afflicts. The numbers are staggering. "Studies have consistently shown that 20 percent to 30 percent of medication prescriptions are never filled, and that approximately 50 percent of medications for chronic disease are not taken as prescribed," according to a review in Annals of Internal Medicine. People who do take prescription medications — whether it's for a simple infection or a life-threatening condition — typically take only about half the prescribed doses. **This lack of adherence**, the Annals authors wrote, **is estimated to cause approximately 125,000 deaths** and at least 10 percent of hospitalizations, and to cost the American health care system between $100 billion and $289 billion a year. Former Surgeon General C. Everett Koop put it bluntly: "Drugs don't work in patients who don't take them." This partly explains why new drugs that perform spectacularly well in studies, when patients are monitored to be sure they follow doctors' orders, fail to measure up once the drug hits the commercial market. More important, it explains why so many patients don't get better, suffer surprising relapses or even die when they are given drug prescriptions that should keep their disorders under control. Studies have shown that a third of kidney transplant patients don't take their anti-rejection medications, 41 percent of heart attack patients don't take their blood pressure medications, and half of children with asthma either don't use their inhalers at all or use them inconsistently. "When people don't take the medications

prescribed for them, emergency department visits and hospitalizations increase and more people die," said Bruce Bender, co-director of the Center for Health Promotion at National Jewish Health in Denver. "Nonadherence is a huge problem, and there's no one solution because there are many different reasons why it happens." For example, he said parents often stop their children's asthma treatment "because they just don't like the idea of keeping kids on medication indefinitely." Although a child with asthma may have no apparent symptoms, there is underlying inflammation in the lungs and without treatment, "if the child gets a cold, it can result in six weeks of illness," Dr. Bender explained. When Dr. Lisa Rosenbaum, a cardiologist at Brigham and Women's Hospital in Boston, asked patients who had suffered a heart attack why they were not taking their medications, she got responses like "I'm old-fashioned — I don't take medicine for nothing" from a man with failing kidneys, peripheral vascular disease, diabetes and a large clot in the pumping chamber of his heart. Another common response: "I'm not a pill person." When Dr. Rosenbaum told her hairdresser that she was studying why some people with heart disease don't take their medications, he replied, "Medications remind people that they're sick. Who wants to be sick?" He said his grandmother refuses to take drugs prescribed for her heart condition, but "she'll take vitamins because she knows that's what keeps her healthy," so he tells her that the pills he gives her each night are vitamins. Other patients resist medications because they view them as "chemicals" or "unnatural." One man told Dr. Rosenbaum that before his heart attack, he'd switched from the statin his doctor prescribed to fish oil, which unlike statins has not been proved to lower cholesterol and stabilize arterial plaque. "There's a societal push to do things naturally," she said in an interview. "The emphasis on diet and exercise convinces some people that they don't have to take medications." Dr. Bender said, "People often do a test, stopping their medications for a few weeks, and if they don't feel any different, they stay off them. This is especially common for medications that treat 'silent' conditions like heart disease and high blood pressure. Although the consequences of ignoring medication may not show up right away, it can result in serious long-term harm." Some patients do a cost-benefit analysis, he said. "Statins are cheap and there's big data showing a huge payoff, but if people don't see their arteries as a serious problem, they don't think it's worth taking a drug and they won't stay on it. Or if they hear others talking about side effects, it drives down the decision to take it." Cost is another major deterrent. "When the co-pay for a drug hits $50 or more, adherence really drops," Dr. Bender said. Or when a drug is very expensive, like the biologics used to treat rheumatoid arthritis that cost $4,000 a month, patients are less likely to take them or they take less than the prescribed dosage, which renders them less effective. Dr. William Shrank, chief medical officer at the University of Pittsburgh Health Plan, said that when Aetna offered free medications to patients who survived a heart attack, adherence improved by 6 percent and there were 11 percent fewer heart attacks and strokes, compared with patients who paid for their medications and had an adherence rate of slightly better than 50 percent.

Other countries treat drugs like basic necessities (Kliff - Vox)

Sarah Kliffsarah, Vox, 5-10-2018, "The true story of America's sky-high prescription drug prices," [vox staff writer, one of the country's leading health policy journalists, who has spent seven years chronicling Washington's battle over the Affordable Care Act. Recently, her reporting has taken her to the White House for a wide-ranging interview with President Obama on the health law — and to rural Kentucky, for a widely-read story about why Obamacare enrollees voted for Donald Trump.]
https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained (NK)

But if you do succeed — and Australia deems your drug worthy to cover — then you'll have to decide whether the committee has offered a high enough price. If so, congrats! You've entered the Australian drug market. **Other countries regulate the price of drugs because they see them as a public utility Countries like Australia, Canada, and Britain don't regulate the price of other things that consumers buy, like computers or clothing. But they and dozens of other countries have made the decision to regulate the price of drugs to ensure that medical treatment remains affordable for all citizens, regardless of their income**. Medication is treated differently because it is a good that some consumers, quite literally, can't live without. This decision comes with policy trade-offs, no doubt. Countries like Australia will often refuse to cover drugs that they don't think are worth the price. In order for regulatory agencies to have leverage in negotiating with drugmakers, they have to be able to say no to the drugs they don't think are up to snuff. This means certain drugs that sell in the United States aren't available in other countries — and there are often public outcries when these agencies refuse to approve a given drug.

Brody 17 Jane E. Brody, 4-17-2017, "The Cost of Not Taking Your Medicine," New York Times, https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html //DF

There is an out-of-control epidemic in the United States that costs more and affects more people than any disease Americans currently worry about. It's called nonadherence to prescribed medications, and it is — potentially, at least — 100 percent preventable by the very individuals it afflicts. The numbers are staggering. "Studies have consistently shown that 20 percent to 30 percent of medication prescriptions are never filled, and that approximately 50 percent of medications for chronic disease are not taken as prescribed," according to a review in Annals of Internal Medicine. People who do take prescription

medications — whether it's for a simple infection or a life-threatening condition — typically take only about half the prescribed doses. **This lack of adherence**, the Annals authors wrote, **is estimated to cause approximately 125,000 deaths** and at least 10 percent of hospitalizations, and to cost the American health care system between $100 billion and $289 billion a year. Former Surgeon General C. Everett Koop put it bluntly: "Drugs don't work in patients who don't take them." This partly explains why new drugs that perform spectacularly well in studies, when patients are monitored to be sure they follow doctors' orders, fail to measure up once the drug hits the commercial market. More important, it explains why so many patients don't get better, suffer surprising relapses or even die when they are given drug prescriptions that should keep their disorders under control. Studies have shown that a third of kidney transplant patients don't take their anti-rejection medications, 41 percent of heart attack patients don't take their blood pressure medications, and half of children with asthma either don't use their inhalers at all or use them inconsistently. "When people don't take the medications prescribed for them, emergency department visits and hospitalizations increase and more people die," said Bruce Bender, co-director of the Center for Health Promotion at National Jewish Health in Denver. "Nonadherence is a huge problem, and there's no one solution because there are many different reasons why it happens." For example, he said parents often stop their children's asthma treatment "because they just don't like the idea of keeping kids on medication indefinitely." Although a child with asthma may have no apparent symptoms, there is underlying inflammation in the lungs and without treatment, "if the child gets a cold, it can result in six weeks of illness," Dr. Bender explained. When Dr. Lisa Rosenbaum, a cardiologist at Brigham and Women's Hospital in Boston, asked patients who had suffered a heart attack why they were not taking their medications, she got responses like "I'm old-fashioned — I don't take medicine for nothing" from a man with failing kidneys, peripheral vascular disease, diabetes and a large clot in the pumping chamber of his heart. Another common response: "I'm not a pill person." When Dr. Rosenbaum told her hairdresser that she was studying why some people with heart disease don't take their medications, he replied, "Medications remind people that they're sick. Who wants to be sick?" He said his grandmother refuses to take drugs prescribed for her heart condition, but "she'll take vitamins because she knows that's what keeps her healthy," so he tells her that the pills he gives her each night are vitamins. Other patients resist medications because they view them as "chemicals" or "unnatural." One man told Dr. Rosenbaum that before his heart attack, he'd switched from the statin his doctor prescribed to fish oil, which unlike statins has not been proved to lower cholesterol and stabilize arterial plaque. "There's a societal push to do things naturally," she said in an interview. "The emphasis on diet and exercise convinces some people that they don't have to take medications." Dr. Bender said, "People often do a test, stopping their medications for a few weeks, and if they don't feel any different, they stay off them. This is especially common for medications that treat 'silent' conditions like heart disease and high blood pressure. Although the consequences of ignoring medication may not show up right away, it can result in serious long-term harm." Some patients do a cost-benefit analysis, he said. "Statins are cheap and there's big data showing a huge payoff, but if people don't see their arteries as a serious problem, they don't think it's worth taking a drug and they won't stay on it. Or if they hear others talking about side effects, it drives down the decision to take it." Cost is another major deterrent. "When the co-pay for a drug hits $50 or more, adherence really drops," Dr. Bender said. Or when a drug is very expensive, like the biologics used to treat rheumatoid arthritis that cost $4,000 a month, patients are less likely to take them or they take less than the prescribed dosage, which renders them less effective. Dr. William Shrank, chief medical officer at the University of Pittsburgh Health Plan, said that when Aetna offered free medications to patients who survived a heart attack, adherence improved by 6 percent and there were 11 percent fewer heart attacks and strokes, compared with patients who paid for their medications and had an adherence rate of slightly better than 50 percent.

Self-Driving Cars

Contention 2 is better investment.

The pharma industry attracts the most investment now because investors know that they are guaranteed high returns. Anderson 14 writes: the industry generates higher profit margins than any other. Five pharmaceutical companies make a profit margin of 20% or more.

But all this spending on drugs doesn't do much good for most people. Pearl 17 at Stanford explains: Increasingly, drug companies are not investing in R&D proportional to the profits they earn from the drugs they bring to market. Many have figured out that it's simpler and safer from a financial

perspective to obtain a medication already in existence and, using monopolistic control, raise the price as much as 500% or more, as in the case of the EpiPen.

A better decision for public health would be to move these investments into areas where they'll make a difference. Price controls on the pharmaceutical industry will do just that. By capping the price of medications, price controls will make the sector less profitable in the eyes of investors. Easton 18 at Bionest Partners explains: if profitability for new drugs declined, the appetite of the venture community for risky, long-term biopharmaceutical investments would shrink exponentially. Price controls on drugs would have the surprising effect of accelerating the flow of investment into high technology, where timelines to market are shorter, less regulated, and less risky.

In this field, the money is likely to go towards self-driving cars, whose promise to shake-up the transportation industry are tantalizing for investors. Rosevear 18 writes that like any revolutionary technological advance, the advent of driverless-vehicle technology could be a bonanza for investors.

Indeed, Easton explains that If we force pharma into a model where there is no venture investing, we will be trading drugs for better and sooner self-driving cars.

Self-driving cars are a lifesaving technology. Lafrance 15 at the Atlantic finds that self-driving cars could save nearly 30,000 lives a year, estimates that are on par with the efficacy of modern vaccines.

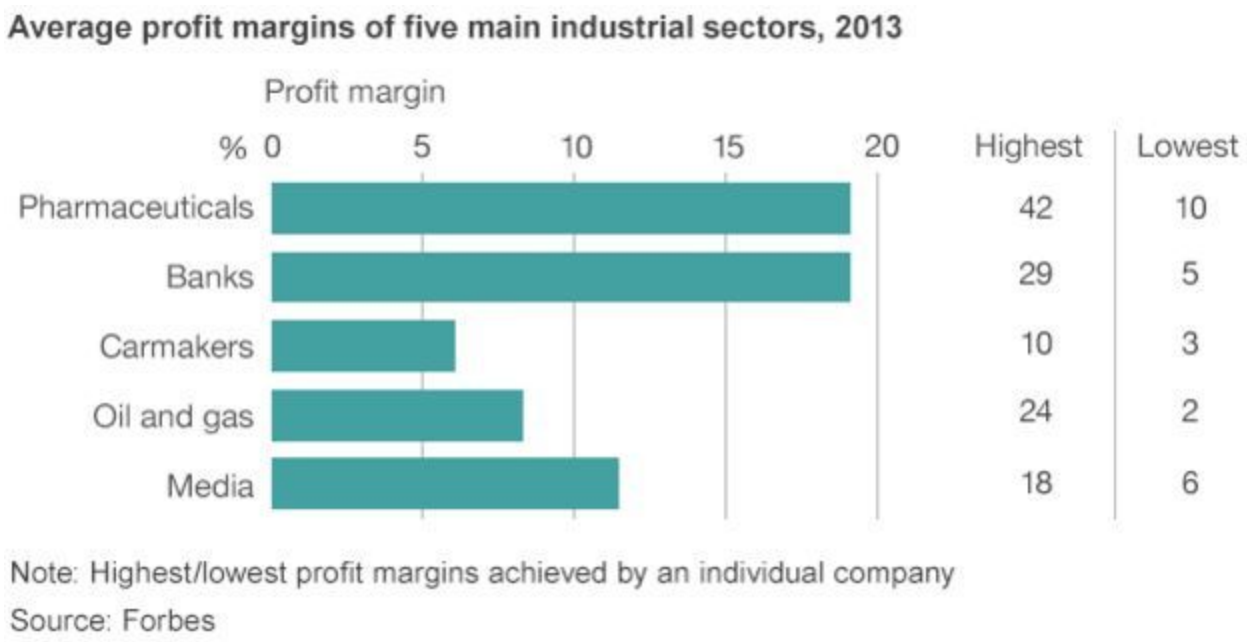
More investment in self-driving cars that quickens their adoption is important. Faster adoption of self-driving cars will save more lives because it will create a network of cars that can learn from each other. According to Berkeley Wellness 18: wide use of autonomous vehicles when they are just 10 percent better than current American drivers would save half a million additional American lives over 30 years, compared to waiting until they are 75 percent or 90 percent better.

Contention 2 is better investment.

The pharma industry attracts the most investment now because investors know that they are guaranteed high returns. Anderson 14 writes: the industry generates higher profit margins than any other. Five pharmaceutical companies make a profit margin of 20% or more.

Richard Anderson [Business reporter, BBC News], 11-6-2014, "Pharma industry gets high on profits," BBC News, https://www.bbc.com/news/business-28212223 //DF

Imagine an **industry that generates higher profit margins than any other** and is no stranger to multi-billion dollar fines for malpractice. Throw in widespread accusations of collusion and over-charging, and banking no doubt springs to mind. In fact, the industry described above is responsible for the development of medicines to save lives and alleviate suffering, not the generation of profit for its own sake. Pharmaceutical companies have developed the vast majority of medicines known to humankind, but they have profited handsomely from doing so, and not always by legitimate means. Last year, US giant Pfizer, the world's largest drug company by pharmaceutical revenue, made an eye-watering 42% profit margin. As one industry veteran understandably says: "I wouldn't be able to justify [those kinds of margins]." Stripping out the one-off $10bn (£6.2bn) the company made from spinning off its animal health business leaves a margin of 24%, still pretty spectacular by any standard. In the UK, for example, there was widespread anger when the industry regulator predicted energy companies' profit margins would grow from 4% to 8% this year. Last year, five pharmaceutical companies made a profit margin of 20% or more - Pfizer, Hoffmann-La Roche, AbbVie, GlaxoSmithKline (GSK) and Eli Lilly.



But all this spending on drugs doesn't do much good for most people. Pearl 17 at Stanford explains: Increasingly, drug companies are not investing in R&D proportional to the profits they earn from the drugs they bring to market. Many have figured out that it's simpler and safer from a financial perspective to obtain a medication already in existence and, using monopolistic control, raise the price as much as 500% or more, as in the case of the EpiPen.

Robert Pearl, *(Former CEO of The Permanente Medical Group, the largest medical group in the nation, and clinical professor of surgery at Stanford University, M.D.)*, 1-19-2017, "Why Patent Protection In The Drug Industry Is Out Of Control," Forbes, https://www.forbes.com/sites/robertpearl/2017/01/19/why-patent-protection-in-the-drug-industry-is-out-of-control/#14ee64fe78ca //AM

The intent of the patent process and the balance between the dual objectives have been warped over the past decade. ***Increasingly, drug companies are not investing in R&D proportional to the profits they earn*** **from the drugs they bring to market**, despite their protests to the contrary. Instead, **many have figured out that it's simpler and safer from a financial perspective to** either buy the rights to drugs developed by others and raise the prices many times over, as with Sovaldi, or **to obtain a medication already in existence and, using monopolistic control, raise the price as much as 500% or more, as in the case of the EpiPen.** As a consequence, the patent protection process now primarily serves the drug companies, most often not on behalf of the American people, but, rather, at their expense.

This is compounded by the fact that drugs are becoming costlier to produce and less medically effective. Stott 18 at Endpoints News explains: As each new drug improves the current standard of care, this only raises the bar for the next drug, making it more expensive, difficult and unlikely to achieve any incremental improvement. Thus, the more we improve the standard of care, the more difficult and costly it becomes to improve further, so we spend more and more to get diminishing incremental benefits and added value for patients which results in diminishing return on investment. Indeed, he projects that the return on investment in pharma R&D will be 0% by 2020.

Kelvin Stott [biotech analyst and writer with decades of prize-winning experience in journalism. A co-founder of Endpoints News, he has covered biopharma for the past 15 years], 11-1-2018, "Pharma's broken business model: An industry on the brink of terminal decline," Endpoints News [independent news organization, reporting and analyzing the top global biotech and pharmaceutical R&D news of the day], https://endpts.com/pharmas-broken-business-model-an-industry-on-the-brink-of-terminal-decline/ //DF

Now the scariest thing about this analysis, is just how robust, consistent and rapid is the downward trend in return on investment over a period of over 20 years. But moreover, these results confirm that return on investment in pharma R&D is already below the cost of capital, and projected to hit zero within just 2 or 3 years. And this despite all efforts by the industry to fix R&D and reverse the trend. I mentioned earlier that this analysis is based on one assumption, the average investment period which is quite stable and well-defined, but here below we see that the results are not sensitive to this single assumption in any case. The downward trend is just as clear, as is the projected IRR of 0% by 2020:So what is driving this trend, and why haven't we been able to do anything about it? Law of Diminishing Returns Many different causes and drivers have been suggested to explain the steady decline in pharma R&D productivity, including rising clinical

trial costs and timelines, decreasing success rates in development, a tougher regulatory environment, as well as increasing pressure from payers, providers, and increasing generic competition, however there is one fundamental issue at play that drives all these factors together: The Law of Diminishing Returns**. As each new drug improves the current standard of care, this only raises the bar for the next drug, making it more expensive, difficult and unlikely to achieve any incremental improvement**, while also reducing the potential scope for improvement. Thus, **the more we improve the standard of care, the more difficult and costly it becomes to improve further, so we spend more and more to get diminishing incremental benefits and added value for patients which results in diminishing return on investment**, as illustrated here: But why does the analysis above suggest a linear decline that will hit 0% IRR by 2020? Shouldn't the decline slow down and curve away so that it never reaches 0% IRR? No. 0% IRR corresponds to breaking even and getting exactly your original investment back, but as anyone who has worked in pharma will know all too well, you can easily lose all your original R&D investment as most drugs fail without making any return at all, so the minimum theoretical IRR is in fact negative 100%. There is no reason why the IRR should stop declining before it reaches 0%, or even -100%, besides the limited patience of investors.

A better decision for public health would be to move these investments into areas where they'll make a difference. Price controls on the pharmaceutical industry will do just that. By capping the price of medications, price controls prevent big pharma from reaping massive profits through price gouging, and will make the sector less profitable in the eyes of investors. Easton 18 at Bionest Partners explains: if profitability for new drugs declined, the appetite of the venture community for risky, long-term biopharmaceutical investments would shrink exponentially. Price controls on drugs would have the surprising effect of accelerating the flow of investment into high technology, where timelines to market are shorter, less regulated, and less risky.

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

An important corollary is that, **if profitability** and value creation opportunities **for new drugs declined**, **the appetite of the venture community for risky, long-term biopharmaceutical investments would shrink exponentially. Price controls on drugs would have the** surprising **effect of accelerating the flow of investment into high technology, where timelines to market are shorter, less regulated, and less risky. The venture capital community is flush with cash and anxious to invest where high returns can be achieved — ideally within a much shorter time than is typically possible in the realm of drug R&D**. As a society, **if we force pharma into a** chemical industry **model, where there is** no biotech equivalent and **no venture investing, we will be trading** better and sooner effective **drugs for better and sooner** virtual reality devices and **self-driving cars**. Squeezing pharmaceutical R&D spending down to one-fifth of what it is today would also have an enormous impact on the problems that drug developers often choose to address. Orphan diseases would be deprioritized, as the returns under price controls would not warrant the investment. Complex diseases would also be deselected. While Alzheimer's disease and diabetes have huge patient populations, the extremely high cost of conducting the difficult research and the need for huge and complex clinical trials would dissuade all but the largest companies from pursuing those illnesses if the potential pricing upside was to be significantly constrained. Moreover, for difficult diseases like schizophrenia, where today's treatments are mostly inadequate, the flow of more effective new treatments would slow from a trickle to a rivulet, depriving those with these conditions from the possibility of relief.

Chen 15 at Forbes confirms that after health technology, technology services are the second most profitable industry.

Liyan Chen [Charting the world's largest companies and wealthiest people], 12-21-2015, "The Most Profitable Industries In 2016," Forbes, https://www.forbes.com/sites/liyanchen/2015/12/21/the-most-profitable-industries-in-2016/#2964ae975716 //DF

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. Surprisingly, both energy minerals and non-energy minerals are projected to rebound from a disastrous 2015 when they ranked last among all sectors. Factset estimates that net margin for energy minerals will rise to 3.9% from a mere 0.2% in 2015, while non-energy minerals will surge to 4.7% next year, a significant jump from net loss of 2.1% in 2015. That's a nice pick up for these two sectors that have been hammered by the plunge of energy and commodities prices.

In this field, the money is likely to go towards self-driving cars, whose promise to shake-up the transportation industry is tantalizing for investors. Rosevear 18 writes that like any revolutionary technological advance, the advent of driverless-vehicle technology could be a bonanza for investors.

John Rosevear [senior auto specialist for Fool.com. John has been writing about the auto business and investing for over 20 years], 6-14-2018, "What Investors Need to Know About Driverless Cars," TheMotleyFool, https://www.fool.com/investing/2018/06/14/what-investors-need-to-know-about-driverless-cars.aspx#invest //DF

Self-driving vehicles have the potential to transform how humans and goods get moved from place to place. And they could transform much more: If autonomous vehicles become the norm, our thinking around everything from private car ownership to truck transportation and even urban design and planning will be challenged and could become obsolete. Like any revolutionary technological advance, the advent of driverless-vehicle technology could be a bonanza for investors. Here's an overview of what you need to know about this fast-approaching technology, as well as our best estimates about when autonomous vehicles will become commonplace on the world's roads. In this detailed run down of everything investors need to know about investing in driverless cars we will cover:

Indeed, Easton explains that If we force pharma into a model where there is no venture investing, we will be trading drugs for better and sooner self-driving cars.

Self-driving cars is a lifesaving technology. Lafrance 15 at the Atlantic estimates that self-driving cars could save nearly 30,000 lives a year, estimates that are on par with the efficacy of modern vaccines.

Adrienne Lafrance [editor of TheAtlantic.com. She was previously a senior editor and staff writer at The Atlantic], 9-19-2015, "Driverless Cars Could Save Tens of Millions of Lives This Century," Atlantic, https://www.theatlantic.com/technology/archive/2015/09/self-driving-cars-could-save-300000-lives-per-decade-in-america/407956/ //DF

This is not merely theoretical. There's already some precedent for change of this magnitude in the realms of car culture and automotive safety. In 1970, about 60,000 people died in traffic accidents in the United States. A dramatic shift toward safety—including required seat belts and ubiquitous airbags—helped vastly improve a person's chance of surviving the American roadways in the decades that followed. By 2013, 32,719 people died in traffic crashes, a historic low. Researchers estimate that driverless cars could, by midcentury, reduce traffic fatalities by up to 90 percent. Which means that, using the number of fatalities in 2013 as a baseline, **self-driving cars could save 29,447 lives a year.** In the United States alone, that's nearly 300,000 fatalities prevented over the course of a decade,

and 1.5 million lives saved in a half-century. For context: Anti-smoking efforts saved 8 million lives in the United States over a 50-year period. **The life-saving estimates for driverless cars are on par with the efficacy of modern vaccines,** which save 42,000 lives for each U.S. birth cohort, according to the Centers for Disease Control. Globally, there are about 1.2 million traffic fatalities annually, according to the World Health Organization. Which means driverless cars are poised to save 10 million lives per decade—and 50 million lives around the world in half a century. "By midcentury, the penetration of [autonomous vehicles] and other [advanced driver-assistance systems] could ultimately cause vehicle crashes in the United States to fall from second to ninth place in terms of their lethality ranking among accident types," wrote Michele Bertoncello and Dominik Wee in a paper for the consulting firm, McKinsey & Company. Bertoncello and Wee further estimate that better road safety will save as much as $190 billion a year in health-care costs associated with accidents.

More investment in self-driving cars that quickens their adoption is important. Faster adoption of self-driving cars will save more lives because it will create a network of cars that can learn from each other. According to Berkley Wellness 18: wide use of autonomous vehicles when they are just 10 percent better than current American drivers would prevent thousands of U.S. fatalities during the first decade, and possibly save half a million lives over 30 years, compared to waiting until they are 75 percent or 90 percent better.

3-13-2018, "Self-Driving Cars: How Many Lives Will They Save?," Berkley Wellness, http://www.berkeleywellness.com/healthy-community/health-care-policy/article/self-driving-cars-how-many-lives-will-they-save //DF

How perfect do they need to be? According to a new report from the nonprofit RAND Corporation, the U.S., in particular, has a lot to gain from self-driving cars. It concluded that such vehicles should only have to be moderately better than human drivers before being widely used—that is, we shouldn't wait until the technology is perfected. Based on numerous ways of calculating likely outcomes, the researchers found that **wide use of autonomous vehicles when they are just**, say, **10 percent better than current American drivers would prevent thousands of U.S. fatalities during the first decade, and possibly save half a million lives over 30 years, compared to waiting until they are 75 percent or 90 percent better**. "If we wait until these vehicles are nearly perfect, our research suggests the cost will be many thousands of needless vehicle crash deaths caused by human mistakes," one of the authors noted. "It's the very definition of perfect being the enemy of good." Developers are testing self-driving cars in various cities, while lawmakers are considering new regulations to govern their use. What remains unknown is how good the vehicles will have to be before they are made widely available. Of course, even when self-driving cars are proven much safer than average human drivers, they will still get into crashes, and people may be less tolerant of mishaps involving computers than of those caused by humans. "But if we can accept that early self-driving cars will make some mistakes—but fewer than human drivers—developers can use early deployment to more rapidly improve self-driving technology, even as their vehicles save lives," one author noted.

Frontlines

R/T Innovation Pre-Req

It doesn't matter how good innovations are if consumers can't afford them; Hep C deaths are rising even though a cure exists (Alexander 17)

G. Caleb Alexander [chair of the FDA's Peripheral and Cen- tral Nervous System Advisory Committee, serves as a paid consultant to QuintilesIMS, serves on the Advisory Board of MesaRx Innovations, and serves as a paid member of OptumRx's National P&T Committee. This arrangement was reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies], 2017 "Reducing Branded Prescription Drug Prices: A Review of Policy Options," Journal of Pharmacotherapy, doi: 10.1002/phar.2013 //DF

Although budgetary impacts of high-cost spe- cialty drugs are noteworthy, an even greater con- cern is that **these prices are restricting access to care. For example, in the case of hepatitis C, despite the availability of remarkably efficacious and safe treatments, fewer than one in five patients with the disease are receiving treatment**.7 A Senate Finance Committee report found that t**he manufacturer's pricing models never assumed that most people** with hepatitis C **would get access to the drug**.8 A study by the Centers for Disease Control and Prevention (CDC) found that *d***espite the availability of a cure that is nearly 100% effective, deaths from hepatitis C continue to rise while deaths from other infectious diseases** reported to the CDC *have continued to* fall.9 Public programs, ranging from state Medicaid programs to the Veterans Administration and Bureau of Prisons,10 are faced with difficult choices about who should receive certain drugs given their budget constraints.11 Fourteen state Medicaid programs spent more on one hepatitis C drug (Sovaldi [sofosbuvir], Gilead Sciences, Inc, Foster City, CA) than on any other drug, yet only 2.4% of ~700,000 Medicaid enrollees infected with hepatitis C were treated in 2014.12 In the private insurance market, health plans have cre- ated high cost-sharing tiers for specialty products with coinsurance levels as high as 25–33%.13 Even though Medicare has an out-of-pocket maxi- mum for pharmaceuticals, beneficiaries still must pay 5% of the cost once their out-of-pocket maxi- mum is reached.14 This means that a Medicare beneficiary with prescription drug coverage could still pay as much as 40% of total annual income from Social Security for a drug to treat hepatitis C. The ongoing policy challenge is to ensure patients have access to needed medications even if they have prescription drug insurance.

R/T Innovation Oughtweighs in the long-term

DIMINISHING RETURNS EVIDENCE

R/T Developing World Outweighs

Im sorry we cant read america first
This is a link debate

R/T Scope

R/T Magnitude

R/T Shortages

Production is cheap; does not make sense to cut production in order to save money (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)

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. 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").

R/T Prices Won't Decrease

Rly

Baker in case says prices are 2x higher in other countries

Hirshler says this is true among a wide variety of worldwide healthcare systems

R/T PBMs will increase their prices

PBM's are not the ones who set market prices - that is soley left up to pharma companies. PBM's have actually only been good - since their creation they have saved consumers 50 % of their prescription costs (Eyles - Health Affairs)

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

The recent Health Affairs blog post, "A Six-Step Solution to the PBM Problem," by Michael Carrier, focuses on the very real problem that drug prices are out of control. However, this piece overlooks a critical but simple fact: **Drug prices are set by just one player in the supply chain—pharmaceutical companies.** As the trade association representing the United States' health insurance plans, our members' mission is to improve and protect the health and financial security of US families through affordable, comprehensive coverage. We negotiate lower costs for the people we serve for the medical services they need—including lower drug costs. P**harmacy benefit managers (PBMs) play an important role in those negotiations, and the savings achieved are passed on through lower premiums and lower out-of-pocket costs that we offer to our members**. However, drug prices continue to rise because competition is limited, and there often are no alternatives to the life-saving medications patients need. A recent

investigation by the Associated Press found that in the first seven months of 2018, there were 96 drug price hikes for every drug price cut. Families find themselves having to choose between putting food on their tables and getting their medications. Carrier points to so-called gag clauses and clawbacks as driving the rising cost of drugs. AHIP and our members firmly believe that pharmacists should be able to inform their customers of the lowest prices available to them. In the relatively uncommon instance that their medication would cost less if they pay out of pocket instead of use their insurance, consumers should be told that. Our association has supported legislation that would eliminate gag clauses and clawbacks. However, gag clauses and clawbacks are uncommon—in fact, we are unaware of them being included in any insurance provider contract today. That means that a focus on gag clauses or clawbacks does not solve the fundamental problem of high drug prices for patients. Competition—Or The Lack Thereof The real issue is the lack of competition in the prescription drug market—where drug makers protect their monopolies through a deliberate strategy to create patent fortresses. Drug makers accumulate redundant patents specifically to block any generic alternatives. For example, the world's top-selling drug, Humira (adalimumab), has sought more than 100 patents—many of which only exist to extend its monopoly. All of us remember Mylan's $600 EpiPen—and its 40-year "layered patents." Patent monopolies, and the high prices that they empower drug makers to maintain, have been a problem for decades and only have gotten worse over time. PBMs were developed several decades ago as a private-market solution to this very problem. **Since their creation, PBMs have negotiated directly with drug makers to lower prescription drug prices, drive competition for more generic drugs, and secure savings through rebates and discounts for employers, unions, and other customers, including hardworking families**. Contrary to the article's claims, **PBMs save payers and patients 40–50 percent on their annual prescription drug and related medical costs compared to what they would have spent without PBMs.** That's an average of $941 per person per year, according to an analysis prepared for Pharmaceutical Care Management Association. In fact, an overwhelming body of independent research shows that, thanks to their ability to negotiate, PBMs are part of the solution to lowering health care costs: This includes research from the Federal Trade Commission (FTC), the Congressional Budget Office, and the Government Accountability Office. By negotiating the cost of prescription drugs, PBMs save plans money—money that is ultimately passed onto the consumer. In fact, two of the largest PBMs—CVS and Express Scripts—report that they return up to 98 percent and 95 percent of rebates, respectively, to those they serve in the commercial market.

R/T Lobbying

LOBBYING SKYROCKETED WHEN PHARMA PROFITS INCREASED IN THE 90'S (ANGELL 10)

R/T Drug Delays DA

1. The comparison is a 4 week delay versus 20 years because people can't afford the drug

R/T Hill Evidence

The original study says nothing about price controls - is just talking about amenable deaths (EuroStat)

EuroStat, 2018, "Amenable and preventable deaths statistics", https://ec.europa.eu/eurostat/statistics-explained/index.php/Amenable_and_preventable_deaths_statistics#deaths_from_potentially_avoidable_causes (NK)

In 2015, **over 570 000 deaths in the EU could have potentially been avoided with health care systems offering timely and effective medical treatments (amenable deaths)** and more than 1 million deaths could have been prevented through better public health interventions (preventable deaths). The total number of potentially avoidable deaths - which accounts for the fact that certain diseases are both preventable and amenable – is more than 1.2 million in 2015.[2] The leading cause of avoidable mortality was ischaemic heart diseases. 571 000 deaths from potentially avoidable causes In 2015, deaths from potentially avoidable causes in the EU amounted to 571 000 In the European Union (EU), 1.7 million persons aged less than 75 years died in 2015. Among them, around 571 000 deaths (or 127 deaths per 100 000 inhabitants) could have been avoided in the light of better healthcare systems (amenable deaths). The change compared to 2014 is negligible, showing that these figures are rather stable in the short run. Across EU Member States a substantial number of deaths can be considered as potentially avoidable and variations depend on Member States' population size.

However, despite spending 2x more on healthcare than European companies, our improvements in amenable mortality is half as good as it has been in these countries (Science direct - 2013) https://www.sciencedirect.com/science/article/pii/S2049080113700189

R/T Biosimilar Does not need patent

They do tho (Ossola - Popular Science)

Alexandra Ossola, 4-19-2016, "What Is A Biosimilar Drug?," Popular Science, https://www.popsci.com/what-is-biosimilar (NK)

And that means there's no way to guarantee that each dose of the drug will be identical. Biologic drugs can help with lots of different conditions in the body, like monoclonal antibodies to fight cancer, or Neupogen to boost white blood cells for patients undergoing chemotherapy. Great. So a biosimilar is what? **When the patent surrounding a biologic's formula is no longer protected, multiple companies can release a drug with the same chemical recipe, driving the cost down. That new biologic drug is a biosimila**r. That's important because biologics are blockbusters—in 2014, six of the top 10 best selling drugs in the world were biologics, according to the New York Times—and those patents have started to expire in the past few years, say Wahl. "[Those expired patents] open the road for other companies to start developing biosimilars," she says. It's understandable why there's been a bit of a delay before biosimilars have hit the market, since biologics have to go through more tests because of how they are synthesized.

R/T Pharma Lowering Prices

Yikes (Johnson - AP)

Linda A. Johnson and Nicky Forster, 9-24-2018, "AP investigation: Drug prices going up despite Trump promise," Associated Press, https://apnews.com/b28338b7c91c4174ad5fad682138520d (NK)

That hasn't happened, and an Associated Press analysis of brand-name prescription drug prices shows it's been business as usual for drugmakers, with far more price hikes than cuts. The number of increases slowed somewhat and were not quite as steep as in past years, the AP found. **Over the first seven months of the year, there were 96 price hikes for every price cut, the AP found**. Health and Human Services Secretary Alex Azar, the administration's point person for efforts to lower drug prices, conceded in a recent AP interview that it will be a while before drug prices fall. He noted the complexity of the medicine market and its incentives for drugmakers to boost prices so they and middlemen make bigger profits. "I am not counting on the altruism of pharma companies lowering their prices," said Azar, who was a senior executive in Eli Lilly & Co.'s U.S. business for a decade when it dramatically raised prices for its insulin products.

Merck's promise to lower prices was total bogus because they didn't lower prices on drugs that actually make them money

Hiltzik 18 Michael Hiltzik, 7-20-2018, "Merck joins the parade of Big Pharma companies offering Trump bogus cuts in drug prices," latimes, http://www.latimes.com/business/hiltzik/la-fi-hiltzik-merck-prices-20180720-story.html //DF

The big drug company Merck, scurrying to get on President Trump's good side on drug prices, announced Thursday a raft of initiatives aimed at showing its "commitment to responsible pricing." The company said it would lower the price of its hepatitis C treatment Zepatier by 60% and cut prices on six other drugs by 10%. Merck also pledged to not increase the average net price of its overall product portfolio by more than the inflation rate annually. Hold your applause. **Not a single one of these initiatives will do anything significant to lower prices or even stem the rise in key products. The pledge on average net prices amounts to a huge loophole allowing Merck to hike the price at will of the drugs it really cares about**. In other words, **this is a bogus commitment**, just like Pfizer's pledge a few days ago to roll back some of its recent price increases ... temporarily. The drug industry's desire to meet Trump's demand for lower prices is understandable. What company wants to be in the crosshairs of the tweeter-in-chief? But offering price cuts with imaginary impacts isn't going to cut it in the long run. "What Merck did was not of much benefit at all," says Walid Gellad, an expert at pharmaceutical policy and pricing at the University of Pittsburgh. "In fact, it's counterproductive if the industry is saying it wants to help but really is just pretending." Let's open up Merck's announcement to find the pretense. First, Zepatier. This product has been an also-ran in the shrinking market for hepatitis C cures, badly trailing Gilead Sciences' Harvoni and Sovaldi even though its list price of about $54,000 is almost half their list price. But the Gilead products have been heavily discounted, in part to meet the competition

from Merck and AbbVie, the maker of another hepatitis C drug, and in part because these formulations are so effective as cures that the available patient pool is falling fast. Zepatier sales peaked last year at about $1.7 billion and had fallen so low by the first quarter of this year that the company essentially listed the drug's U.S. sales in its quarterly financial report as zero. Sales of Gilead's hepatitis C products, by contrast, peaked in 2015 at $19.1 billion. They've fallen every year since, but the company still dominates the market. Even with a 60% price reduction, Gellad conjectures, the list price of Zepatier will still be higher than most insurers are paying for it now. As for the other six drugs cited by Merck, lower-priced generic versions of all of them have been available for years, including Prinivil, a medicine for high blood pressure on which Merck's patent expired in 2002. As Merck acknowledges in its financial disclosures, the introduction of generic competition for a drug "typically leads to a significant and rapid loss of sales for that product." Umer Raffat, a drug industry analyst at Evercore ISI, calculated that the six drugs account for less than 0.1% of Merck's $40 billion in annual sales, according to statnews.com. Merck seemed to acknowledge in its announcement that it chose drugs on which the price reductions would be almost invisible on the bottom line. It said its product selections "were based on a range of factors including the gap between list price and actual discounted (net) prices paid in the market." In other words, the reductions may have brought the list prices down to what Merck was receiving from payers anyway, after discounts. Finally, there's Merck's pledge to hold the average net price increase on its overall portfolio to the rate of inflation. "That's not of much benefit at all," Gellad told me. "That is utterly confusing and probably not having a big impact at all, when you look at what really matters to people." By limiting its cost increases on a portfolio-wide basis, he says, Merck leaves itself the opportunity to raise prices on individual drugs. What's most important is that Merck made no commitments on the products that actually are important to its bottom line — blockbusters such as the diabetes drug Januvia, which accounted for nearly $6 billion in sales last year, and Keytruda, a cancer drug that brought in $3.8 billion. Together, those two drugs accounted for roughly 25% of Merck's total sales. Merck has raised the price of Januvia by more than 18% since January 2017. Gellad says there's reason for optimism in some of the Trump administration's policy prescriptions on drug pricing. The administration reportedly is contemplating rules to discourage rebates that often prompt drugmakers to raise prices, in favor of fixed discounts that wouldn't have the same effect. The administration's focus on drug prices is a positive development, he says, even if it has resulted in misleading initiatives by the companies thus far.

Pfizer's pledges to stop price increases is a sham; their prices are still going up!

Hiltzik 18 Michael Hiltzik, 7-11-2018, "Pfizer doesn't deserve any credit for 'rolling back' its price increases at Trump's demand. Here's why," latimes, http://www.latimes.com/business/hiltzik/la-fi-hiltzik-pfizer-drugs-20180711-story.html //DF

If you know anything about the drug industry or Trump's penchant for taking credit he doesn't deserve for policies that often don't even exist, you'll know the punchline: The rollback isn't really a rollback. It's a sop to Trump and nothing like good news for the American people. To begin with, **Pfizer isn't rolling back its price increases, which affected 100 products**, including Viagra, and was the second such price hike this year alone. **It's "deferring" them — and making clear that the deferral is temporary**. "The company will return these prices to their pre-July 1 levels as soon as technically possible," the company's statement said. "The prices will remain in effect until the earlier of when the president's blueprint goes into effect or the end of the year – whichever is sooner." In the wake of the announcement, Peter Maybarduk, director of the Access to Medicines Program at the advocacy group Public Citizen, said: "Pfizer's alleged concession to Trump is a sham. Pfizer is only deferring price increases — not canceling them, and certainly not lowering its prices." The "blueprint" mentioned in the announcement is the policy statement Trump issued May 11, setting forth several initiatives and proposals for bringing drug prices down. Most experts in the field faulted the blueprint for neglecting some of the most potentially effective options. Pharmaceutical stocks jumped after the announcement and haven't looked back: Pfizer has gained 4.2% over the intervening two months and Merck is up by 7.5%. Gilead, the maker of hepatitis C drugs that can cost more than $80,000 per treatment and therefore might be ripe for a price cut, is up 17.2%. Maybarduk saw the byplay between Trump and Pfizer as a reflection of the ineffectiveness of the blueprint. "The administration's 'blueprint' fails to discipline Big Pharma in any meaningful way," he stated. "Instead, the administration aims to protect manufacturers and help them survive a public health and public relations crisis. ... You can't fix a systematically corrupt industry by tweeting." Given that context, Pfizer's action looks more like an effort to keep an obstinate but easily gulled president mollified, at least in the short term. That's especially true since its price increase embarrassed Trump, who only weeks earlier had promised that major drugmakers would shortly be announcing "massive drops in prices." Pfizer has essentially issued Trump an ultimatum — implement the blueprint by January 1, or we shoot the price rollback and dump it over the side. It shouldn't escape notice that Pfizer's deadline probably times the revival of its price increases to after the November midterm elections, allowing Trump to keep claiming credit through the campaign season. There's no evidence that Trump's table-pounding has done anything to moderate price increases in the pharmaceutical industry. A recent survey by Wells Fargo, reported by Politico, identified price increases in 104 drugs in June and the first two days of July, averaging 31.5%. Pfizer has been among the most aggressive price-hikers. An

analysis by the drug consulting firm Pharmacy Benefit Consultants found significant price increases dating back to January 2017 for some of Pfizer's most popular prescription drugs, averaging nearly 30%, not counting the now-deferred July increases: Lipitor up 31.1%, arthritis treatment Celebrex up 19.8%, depression drug Zoloft up 31.1% and Viagra up by 39.5%.

R/T Gag Rule

Gag clauses are in virtually no insurance contracts lol (Eyles - Health Affairs)

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

Families find themselves having to choose between putting food on their tables and getting their medications. Carrier points to so-called gag clauses and clawbacks as driving the rising cost of drugs. AHIP and our members firmly believe that pharmacists should be able to inform their customers of the lowest prices available to them. In the relatively uncommon instance that their medication would cost less if they pay out of pocket instead of use their insurance, consumers should be told that. Our association has supported legislation that would eliminate gag clauses and clawbacks. **However, gag clauses and clawbacks are uncommon—in fact, we are unaware of them being included in any insurance provider contract today. That means that a focus on gag clauses or clawbacks does not solve the fundamental problem of high drug prices for patients.** Competition—Or The Lack Thereof The real issue is the lack of competition in the prescription drug market—where drug makers protect their monopolies through a deliberate strategy to create patent fortresses. Drug makers accumulate redundant patents specifically to block any generic alternatives.

R/T Generics Solve

Generics aren't coming to market because there is a massive backlog for approving them

Holbrook 18 Timothy Holbrook [Professor of Law, Emory University], 6-23-2018, "Government Is The Big Reason EpiPen And Other Generics Are So Expensive," American Council on Science and Health, https://www.acsh.org/news/2018/06/23/government-big-reason-epipen-and-other-generics-are-so-expensive-13114 //DF

What explains such a rapid rise in price for a drug that has been around for several years? As a patent lawyer with particular experience in the pharmaceutical industry, I think it's important to look at the role of patents and also FDA approvals in drug discovery and sales. **Currently, a backlog of about 4,000 generic drugs is awaiting FDA approval.** Both factors play a role in how both rare and common drugs, such as EpiPens, can shoot up in price so rapidly. Patents encourage innovation High prices for medications are nothing new. They are often expected, given the role of the patent system in fostering innovation in the pharmaceutical industry. Patents create incentives for persons to innovate by giving them a limited period of exclusivity, currently from the date the patent issues until 20 years after its application date. During the patent's term, the owner can stop others from making, using or selling the patented invention. Without this period of exclusivity, companies would have little incentive to engage in research and development. Pharmaceutical research and regulatory approval is a costly endeavor. The average cost to bring a drug to market is $2.6 billion, according to the Tufts Center for the Study of Drug Development. Imagine the world of pharmaceuticals without patents. The National Institutes of Health predicts drug development would greatly diminish. Once a company put a drug on the market, others could purchase it and likely figure out how to synthesize a competing version, without incurring all of the research and development costs to identify that particular chemical entity. When competitors enters the market, they would be able to undersell the original innovator, whose price must reflect those sunk costs of research and development. Likely, it would not be profitable to have ever engaged in the drug innovation to begin with. Patents help stimulate innovation by temporarily avoiding this dynamic. Playing monopoly During the patent term, particularly for pharmaceuticals, the patent holder may effectively have a monopoly, allowing the company to charge prices higher than a competitive market would allow. As a society, we largely have accepted this elevated price because we believe it helps pharmaceutical companies to recoup their sunk research and development costs and to perform later research for the next generation of drugs. Once the patent expires, however, others can enter the market, creating competition and lowering the price for the drug. There are opponents to the power of these patents. Critics argue that these patents deny patients access to those drugs to patients in need. Interestingly, though, the patent system is not to blame for many of these price hikes we hear about in the news. Instead, these drugs, such as the EpiPen, are off-patent, suggesting that generic competition should help keep prices lower. So, if it isn't the patent system, then what is at play? It is conceivable the cost of producing some of these drugs has gone up. Similarly, there could be surging demand that drives up prices as well. Neither, though, explain the abrupt, dramatic hikes of some of these medicines. At the simplest level, there is simply a lack of competition for these drugs, even absent patent protection. Some of this dynamic could be the well-recognized consolidation in the pharmaceutical industry, which may have reduced competition. The low profit margins on some of these drugs may have led some companies to leave the market altogether, leaving only one company. But even absent consolidation, there is another barrier that appears to be in play: regulations by the FDA, and the huge backlog. **Even generic drugs need regulatory approval to be sold**, which makes

sense. We don't want fly-by-night companies selling impure or otherwise harmful drugs. But **obtaining approvals does add costs and time to competitors attempting to enter the market.** One potential EpiPen competitor, Teva Pharmaceuticals, failed to obtain regulatory approval, delaying their entry into the market. Another competitor, Sanofi, recalled its competing epinephrine delivery device because it may be delivering in incorrect dosage. That leaves Mylan alone in the market, with the power to raise prices, which is what it did. Congress and the FDA are well aware of the backlog, even though the FDA says it is picking up the pace, thanks to fees charged to the drug companies seeking approval. In theory, some of these are just short-run problems. Eventually exorbitant prices will draw other competitors to the market and prices will come down, or so goes the thinking of basic supply and demand. But, FDA regulations – if unduly onerous – could continue to create long delays, resulting in higher prices and loss of access to some of these medications. It may be time for the FDA to reconsider some of its regulations governing these well-known, generic drugs to reduce the cost of approval and to facilitate competition. For example, the FDA may need to consider some sort of accelerated approval for importing drugs already sold in countries with regulatory systems comparable to our own. In that way, competition for these unpatented drugs could return more quickly.

They just pay generic companies to to release, costing consumer 3.5 billion / yr (Fox - Harvard)

Erin Fox, 4-6-2017, "How Pharma Companies Game the System to Keep Drugs Expensive," Harvard Business Review, https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive (NK)

Not anymore. The system intended to reward drug companies for their innovations, but eventually protect consumers, is systematically being broken. Drug companies are thwarting competition through a number of tactics, and the result is high prices, little to no competition, and drug quality problems. The ways companies stop generics **One of the ways branded drug manufacturers prevent competition is simple: cash. In so-called "pay for delay" agreements, a brand drug company simply pays a generic company not to launch a version of a drug. The Federal Trade Commission estimates these pacts cost U.S. consumers and taxpayers $3.5 billion in higher drug costs each year**. "Citizen petitions" offer drug companies another way to delay generics from being approved. These ask the Food and Drug Administration to delay action on a pending generic drug application. By law, the FDA is required to prioritize these petitions. However, the citizens filing concerns are not individuals, they're corporations. The FDA recently said branded drug manufacturers submitted 92% of all citizen petitions. Many of these petitions are filed near the date of patent expiration, effectively limiting potential competition for another 150 days.

They restrict access to samples so the generic companies can't do testing (Fox - Harvard)

Erin Fox, 4-6-2017, "How Pharma Companies Game the System to Keep Drugs Expensive," Harvard Business Review, https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive (NK)

"Authorized generics" are another tactic to limit competition. These aren't really generic products at all; they are the same product sold under a generic name by the company that sells the branded drug. Why? By law, the first generic company to market a drug gets an exclusivity period of 180 days. During this time, no other companies can market a generic product. But the company with the expiring patent is not barred from launching an "authorized generic." By selling a drug they're already making under a different name, pharmaceutical firms are effectively extending their monopoly for another six months. **Another way pharmaceutical firms are thwarting generics is by restricting access to samples for testing. Generic drug makers need to be able to purchase a sample of a brand-name product to conduct bioequivalence testing. That's because they have to prove they can make a bioequivalent product following the current good manufacturing practices (CGMP) standard.** These manufacturers don't need to conduct clinical trials like the original drug company did. But the original drug developer often declines to sell drug samples to generics manufacturers by citing "FDA requirements," by which they mean the agency's Risk Evaluation and Mitigation Strategies program. The idea behind this program is a good one: give access to patients who will benefit from these personalized medicines, and bar access for patients who won't benefit and could be seriously harmed. However, brand drug makers are citing these requirements for the sole purpose of keeping generics from coming to market.

There are far less generics today than in the past

Beyer 17 Katie Beyer [currently in her second year at UC Hastings College of the Law and has a concentration in Law and Health Sciences. She has received two CALI Awards for Academic Excellence and is a member of the Hastings Law Journal],, 8-3-2017, "Drug Money Part 2: A Look at 2017 State Legislative Efforts to Reduce Prescription Drug Prices," The Source on Healthcare Price & Competition, A project of the UC Hastings College of Law http://sourceonhealthcare.org/drug-money-part-2-a-look-at-2017-state-legislative-efforts-to-reduce-prescription-drug-prices/ //DF

When new drugs are patented, the drug manufacturer of the patented brand name drug controls both the price and available supply.[18] The patent holder has a monopoly over the drug for 20 years.[19] When patents expire, drug manufacturers are able to produce and distribute generic drugs on the market at a lower cost.[20] These drugs frequently average 80 to 85 percent less than the branded drug originals.[21]

Unfortunately, **the number of drugs coming off patent is decreasing at a rapid rate**.[22] **In 2017, $11.1 billion worth of pharmaceuticals will go off patent**.[23] This is **a 41.3% decrease from 2016**.[24] **Fewer patent expirations means fewer generic drugs will enter the market**.[25] In 2017, states sought to encourage pharmacists to substitute lower price equivalent drug products or interchangeable biological products known as biosimilars or biological equivalents for expensive brand named products. Most states already allow generic substitution for regular chemical compounds. Like a generic drug, a biosimilar is proven to be an effective substitute for an existing approved innovative biological product.[26] However, active ingredients in biosimilars and the original biological product are not identical, which leads to unique therapeutic options for each patient.[27] Twelve states – Alaska, Illinois, Iowa, Maryland, Massachusetts, Michigan, Minnesota, New Mexico, New Nork, South Carolina, Vermont, and Wyoming – introduced legislation authorizing pharmacists to substitute expensive biologic prescriptions for more affordable biological equivalents. Only Iowa, Maryland, Minnesota, and Wyoming enacted the legislation. Montana and West Virginia tried to catch up with the rest of the states by introducing legislation allowing pharmacists to substitute a therapeutically equivalent generic drug for a higher priced brand name drug. Unfortunately, both measures failed.

The top-selling drugs have an average of 71 patents

Loftus 18 Peter Loftus and Denise Roland, 10-25-2018, "By Adding Patents, Drugmaker Keeps Cheaper Humira Copies Out of U.S.," WSJ, https://www.wsj.com/articles/biosimilar-humira-goes-on-sale-in-europe-widening-gap-with-u-s-1539687603?mod=searchresults&page=1&pos=13 //DF

For now, AbbVie has a U.S. monopoly on a drug whose price has risen to more than $60,000 annually for some patients in the 15 years since it launched, and which racked up more than $12 billion in U.S. sales last year. Slow approval of biosimilars, as well as limited uptake once such drugs do go on sale in the U.S., is costing the American health-care system an estimated $15 billion-$18 billion a year in missed savings, according to Gary Stibel, founder and CEO of the New England Consulting Group. **A decade ago, the best-selling non-biologic drugs in the U.S. had an average of five patents each**, according to Lisa Larrimore Ouellette, a law professor at Stanford University. **Now, the 12 top-selling drugs in the U.S., many of which are biologics, have an average of 71 patents per drug**, according to a recent study from I-MAK, a group that files legal challenges against the validity of brand-name drug patents. Some elected and appointed officials have raised questions about patents as impediments. FDA Commissioner Scott Gottlieb in July criticized "patent thickets" for brand-name biologic drugs "that are purely designed to deter the entry of approved biosimilars," saying they've thwarted competition. He didn't identify companies he believes are doing so. AbbVie in particular has attracted sharp criticism over its patenting activities. In December 2017, Sen. Susan Collins (R-Maine), said AbbVie's patents have "blocked competitors from coming to the market" and called for ways to counter such practices.

For example, the company Abbvie has prevented generic versions of the drug Humira from coming on to the US, even though they're available in Europe

Loftus 18 Peter Loftus and Denise Roland, 10-25-2018, "By Adding Patents, Drugmaker Keeps Cheaper Humira Copies Out of U.S.," WSJ, https://www.wsj.com/articles/biosimilar-humira-goes-on-sale-in-europe-widening-gap-with-u-s-1539687603?mod=searchresults&page=1&pos=13 //DF

Cheaper copies of the world's biggest-selling drug will roll out across Europe this week after a key European patent for Humira expires Tuesday, but U.S. patients and insurers will have to wait to access less-expensive versions of the blockbuster drug. The reason: a formidable wall of patents built up by Humira-maker AbbVie Inc., that prevents the developers of "biosimilar" versions launching their products in the U.S. Biosimilars are near-copies of biologic drugs, such as Humira, that are made from living cells in a process that resembles brewing. They are analogous to generic copies of traditional pill-form medicines. Biologic drugs are some of the costliest in the world, and the availability of lower-cost versions as patents expire promises big savings. Humira—a drug used to treat diseases from rheumatoid arthritis to gut disorders—alone has more than $18 billion in global sales. Companies haven't revealed pricing for the Humira biosimilars, but they're expected to sell at a 10% to 25% discount to Humira's $10,000 to $22,000 annual price tag in Europe's biggest drug markets, according to Alexandra Annis, an analyst at health-care-market intelligence firm GlobalData. The main U.S. patent for Humira expired in 2016. But AbbVie has obtained more than 100 additional U.S. patents, a number legal experts describe as exceptional for a single

drug. The shelf lives of those patents extend into the 2020s and 2030s. AbbVie cited these newer patents, which cover manufacturing processes and other aspects of the drug, in lawsuits to block the two biosimilar versions approved in the U.S. Other companies say that has deterred them from bringing biosimilars to market quickly. Critics, including lawmakers and industry officials, say AbbVie has created a "patent thicket" that abuses the U.S. patent system in order to preserve its profits. AbbVie says it is protecting investments it made developing an innovative drug. "There's nothing about our intellectual property around Humira, or the licensing agreements we've done ... that's anything close to gaming the system," AbbVie Chief Executive Richard Gonzalez said on a conference call with analysts in July. "We invested a tremendous amount in research and development" to test Humira in a range of diseases and gain regulatory approval for those uses, Mr. Gonzalez said. "And we've improved and refined the manufacturing and the formulation of Humira over time, and there's nothing inappropriate about protecting that investment in innovation," he added.

Humira has over 100 patents →
https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug

Epi Pens have been around since '87, but have had four patents - some of which were awarded in the last six years (Liss - St. Louis Today)

Samantha Liss St. Louis Post-Dispatch, 7-8-2016, "Behind the EpiPen controversy are questions about patents granted to drugmaker," stltoday, https://www.stltoday.com/business/local/behind-the-epipen-controversy-are-questions-about-patents-granted-to/article_54bbc38b-57b1-5a41-bbe4-a92aa9f85751.html (NK)

Drugmaker Mylan NV has received the brunt of criticism for alleged price-gouging on the lifesaving EpiPen, but other factors — and players — contributed to the monopoly it enjoys today, say experts familiar with the drug industry. **First approved in 1987, the EpiPen is protected from competition until 2025 by four patents. Three of those patents were awarded within the last six years**. Not all of the patents for improvements were sought under Mylan's ownership. A key patent that was responsible for keeping another drugmaker from coming to market with a generic alternative to the EpiPen was inherited by Mylan. The patent in that case has ties to a company with St. Louis operations that produces the EpiPen and, soon, its generic version for Mylan.

Angel p.76

R/T Most drugs are generics

Despite representing about 1 percent of prescriptions in 2014, these types of high-cost drugs accounted for some 32 percent of all spending on pharmaceutical (Emanuel - NYT)

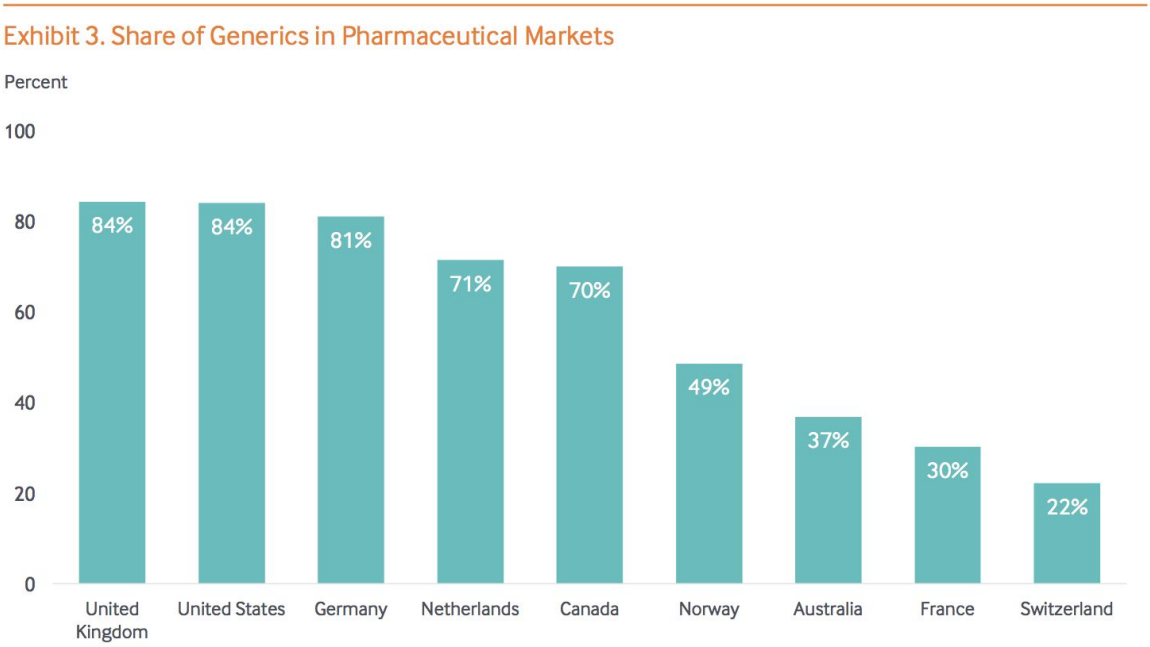
Ezekiel J. Emanuel, 9-9-2015, "The Solution To Drug Prices" NYT, [provost at the University of Pennsylvania.] https://www.nytimes.com/2015/09/09/opinion/the-solution-to-drug-prices.html (NK)

WE'RE paying too much for prescription drugs. The price for cancer drugs like Yervoy, Opdivo and Keytruda routinely exceeds $120,000 a year. Some other specialty drugs have even higher prices. Cerezyme for Gaucher disease costs about $300,000 per year for life. Kalydeco for cystic fibrosis also costs about $300,000 per year. **Despite representing about 1 percent of prescriptions in 2014, these types of high-cost drugs accounted for some 32 percent of all spending on pharmaceutical**s. Polls show that Americans are fed up with high drug costs. A commonly proposed solution has been to let the federal government, through Medicare, negotiate with drug companies. Currently, while Medicare tells hospitals and doctors what it will pay for services, by law it cannot negotiate with companies for lower drug prices. Some independent estimates suggest that negotiated drug prices could save the federal government $15 billion or more per year. But this approach will not solve the problem of stratospheric drug prices, for several reasons. For many diseases, there exist only a couple of effective drugs, with little price competition. Also, Medicare would have little negotiating leverage since, unlike private insurers, it cannot maintain an approved drug list and exclude overly expensive drugs from coverage.

R/T Less Generics

We have the same amount of generics as the UK and Germany - clearly not true (Sarnak - Commonwealth Fund)

Sarnak, Commonwealth Fund, 2017, "Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?" https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2017_oct_sarnak_paying_for_rx_ib_v2.pdf (NK)



R/T Creates Act

1. Big pharma doesn't support this bill (Bartz 18)

Diane Bartz, 10-31-2018, "Privacy, drug price bills have a fighting chance in a post-election...," U.S., https://www.reuters.com/article/us-usa-election-congress-business/privacy-drug-price-bills-have-a-fighting-chance-in-a-post-election-u-s-congress-idUSKCN1N51CH?feedType=RSS&feedName=USLegal //DF

Food and Drug Administration Commissioner Scott Gottlieb specifically addressed the issue in May 2018, saying the agency would inform the Federal Trade Commission if drug companies refuse to provide samples and inaccurately tell generic companies it is because of REMS distribution restrictions. Democratic Representative David Cicilline will introduce the CREATES Act again in the next Congress, according to a congressional aide. "Prospects for the CREATES Act improve if the Democrats take over the House," said Erik Komendant of the Association for Accessible Medicines, which represents the generic pharmaceutical industry. PhRMA, which represents some of the country's biggest drug companies, said in an email statement that they do not support the bill as written, but take seriously concerns that the FDA system can be used to delay generic drugs

coming to the market. CALIFORNIA PRIVACY The prospect of an online privacy bill, which went nowhere for years, increased in June when California Governor Jerry Brown, a Democrat, signed legislation in his state to give consumers more control over how companies collect and manage their personal information, including allowing consumers to request data be deleted and allow them to forbid its sale.

Pharma opposition likely means that the bill will not pass; they sunk it the last time

Kelly Davio [Senior Editor, American Journal of Managed Care], 11-1-2018, "5 Things to Know About the CREATES Act," AJMC, https://www.ajmc.com/newsroom/5-things-to-know-about-the-creates-act //DF

Despite broad bipartisan support, the bill has struggled to reach a vote. The legislation, sponsored by Senator Patrick Leahy, D-Vermont (with cosponsors including Republicans Ted Cruz of Texas, Claire McCaskill of Missouri, and Rand Paul of Kentucky, as well as Democrats Amy Klobuchar of Minnesota, Dianne Feinstein of California, and Sherrod Brown of Ohio), was first introduced in a different version in 2016 and, since then, has enjoyed broad bipartisan support. However, **the bill languished without a vote as it faced opposition from pharmaceutical companies**; The Hill reported in April 2018 that **the Pharmaceutical Research and Manufacturers of America, known as PhRMA, spent approximately $10 million** on lobbying efforts—including efforts **to halt progress of the CREATES Act**—in the first quarter of 2018. 3. The legislation has support from a pioneer of the generics industry. Among the most vocal supporters of the bill is former Representative Henry Waxman, D-California, who cosponsored (with Senator Orrin Hatch, R-Utah) the legal foundation for the US generics drug market: The Drug Price Competition and Patent Term Restoration Act of 1984, referred to colloquially as "Hatch-Waxman."

At most, the CREATES ACT will save consumers $5 billion

Kelly Davio, 11-2-2018, "5 Things to Know About the CREATES Act," AJMC, https://www.ajmc.com/newsroom/5-things-to-know-about-the-creates-act //DF

Among the most vocal supporters of the bill is former Representative Henry Waxman, D-California, who cosponsored (with Senator Orrin Hatch, R-Utah) the legal foundation for the US generics drug market: The Drug Price Competition and Patent Term Restoration Act of 1984, referred to colloquially as "Hatch-Waxman." Waxman told The Center for Biosimilars®, a sister publication of The American Journal of Managed Care® (AJMC®), in February 2018 that the CREATES Act "…Tackles one of the numerous problems driving high drug prices—drug manufacturers' use of anti-competitive tactics to block access to generic drugs. **If passed, the CREATES Act would increase the development and availability of generic drugs.** Not only is it good policy, but **it could save patients more than $5 billion** and the federal government more than $3 billion **over 10 years**, helping to pay for other necessary federal spending, including Community Health Centers."

That's compared to the 80$ billion they'd save per year with price controls

Alfred B. Engleberg, 10-29-2015, "How Government Policy Promotes High Drug Prices," Health Affairs, https://www.healthaffairs.org/do/10.1377/hblog20151029.051488/full/ //DF

In 1984, I represented the Generic Pharmaceutical Industry Association in the negotiations with Congress and PhRMA which sought to strike a balance between the pharmaceutical industry's demand for greater incentives to invest in innovation and the public's need for low-cost medicines. The deal which was struck then has not withstood the test of time. The monopolies created by Hatch-Waxman and subsequent legislation providing 12 years of exclusivity for biologic drugs clearly went too far in compensating the pharmaceutical industry at the public's expense. For decades, Congress has simply been transferring wealth from ordinary citizens to the pharmaceutical industry. While claiming to believe in free market capitalism, it has created a web of monopolies which cause the United States to pay the world's highest prices for drugs even though it is the largest purchaser. **The US would save $80 billion annually if its per capita drug costs were only 50 percent higher** ($750 per capita), **rather than 100 percent higher, than those of other developed countries.** Investing some of those savings to accelerate the development of cures for our most costly diseases could eventually reduce health care costs and justify a high price for life-saving medicines.

R/T Europe R&D Decreased

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.

Peter Stolk, University of California San Francisco, “Did the U.S. eclipse European pharmaceutical research productivity?” 2010, http://www.lygature.org/sites/lygature.c1.s3.aegirhost.nl/files/atoms/files/Escher-Report_12-10-08.pdf

The 2003 Call for Action correctly identifies ‘research productivity’ (Indicator 7) as one of its key indicators, but then only measures R&D expenditures (see Appendix 1). As shown in the reanalysis of the Grabowski and Wang article, the two are not the same, though related. We believe that industry and academia should come together to define research productivity and then measure it directly. Any message that is provided by the data may be confounded by factors that are not necessarily the hallmark of an innovative company. Therefore, any benchmarks should be carefully selected. 72 Innovation and industrial leadership. p 43-50. 33 To summarize, **our reassessment of key reports and statements**, most sponsored by DG Enterprise, **find unclear evidence to support the strong conclusions about the EU losing out to the US in pharmaceutical research productivity.** At times, the evidence provided directly contradicts the conclusions drawn. At other times, projected “facts” are made to support foregone and inaccurate conclusions. The members of the European Parliament and officers of the European Commission, as well as leaders of the pharmaceutical industry, need clear measures of research performance in order to make good policy. In this report we have devoted considerable attention to the first key report for DG Enterprise in 1994 and its policy conclusion that the pharmaceutical industry in Europe was in serious decline**. We have shown that based on a widely used outcome measure for research productivity, NCEs, that from 1982 to at least 2003, the European researchers were highly productive and became more so in recent years, not less. Many analyses on which the sweeping assumptions about the research productivity of European pharmaceutical industry are based suffer from using measures of other factors and synthetic indices of large, undifferentiated data sets** so that policy leaders cannot know what is really happening on the ground. In this report we saw that this happened at different levels: assigning molecules to certain countries is ambiguous, sales data do not provide a clear picture, and **NCE counts do not show which drugs truly add clinical value.** Furthermore, analyses such as the ones that focus on labor productivity do not seem to provide a coherent picture. Moreover, all these measures are subject to strong between-year variability, which makes basing policies on short term trends unwarranted. Therefore, clear and unambiguous benchmarks are needed that measure inputs and outputs of European pharmaceutical R&D as clearly as possible. These indicators should be unambiguous and really link to what is expected of a healthy industry. The G10 has made a start towards clear measures through its process of developing benchmarks. However, the indicators mentioned in the 2004 Call for Action (Appendix 1) as the outcome of this process do not provide indicators of the level and quality of research innovation that are needed for policy assessments. Although the reports that we have discussed here have been published several years ago, the critical issues highlighted remain. For example, the 2006 report by the Independent Expert Group on R&D and Innovation, Creating)an)Innovative)Europe, is much more focused on the conditions for innovation than the previous reports 73. Yet it presents no data or detailed empirical analysis, and in several places it signals a trend based on a 1R2 year changes. It also

uses selected years and measures that fluctuate significantly from year to year, such as how many of the top ten bestRselling drugs came from Europe in 2002.

R/T Overdoses

R/T FDA regulation causes increase

R/T Naoloxone is cheap

R/T PC Increases Addiction

FiND EVIDENCE THAT PEOPLE CAN'T AFFORD LONG TERM PRESCRIPTION

Kim 18 Victoria Kim, 7-5-2018, "Fentanyl Use Rising Across The US," Fix, https://www.thefix.com/fentanyl-use-rising-across-us //DF

The use of fentanyl, the synthetic opioid said to be 50 times as potent as heroin, is growing on both a local and national level, according to new research. A new analysis, conducted by Indiana University-Purdue University Indianapolis (IUPUI) researchers, found that fentanyl was present in nearly 50% of overdose deaths in Marion County, Indiana in 2017. This is a significant increase compared to less than a decade prior, when fentanyl was present in fewer than 15% of overdose deaths. "We found fentanyl present in 47% of cases," said Brad Ray, assistant professor at IUPUI's School of Public and Environmental Affairs. "That's nearly half of every single person that dies of a drug overdose. That's far outpaced heroin." These numbers mirror national statistics. In May, the Journal of the American Medical Association published research that showed that of the 42,249 opioid-related deaths in the United States in 2016, almost 46% involved fentanyl. Six years prior—similar to the IUPUI research—fentanyl was involved in just 14% of opioid-related deaths. The IUPUI research also found that over time, the potent opioid has been showing up more on its own, rather than mixed with other drugs, according to the Indy Star. When fentanyl first emerged as a threat to public health, it was said primarily to be used to boost the potency of heroin and other drugs. A previous study by IUPUI's School of Public and Environmental Affairs from 2017 reported an association between tighter opioid restrictions and an increase in opioid-related deaths. Researchers looked at prescription data from Indiana's prescription drug monitoring program and analyzed that alongside toxicology data from the Marion County Coroner's office, which tracks the specific substances involved in each drug-related death. With that, they found an "alarming trend": the prescription drug crackdown occurred alongside a "considerable" rise in heroin and fentanyl overdoses. "As people move away from pills, they do move on to heroin," explained Ray, who was the lead author of that study. "It's a cheaper substance to purchase but it's much more dangerous because you don't know what's in it, you don't know how much to take." Ray went on to say that a lack of treatment options in Indiana exacerbates the issue.

R/T Safety Net

R/T Ohio Study

Bad study. They ignore a lot of things, only focus on the implementation of certain policy. Biased in two main ways: 1) Assumes that many laws are rolled out immediately, but many aren't. It makes sense that more people would die if a policy was not rolled out bc/ no protection. 2) they examine

areas that greatly increased medicare spending, where the crisis is the worst. More healthcare spending means more hospital visits (Frank - Health Affairs)

Richard Frank, 3-19-2018, "Does Naloxone Availability Increase Opioid Abuse? The Case For Skepticism," No Publication, https://www.healthaffairs.org/do/10.1377/hblog20180316.599095/full/ (NK)

Their main treatment variable—the passage of any of a few state specific naloxone laws—creates three important vulnerabilities that undermine our confidence in both this paper and in another paper by Daniel I. Rees and colleagues that uses similar methodologies to reach quite different policy conclusions. F**irst, this variable amalgamates different policies that range in possible impact from trivial to significant**. A state that enacts third-party prescription laws (allowing naloxone to be prescribed to someone intending it for use on someone else) can give everyone de facto naloxone access. That's probably more powerful than legal immunity laws involving naloxone because legal scholars note that no user or prescriber of naloxone in the United States has ever been held criminally or civilly liable for their actions. **Doleac and Mukherjee's paper implicitly treats all naloxone polices as equally important.** Timing And Completeness Of Policy Changes Examined Second, **Doleac and Mukherjee presume that a naloxone law's passage has immediate effects. In practice, there is generally a significant lag between when laws are enacted and when they have their most powerful on-the-ground effects.** Some intended impacts never happen at all: **After the West Virginia legislature passed a law authorizing police to carry naloxone, sheriffs in the counties with the highest heroin death rates nonetheless decided not to carry it.** This is a particular empirical challenge here, since more than half of the Naloxone access laws noted in this paper were enacted in 2015 or later. Third, **Doleac and Mukherjee examine only one subset of policies designed to increase naloxone use. They do not examine other key policies such as Medicaid expansion, targeted federal grants for the purchase of naloxone, and the implementation of parity regulations that require equal insurance coverage of services used to treat mental illnesses and substance use disorders**. Medicaid spending on outpatient naloxone prescriptions reached just under $20 million in 2016. Federal grants for naloxone purchases exceeded $20 million in 2015. In that same year, $100 million in federal grants were directed at high need community health centers. Important resources were thus provided to expand naloxone access in precisely the areas that registered the most prevalent opioid use disorders, the highest opioid related mortality, and greatest community concern. T**he timing and distribution of these resources strikingly coincides with the maps showing policy changes presented by Doleac and Mukherjee**. Elected officials such as Governor John Kasich of Ohio underscored the importance of that point, **when they noted their states expanded Medicaid in part to fight the opioid epidemic and to expand drug users' access to treatment resources. These confounding public investments likely increased naloxone use while expanding the use of emergency department services, a key outcome measure in Doleac and Mukherjee's analysis.** Indeed, data from the Oregon Health Insurance Experiment suggest that M**edicaid expansion significantly increases emergency department use**. The implications for the analysis here are therefore two. 1) T**here are unaccounted for confounding factors that are positively correlated with both the policie**s Doleac and Mukherjee study and the outcomes they consider. Moreover, the unaccounted for confounders are likely to have a much larger impact on actual naloxone use (see below) than t**he factors studies by the authors thereby creating biased estimates.**

R/T Government Naloxone Initiatives

This just like mitigatory

R/T Marketing Causes Opioids

Deepak Manjiani,, 2014, "Availability and Utilization of Opioids for Pain Management: Global Issues," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4052588/ (NK

The WHO 3-step analgesic ladder model has provided a cost-effective pain treatment approach for many cancer sufferers; however, different models of analgesia treatment must be developed to address the increasing complexity of cancer and its treatments.[26] Additionally, in the 3-step analgesic ladder, the use of morphine for cancer pain management has not been the **gold standard approach although opioids continue to be the mainstay of pain treatment, morphine is relatively cheap, and morphine is the most widely available opioid analgesic.**[14,27] Opioid use for chronic noncancer pain remains controversial; the safety and efficacy of long-term opioid use is described as uncertain.[28] Persistent or chronic pain affects more than 5 million patients in the UK.[28]Opioid use is effective for treating a number of pain states for noncancer conditions but can cause serious problems with long-term use, including tolerance, dependence, and the potential for addiction.[28] Recent studies show that patients with a current or past history of substance misuse or with a diagnosis of psychiatric illness are more likely to develop problems with opioid use.[11,25,2]

https://www.mdmag.com/medical-news/top-10-painkillers-in-us - many have generics

R/T TURN: Decrease Healthcare costs

R/T Nonadherence

R/T Alt Causes for Nonadherence

Maybe, but our evidence says its a HUGE deterrent; 25% of Americans can't afford their meds.

Extras

Costs

UQ – US Prices Highest

US Drug prices far higher than anywhere else - 3x higher than Britain. It's even worse in other places, 16x higher than in India (Hirschler - Reuters)

Ben Hirschler, 2014, "How the U.S. Pays 3 Times More for Drugs," Reuters, https://www.scientificamerican.com/article/how-the-u-s-pays-3-times-more-for-drugs/ (NK)

LONDON (Reuters) - **U.S. prices for the world's 20 top-selling medicines are, on average, three times higher than in Britain, according to an analysis carried out for Reuters**. The finding underscores a transatlantic gulf between the price of treatments for a range of diseases and follows demands for lower drug costs in America from industry critics such as Democratic

presidential candidate Hillary Clinton. The 20 medicines, which together accounted for 15% of global pharmaceuticals spending in 2014, are a major source of profits for companies including AbbVie, AstraZeneca , Merck, Pfizer and Roche. **Researchers from Britain's University of Liverpool also found U.S. prices were consistently higher than in other European markets. Elsewhere, U.S. prices were six times higher than in Brazil and 16 times higher than the average in the lowest-price country, which was usually India. The United States, which leaves pricing to market competition, has higher drug prices than other countries where governments directly or indirectly control medicine costs**. That makes it by far the most profitable market for pharmaceutical companies, leading to complaints that Americans are effectively subsidizing health systems elsewhere.

Overall, prescription costs are 2-6x higher in the US than anywhere else in the world

Jena 18 Dr. Anupam B. Jena [Ruth L. Newhouse associate professor of health care policy a Harvard Medical School, an internist at Massachusetts General Hospital, and a faculty research fellow at the National Bureau of Economic Research], 1-19-2018, "US drug prices higher than in the rest of the world, here's why," TheHill, https://thehill.com/opinion/healthcare/369727-us-drug-prices-higher-than-in-the-rest-of-the-world-heres-why //DF

Americans pay prices for prescription drugs that are two to six times the rest of the world, despite having personal incomes that are on par with many developed countries. For instance, the average price for Humira — a top-selling drug to treat rheumatoid arthritis — is nearly $2,700 per administration in the U.S., more than twice the price in the U.K. American salaries are not twice as high as British salaries. It's not surprising that in countries with different per capita incomes (e.g., U.S. vs India), the prices of drugs are different. But why is it that in countries with similar per capita income as the U.S., drug prices are so much lower than in the U.S.? One answer is that nearly all countries except the U.S. have policies to lower drug prices, including price controls, regulations that limit the profitability of drugs, reference pricing, and cost-effectiveness thresholds (e.g., in the U.K., the National Health Service is the main purchaser of drugs and frequently does not cover therapies whose cost per "quality-adjusted" life year gained exceeds $50,000 per year). This answer provides a good explanation for how some countries achieve lower drug prices but not why drug prices are higher in the U.S. Perhaps the most common explanation for why drug prices are high in the U.S. is what economists call "free riding." The argument goes like this: because the U.S. is willing to pay higher prices for drugs, other countries don't feel the 'need' to do so and therefore don't. This explanation is overly simplistic and misses the two key economic issues at stake.

More cost for Meds that are no better

Dean Baker, 1-10-2016, "End Patent Monopolies on Drugs," NYT, [*Dean Baker is an economist and the co-director of the Center for Economic and Policy Research.*]
https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/end-patent-monopolies-on-drugs (NK)

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

UQ – US Prices Rising

Prices only going up (Amin - CNBC)

Tahir Amin, 6-27-2018, "The problem with high drug prices isn't 'foreign freeloading,' it's the patent system," CNBC, [Co-Founder Of Nonprofit I-Mak.Org] https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html (NK)

Americans continue to suffer the highest prescription drug costs of anyone in the world. One in four are unable to fill prescriptions due to high prices, according to a recent poll. **And even though drug prices tripled over the last decade, analysts predict they will double again in the next ten years**. We have a runaway problem on our hands, and while new proposals from Congress and the president seek to improve the drug pricing system, we will fail to reach lasting solutions unless we address a root factor in this national crisis: patents. Contrary to the Trump administration's recent claims, the source of our prescription drug problems is not "foreign freeloading" governments creating unfair pricing schemes—it's the unfair pricing systems created right here in the U.S. Today's drug patent monopolies are deeper, longer and stronger than at any point in the last century—and it's costing Americans and people around the world. Before a prescription drug even enters the market—before pricing negotiations occur between payers, government agencies, insurers, and so on—the U.S. patent office awards exclusivity to drug makers for intellectual property claims that have a huge impact on the market.

Drug prices will keep rising because of America's aging population

Madhavan 17 Guru Madhavan [biomedical engineer and senior policy adviser. He conductsresearch at the National Academy of Sciencesand has been named a distinguishedyoung scientist by the World EconomicForum] 11-2017, "Making Medicines Affordable: A National Imperative," The National Academies of Science, Engineering, Medicine, https://www.nap.edu/resource/24946/11302017AffordableDrugsHighlights.pdf //DF

The trend of increasing spending on health care, including on biopharmaceuticals, is projected to con- tinue for the foreseeable future as the Baby Boomer generation ages. No other nation in the world approaches the level of U.S. health care expenditure, yet various studies indicate that many nations have healthier populations. The United States now ranks 25th in the world in life expectancy at birth, yet among the 10 nations with the largest gross domestic product (GDP), the United States spends about twice as much on health care as a fraction of GDP as the average of the other nine. Annual expenditures on biopharma- ceuticals in the United States now exceed a half trillion dollars, and prescription drugs are among the fastest- growing segments of health care spending. Research and development of new drugs, the lifeblood of the pharmaceutical industry and its contribution to health care, is also extremely costly. The canonical statement about the cost of a new drug—"The first pill can cost over a billion dollars while the second costs only a dime"—captures an important truth: New drugs are exceptionally expensive to develop, and failures are commonplace.

Prices are rising at an "alarming" rate

Beyer 17 Katie Beyer [currently in her second year at UC Hastings College of the Law and has a concentration in Law and Health Sciences. She has received two CALI Awards for Academic Excellence and is a member of the Hastings Law Journal],, 8-3-2017, "Drug Money Part 2: A Look at 2017 State Legislative Efforts to Reduce Prescription Drug Prices," The Source on Healthcare Price & Competition, A project of the UC Hastings College of Law http://sourceonhealthcare.org/drug-money-part-2-a-look-at-2017-state-legislative-efforts-to-reduce-prescription-drug-prices/ //DF

It is no secret that drug prices have been rising at an alarming rate. In fact, spending on prescription drugs rose 12.4% in 2014 and 9% in 2015.[1] In 2015, the U.S. spent $457 billion on prescription drugs, which accounted for 16.7% of overall healthcare services.[2] In 2016, Americans filled 4.4 billion drug prescriptions, at a total cost of approximately $400 billion.[3] On average, Americans spend $1,370 out of pocket on prescription drugs per year.[4] With an average annual price increase of approximately 10% over the past three years, drug price increases continue to outpace inflation, which is growing at a rate of 2.3%.[5] These high drug costs affect nearly half of all Americans, with 49% of Americans reporting that they used at least one drug in the past 30 days. These

prescription drug users experienced a 208% rise in the prices of the most popular brand name drugs from 2008-2016.[6] The rising cost of life-saving medications is particularly alarming. Bavencio (a cancer drug) costs about $156,000 a year per patient.[7] A new muscular dystrophy drug introduced last year costs $300,000 per year.[8] Daraprim, a popular drug used by AIDS patients spiked from $13.50 to $750 per prescription.[9] The cost of insulin, now more than $700 per patient, tripled between 2002 and 2013 and the cost of an EpiPen spiked 500% since 2007.[10] So what can be done? With little assistance from the federal government, states are taking matters into their own hands. In 2017, 43 states introduced legislation aiming to combat high drug prices. Arkansas, Delaware, Idaho, Kentucky, North Dakota, Ohio, and South Dakota were the only states that stayed silent. As of July 2017, seventeen states passed bills and five states still have bills pending, which is a great improvement from 2016 state efforts. Last year, only ten states introduced legislation requiring pharmaceutical companies to disclose research and development costs.[11] Vermont was the sole state to enact its legislation.[12] In 2017, the Massachusetts legislature lead the charge and introduced ten bills with the purpose of lowering drugs costs. California, Maine, Maryland, New York, and Oregon followed closely behind.

Link – Reference Pricing Solves

Reference-based pricing solves the drug cost issue without stifling innovation

Laszewiski 18 Robert Laszewski [President Of Health Policy and Strategy Associates, He has 20 years of experience in the insurance industry, serving as a chief operating officer for nine of those years, before beginning his Washington, D.C. policy- and market-consulting business], 5-11-2018, "Here's the most obvious way to reduce drug prices that the US is missing," CNBC, https://www.cnbc.com/2018/05/11/the-obvious-way-to-reduce-drug-prices-that-the-us-is-missing.html //DF

What is even more frustrating is to see an easy solution that has worked for years in these other industrialized countries. Even though they are single-payer government-run systems, their drug pricing schemes are as American-style free market as they could be. Would any major U.S. corporation spend loads of money on procurement without first going out to bid on both price and performance? Would the Pentagon buy a new ship or aircraft system without going out to bid on both price and capability? Would the U.S. General Services Administration put up a new government office building without first bidding it out to determine which contractor would construct the best facility for the price? So, if we are looking for market-based solutions to the high cost of prescription drugs, we need look no further than the government-run health care systems in France, Canada, Germany, the U.K., and others. Rather than pointing the finger at these other nations that "pay too little" for their drugs and then condemn them for it, we might first recognize that they are out marketeering –the United States. These foreign bureaucrats are making American capitalists look like little leaguers when it comes to keeping drug prices under control. What these other countries have in common is that they use a system called reference-based pricing. While there are differences among them, they generally request bids and use the market to set a reference price for each prescription drug that also takes clinical results into consideration—it could be the lowest price from a range of alternative drugs in a class (Italy), an average of all of the drugs in a class (Germany), or an average of a group of the lowest priced players (Spain). The health care system then pays no more than the reference price for a drug in the class no matter which pharmaceutical company the consumer and their physician decide to use. In the end, the market sets the price and innovation is still rewarded by paying the price the most competitive player wants to charge. In such a competitive bidding process prices and drug outcome results are completely competitive and fully transparent. If a patient and their doctor want to pay more of an alternative drug, because they think it will do a better job for a particular patient, they know all of the prices and the comparative clinical outcomes upfront. If a drug company is truly able to innovate for an existing class of drug, that drug could be placed in a new class–innovation is still rewarded. The value of reference-based pricing is limited until there is more than one competitor in a class–drug companies are still rewarded for blockbuster breakthroughs. But when more than one player comes to market in the same drug class, they compete based both on price and clinical outcomes.

The US should be able to negotiate drug prices

Engelberg 15 Alfred B. Engelberg [retired intellectual property lawyer and philanthropist. During his legal career, he was a patent examiner at the US Patent Office, a patent trial attorney at the US Department of Justice, and a member of the New York City law firm of Amster, Rothstein and Engelberg. As counsel to the generic drug industry, he played a major role in drafting the Hatch-Waxman Act of 1984, which created the modern generic drug industry], 10-29-2015, "How Government Policy Promotes High Drug Prices," HealthAffairs, https://www.healthaffairs.org/do/10.1377/hblog20151029.051488/full/ //DF

For decades, Congress has simply been transferring wealth from ordinary citizens to the pharmaceutical industry. While claiming to believe in free market capitalism, it has created a web of monopolies which cause the United States to pay the world's highest prices for drugs even though it is the largest purchaser. The US would save $80 billion annually if its per capita drug costs were only 50 percent higher ($750 per capita), rather than 100 percent higher, than those of other developed countries. Investing some of those savings to accelerate the development of cures for our most costly diseases could eventually reduce health care costs and justify a high price for life-saving medicines. Looking Ahead What specific changes to US law could create that virtuous cycle? Here are some specific recommendations: Reduce The Scope And Length Of Monopolies Granting special monopolies to pharmaceutical companies that are not based on the patent law is a costly and inefficient way to induce investment in research. The five year exclusivity for small molecules; 12 year exclusivity for biologics; six-month pediatric exclusivity and all other similar non-patent monopolies are now being granted without any regard for the investment required or value produced. A drug which provides little or no incremental value over existing products gets the same ability to charge a monopoly price for an extended period of time as a life-saving breakthrough that required 10 times the risk and investment to discover. The current system of exclusivities should be repealed and replaced by a system which reasonably rewards research that produces drugs of high therapeutic value and little or no reward to low-risk research that produces "me too" drugs. Paying For Value As the largest payer for prescription drugs, the US government is entitled to the best price. It can achieve that price in one of two ways. It can modify existing law to assure that Medicare, Medicaid, and other public programs utilize the full array of tools for evaluating the value of each new drug and allow government programs to directly negotiate drug prices using those tools, including restricted formularies, reference pricing, and the like, just as it is now done by other developed nations and by pharmacy benefit managers. In the short term, it can modify existing rebate laws so as to base rebates on the lowest price being charged for a drug in one or more OECD countries having a comparable standard of living rather than basing it on the inflated price charged in the US market.

Link – Tethered Pricing Solves

Tethered prices would work best to show that the US won't pay higher prices than other countries

Mohammed 15 Rafi Mohammed [founder of Culture of Profit, a consultancy that helps companies develop and improve their pricing strategies, and the author of The Art of Pricing: How to Find the Hidden Profits to Grow Your Business (Crown Business, 2005) and The 1% Windfall: How Successful Companies Use Price to Profit and Grow (HarperBusiness, 2010)], 9-22-2015, "It's Time to Rein in Exorbitant Pharmaceutical Prices," Harvard Business Review, https://hbr.org/2015/09/its-time-to-rein-in-exorbitant-pharmaceutical-prices //DF

I believe in the free market and rarely advocate any type of price regulation. There are compelling reasons, however, to consider doing so for pharmaceuticals. The biggest expense of a new drug is R&D; once developed, the cost of producing pills is relatively trivial. Most important, everyone in the world can – and should – benefit from pharmaceutical advancements, especially since the variable costs are so low. In other words, the R&D behind new drugs is a common good. Typical solutions to the dilemma of high drug prices include single payer (e.g., U.S. government negotiates "take it or leave it" prices for its territory) and price regulation (e.g., the

government simply specifies prices). These tactics will lower prices but don't address the issue of paying for new pharmaceutical developments. How can we make sure that the cost of developing new drugs is equitably split among the various beneficiaries around the world? That high-price-paying Americans are not essentially subsidizing R&D for pharma multinationals? A tethered price regulation is the answer. Regulators could pass a law that says neither American insurers nor government agencies would pay more than a set percentage above (or below) what other developed countries pay for drugs. In other words, our prices are tethered to theirs. This accomplishes two goals. First, drug prices will be lowered for Americans. Second and just as importantly, pharma companies and other countries will be on notice that sick Americans are no longer going to shoulder a disproportionate share of drug development costs. Tethered regulation should apply only to new drugs, not existing drugs, which were developed with the understanding that U.S. prices will be as high as the market can bear. We made a bad deal, but we should keep our word. A common reaction to any whiff of price regulation is concern that pharma R&D will be reduced. This is a fair concern, but it's not a given that R&D will decrease. Pharma companies may opt to cut sales and marketing costs (which 9 out the top 10 pharma companies spend more on than R&D), executive compensation, or dividends instead, keeping R&D budgets healthy. That said, it is very possible R&D may decrease as a result of regulation. In utopia, it'd be wonderful for pharma companies to have unlimited R&D budgets. But back here in reality, tradeoffs are made. Even today, R&D budgets are not infinite. And if budgets are cut by 20%, instead of funding 100 initiatives, it may be that only the top 80 with the highest potential will be greenlit.

IL + Impact – Overdoses

The inability of the government to regulate the price of naloxone has led to massive price increases

Kate Gibson, 9-11-2018, "As opioid crisis rages, cost of overdose antidote spikes," No Publication, https://www.cbsnews.com/news/as-opioids-kill-more-americans-cost-of-overdose-antidote-spikes/ //DF

As the opioid epidemic continues to kill tens of thousands of Americans each year, the drug naloxone has proved invaluable in preventing overdose-related deaths. Yet a spike in its cost in recent years has constrained access to naloxone, potentially depriving health care professionals, emergency responders and families of a critical treatment than can save lives. Driving that price spike, experts say: An ongoing surge in overdoses that's boosting demand for naloxone; a dearth of federal rules that could limit price increases; a lack of drug industry competition; and pharmaceutical firms' lack of transparency in setting prices for drugs to counter the effects of opioids. The rising price of naloxone comes at a time that drug overdoses have become the leading cause of accidental death in the U.S. for those aged 25 to 64 -- opioids are involved in nearly two-thirds of those fatalities, according to federal health data. The U.S. Centers for Disease Control and Prevention estimates drug overdoes killed a record 72,000 Americans in 2017, up roughly 10 percent from the previous year. Most of those fatalities involved prescription opioids, including OxyContin or Vicodin. Since 2013, an estimated 170,000 people have died from overdosing on both prescription and illegal opioids. That's roughly three times the number of U.S. military personnel killed during the Vietnam war. As a result, demand for naloxone -- a synthetic drug akin to morphine that reverses the effects of an overdose by blocking opiate receptors in the nervous system -- has never been higher, researchers with the Food and Drug Administration's Center for Drug Evaluation and Research note in an upcoming report. Rising demand has helped drive the price of naloxone up more than 50 percent in recent years, the FDA researchers write in a study set to be published in the journal Addictive Behaviors. They estimate that the cost of one injectable form of naloxone has tripled since 2012, while another single-dose formulation rose 244 percent. "We don't have any mechanisms to stop manufacturers from raising prices," Leigh Purvis, director of health services research in AARP's Public Policy Institute, told CBS MoneyWatch. The cost of of naloxone -- which has been around in generic form for more than 30 years -- varies depending on whether it comes packaged as an injection device, auto-injector or nasal spray. Products also come in different dosages, which can affect pricing, while individual manufacturers may offer discounts and rebates to some buyers.

Companies have jacked up the price of lifesaving opioid overdose medicine, putting them out of reach of those who most need it

Wood 18 Stephen P. Wood [fellow in the Center for Bioethics at Harvard Medical School; practicing nurse practitioner in the department of emergency medicine at the Winchester Hospital in Winchester, MA. He has nine years of clinical experience in hospital-based emergency medicine as well as over 25 years of clinical experience in pre-hospital medicine], 6-4-2018, "As opioid overdose numbers rise, so does the cost of naloxone," Bill of Health, Petrie-Flom Center at Harvard Law School http://blogs.harvard.edu/billofhealth/2018/06/04/as-opioid-overdose-numbers-rise-so-does-the-cost-of-naloxone/ //DF

Currently there are seven patents that protect naloxone in its branded formulations, primarily marketed as Narcan and Ezvio. These patent protections extend to the year 2035. However, the protections are not for the drug, whose patent expired long ago, but for the "novel" delivery devices for naloxone, such as nasal actuators and auto-injectors. Naloxone has been historically inexpensive and pharmaceutical companies really didn't care much about it. Only six pharmaceutical companies even made the drug prior to 2014. It wasn't until the onset of the opioid epidemic, and public health initiatives that allowed public access to this drug, that prices began to soar. Naloxone's wholesale, generic cost is around $20.00 for a single dose. By comparison, the cost of a two-injector kit under the brand name Evzio is $4,000.00. This represents a stunning 680 percent increase from the drug's original price in 2014. Meanwhile, the numbers of deaths from opioid overdose continued to rise. Narcan brand nasal spray is slightly cheaper, coming in around $140.00 per dose. However, overdose reversal may require several doses,

adding to its cost. Speaking of novel, how novel is a nasal actuator anyways? Access to these drugs is mostly limited to those with health insurance, and even then, most require a co-pay. The data substantiates that consumers cannot afford and are not buying the drug. In the midst of the epidemic, sales increased from 2.8 million annually, to only 3.2 million from 2009 to 2015. Simply put, those most at risk can't afford this lifesaving drug. These price increases came when the opioid epidemic was at its peak, and they came without any explanation. There have been actions in several states to limit these increases, but little in the way of federal regulation to enforce them, despite recommendations by the CDC to expand access. Many states have tried to meet that challenge, through pharmacy standing orders, pharmacist prescriptive authority or community distribution. These are novel means to increase access, but until the cost is contained, they are not likely to make an impact in increasing access and use. Considering the success of community-based naloxone programs, access is an imperative.

Overdose deaths are increasing now and raising the mortality rate

Lamagna 18 Maria Lamagna [Reporter], 8-16-2018, "More evidence that the opioid epidemic is only getting worse ," MarketWatch, https://www.marketwatch.com/story/how-much-the-opioid-epidemic-costs-the-us-2017-10-27 //DF

The opioid epidemic just keeps getting worse. Approximately 71,568 predicted drug overdose deaths were reported for the 12-month period to January, a jump from 67,114 predicted deaths from drugs in January 2017, according to newly released data from the Centers for Disease Control and Prevention. There are even more suspected deaths, which are still being investigated. The predicted number of deaths from drug overdoses rose 33% in Nebraska and 24% in New Jersey over the same period. Nebraska had the largest increase, but it is also one of the states with the fewer numbers of drug overdoses: Only 152 reported deaths occurred for the 12-month period to January in that state, compared to 2,585 in North Carolina. Twelve states have seen a drop in overdose deaths year over year, most of which are in the Midwest and Rocky Mountain regions. Wyoming saw the greatest drop, at 33% for the 12-month period to January, and has one of the fewest numbers of predicted cases at 61 for the 12 months to January, down from 91 for the same period in 2017. White Americans seem to be at the greatest risk for death by opioid, according to a study published in the American Journal of Preventive Medicine last year. The rise in fatal drug overdoses is almost entirely responsible for the growth in mortality rates for white, non-Hispanic people between the ages of 22 and 56 in recent years, according to a new study published in the American Journal of Preventive Medicine. Mortality rates for that population rose by 21.2 deaths per 100,000 people between 1999 and 2015, the study found. If drug mortality rates had stayed at 1999 levels, mortality rates would have actually declined for men in that population considerably and risen only slightly for women. Recent analysis by the Centers for Disease Control and Prevention found that recent increases in drug overdose deaths "are driven by continued sharp increases in deaths involving synthetic opioids other than methadone, such as illicitly manufactured fentanyl."

IL + Impact – Non Adherence

8% of Americans don't take their meds because of costs (Cohen - CDC)

Robin Cohen, CDC, 2015, "Strategies Used by Adults to Reduce Their Prescription Drug Costs: United States 2013" https://www.cdc.gov/nchs/data/databriefs/db184.htm (NK)

To save money, almost 8% of U.S. adults (7.8%) did not take their medication as prescribed, 15.1% asked a doctor for a lower-cost medication, 1.6% bought prescription drugs from another country, and 4.2% used alternative therapies. Adults aged 18–64 (8.5%) were nearly twice as likely as adults aged 65 and over (4.4%) to have not taken their medication as prescribed to save money. Among adults aged 18–64, uninsured adults (14.0%) were more likely than those with Medicaid (10.4%) or private coverage (6.1%) to have not taken their medication as prescribed to save money. **The poorest adults—those with incomes below 139% of the federal poverty level—were the most likely to not take medication as prescribed to save money.**

Approximately one-fifth (18%) of the $263 billion spent on retail prescription drugs in the United States in 2012 was paid out of pocket (1). Some adults offset the cost of prescription drugs by reducing the dosage and frequency of the recommended pharmacotherapy (2-3). Other cost-saving strategies include asking providers for less-expensive medications or purchasing medications abroad (4). This report updates previously reported estimates for strategies used by U.S. adults aged 18 and over to reduce their prescription drug costs (5), using data from the 2013 National Health Interview Survey.

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

High drug prices are harmful. Medical costs and out-of-pocket expenses result in high rates of bankruptcies, and 10-25 percent of patients either delay, abandon or compromise treatments because of financial constraints. Survival is also compromised. For example, in chronic myeloid leukemia, the 8-10 year survival rate is 80 percent in Europe (where treatment is universally affordable); in the U.S., where finances may limit access to drugs, the 5-year survival is 60 percent. In surveys, 78 percent of Americans worry most about costs of drugs. Sadly, three years after the issue was raised, there has been little progress. The problem is compounded by 2 additional factors. First is the increasing shift in the cost of care and drugs to patients. Insurers justify this "skin-in-the-game" strategy as effective in reducing costs, but the high out-of-pocket expenses have turned this into "deterrence-in-the-game," discouraging patients from seeking care or purchasing drugs. In a recent survey, one-third of insured Texans delayed or did not pursue care because of high out-of-pocket expenses. Second is the spill-over of high drug prices to generics. Complex regulatory issues and shortages allow companies to increase prices of generics to levels as high as patented drugs. The latest scandals – Turing, Valiant and Mylan – are only the most extreme examples of a common strategy in pricing drugs. Generic Imatinib to treat chronic myeloid leukemia is priced at $5,000-8,000/year in Canada, $400/year in India, but $140,000/year in the U.S. For generic drugs to be priced low, four to five generics have to be available. The average cost of filing for FDA approval of a drug is $5 million in 2016, and the average time to approval is 4 years. There are currently more than 3,800 generic drug applications awaiting FDA action. The FDA should overhaul its procedures to reduce the cost of filing to less than $1 million per drug, reduce the timeline to approval to 6-12 months and monitor for the availability of multiple generics at all times.

Nonadherence to medications causes 125k deaths per year, with costs being a major contributor

Brody 17 Jane E. Brody, 4-17-2017, "The Cost of Not Taking Your Medicine," New York Times, https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html //DF

There is an out-of-control epidemic in the United States that costs more and affects more people than any disease Americans currently worry about. It's called **nonadherence to prescribed medications**, and it is — potentially, at least — 100 percent preventable by the very individuals it afflicts. The numbers are staggering. "Studies have consistently shown that 20 percent to 30 percent of medication prescriptions are never filled, and that approximately 50 percent of medications for chronic disease are not taken as prescribed," according to a review in Annals of Internal Medicine. People who do take prescription medications — whether it's for a simple infection or a life-threatening condition — typically take only about half the prescribed doses. **This lack of adherence**, the Annals authors wrote, **is estimated to cause approximately 125,000 deaths** and at least 10 percent of hospitalizations, and to cost the American health care system between $100 billion and $289 billion a year. Former Surgeon General C. Everett Koop put it bluntly: "Drugs don't work in patients who don't take them." This partly explains why new drugs that perform spectacularly well in studies, when patients are monitored to be sure they follow doctors' orders, fail to measure up once the drug hits the commercial market. More important, it explains why so many patients don't get better, suffer surprising relapses or even die when they are given drug prescriptions that should keep their disorders under control. Studies have shown that a third of kidney transplant patients don't take their anti-rejection medications, 41 percent of heart attack patients don't take their blood pressure medications, and half of children with asthma either don't use their inhalers at all or use them inconsistently. "When people don't take the medications

prescribed for them, emergency department visits and hospitalizations increase and more people die," said Bruce Bender, co-director of the Center for Health Promotion at National Jewish Health in Denver. "Nonadherence is a huge problem, and there's no one solution because there are many different reasons why it happens." For example, he said parents often stop their children's asthma treatment "because they just don't like the idea of keeping kids on medication indefinitely." Although a child with asthma may have no apparent symptoms, there is underlying inflammation in the lungs and without treatment, "if the child gets a cold, it can result in six weeks of illness," Dr. Bender explained. When Dr. Lisa Rosenbaum, a cardiologist at Brigham and Women's Hospital in Boston, asked patients who had suffered a heart attack why they were not taking their medications, she got responses like "I'm old-fashioned — I don't take medicine for nothing" from a man with failing kidneys, peripheral vascular disease, diabetes and a large clot in the pumping chamber of his heart. Another common response: "I'm not a pill person." When Dr. Rosenbaum told her hairdresser that she was studying why some people with heart disease don't take their medications, he replied, "Medications remind people that they're sick. Who wants to be sick?" He said his grandmother refuses to take drugs prescribed for her heart condition, but "she'll take vitamins because she knows that's what keeps her healthy," so he tells her that the pills he gives her each night are vitamins. Other patients resist medications because they view them as "chemicals" or "unnatural." One man told Dr. Rosenbaum that before his heart attack, he'd switched from the statin his doctor prescribed to fish oil, which unlike statins has not been proved to lower cholesterol and stabilize arterial plaque. "There's a societal push to do things naturally," she said in an interview. "The emphasis on diet and exercise convinces some people that they don't have to take medications." Dr. Bender said, "People often do a test, stopping their medications for a few weeks, and if they don't feel any different, they stay off them. This is especially common for medications that treat 'silent' conditions like heart disease and high blood pressure. Although the consequences of ignoring medication may not show up right away, it can result in serious long-term harm." Some patients do a cost-benefit analysis, he said. "Statins are cheap and there's big data showing a huge payoff, but if people don't see their arteries as a serious problem, they don't think it's worth taking a drug and they won't stay on it. Or if they hear others talking about side effects, it drives down the decision to take it." Cost is another major deterrent. "When the co-pay for a drug hits $50 or more, adherence really drops," Dr. Bender said. Or when a drug is very expensive, like the biologics used to treat rheumatoid arthritis that cost $4,000 a month, patients are less likely to take them or they take less than the prescribed dosage, which renders them less effective. Dr. William Shrank, chief medical officer at the University of Pittsburgh Health Plan, said that when Aetna offered free medications to patients who survived a heart attack, adherence improved by 6 percent and there were 11 percent fewer heart attacks and strokes, compared with patients who paid for their medications and had an adherence rate of slightly better than 50 percent.

Other countries treat drugs like basic necessities (Kliff - Vox)

Sarah Kliffsarah, Vox, 5-10-2018, "The true story of America's sky-high prescription drug prices," [vox staff writer, one of the country's leading health policy journalists, who has spent seven years chronicling Washington's battle over the Affordable Care Act. Recently, her reporting has taken her to the White House for a wide-ranging interview with President Obama on the health law — and to rural Kentucky, for a widely-read story about why Obamacare enrollees voted for Donald Trump.]
https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained (NK)

But if you do succeed — and Australia deems your drug worthy to cover — then you'll have to decide whether the committee has offered a high enough price. If so, congrats! You've entered the Australian drug market. **Other countries regulate the price of drugs because they see them as a public utility Countries like Australia, Canada, and Britain don't regulate the price of other things that consumers buy, like computers or clothing. But they and dozens of other countries have made the decision to regulate the price of drugs to ensure that medical treatment remains affordable for all citizens, regardless of their income**. Medication is treated differently because it is a good that some consumers, quite literally, can't live without. This decision comes with policy trade-offs, no doubt. Countries like Australia will often refuse to cover drugs that they don't think are worth the price. In order for regulatory agencies to have leverage in negotiating with drugmakers, they have to be able to say no to the drugs they don't think are up to snuff. This means certain drugs that sell in the United States aren't available in other countries — and there are often public outcries when these agencies refuse to approve a given drug.

Brody 17 Jane E. Brody, 4-17-2017, "The Cost of Not Taking Your Medicine," New York Times, https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html //DF

There is an out-of-control epidemic in the United States that costs more and affects more people than any disease Americans currently worry about. It's called nonadherence to prescribed medications, and it is — potentially, at least — 100 percent preventable by the very individuals it afflicts. The numbers are staggering. "Studies have consistently shown that 20 percent to 30 percent of medication prescriptions are never filled, and that approximately 50 percent of medications for chronic disease are not taken as prescribed," according to a review in Annals of Internal Medicine. People who do take prescription

medications — whether it's for a simple infection or a life-threatening condition — typically take only about half the prescribed doses. **This lack of adherence**, the Annals authors wrote, **is estimated to cause approximately 125,000 deaths** and at least 10 percent of hospitalizations, and to cost the American health care system between $100 billion and $289 billion a year. Former Surgeon General C. Everett Koop put it bluntly: "Drugs don't work in patients who don't take them." This partly explains why new drugs that perform spectacularly well in studies, when patients are monitored to be sure they follow doctors' orders, fail to measure up once the drug hits the commercial market. More important, it explains why so many patients don't get better, suffer surprising relapses or even die when they are given drug prescriptions that should keep their disorders under control. Studies have shown that a third of kidney transplant patients don't take their anti-rejection medications, 41 percent of heart attack patients don't take their blood pressure medications, and half of children with asthma either don't use their inhalers at all or use them inconsistently. "When people don't take the medications prescribed for them, emergency department visits and hospitalizations increase and more people die," said Bruce Bender, co-director of the Center for Health Promotion at National Jewish Health in Denver. "Nonadherence is a huge problem, and there's no one solution because there are many different reasons why it happens." For example, he said parents often stop their children's asthma treatment "because they just don't like the idea of keeping kids on medication indefinitely." Although a child with asthma may have no apparent symptoms, there is underlying inflammation in the lungs and without treatment, "if the child gets a cold, it can result in six weeks of illness," Dr. Bender explained. When Dr. Lisa Rosenbaum, a cardiologist at Brigham and Women's Hospital in Boston, asked patients who had suffered a heart attack why they were not taking their medications, she got responses like "I'm old-fashioned — I don't take medicine for nothing" from a man with failing kidneys, peripheral vascular disease, diabetes and a large clot in the pumping chamber of his heart. Another common response: "I'm not a pill person." When Dr. Rosenbaum told her hairdresser that she was studying why some people with heart disease don't take their medications, he replied, "Medications remind people that they're sick. Who wants to be sick?" He said his grandmother refuses to take drugs prescribed for her heart condition, but "she'll take vitamins because she knows that's what keeps her healthy," so he tells her that the pills he gives her each night are vitamins. Other patients resist medications because they view them as "chemicals" or "unnatural." One man told Dr. Rosenbaum that before his heart attack, he'd switched from the statin his doctor prescribed to fish oil, which unlike statins has not been proved to lower cholesterol and stabilize arterial plaque. "There's a societal push to do things naturally," she said in an interview. "The emphasis on diet and exercise convinces some people that they don't have to take medications." Dr. Bender said, "People often do a test, stopping their medications for a few weeks, and if they don't feel any different, they stay off them. This is especially common for medications that treat 'silent' conditions like heart disease and high blood pressure. Although the consequences of ignoring medication may not show up right away, it can result in serious long-term harm." Some patients do a cost-benefit analysis, he said. "Statins are cheap and there's big data showing a huge payoff, but if people don't see their arteries as a serious problem, they don't think it's worth taking a drug and they won't stay on it. Or if they hear others talking about side effects, it drives down the decision to take it." Cost is another major deterrent. "When the co-pay for a drug hits $50 or more, adherence really drops," Dr. Bender said. Or when a drug is very expensive, like the biologics used to treat rheumatoid arthritis that cost $4,000 a month, patients are less likely to take them or they take less than the prescribed dosage, which renders them less effective. Dr. William Shrank, chief medical officer at the University of Pittsburgh Health Plan, said that when Aetna offered free medications to patients who survived a heart attack, adherence improved by 6 percent and there were 11 percent fewer heart attacks and strokes, compared with patients who paid for their medications and had an adherence rate of slightly better than 50 percent.

Self-Driving Cars

Impact

Aarian Marshall, 11-7-2017, "Wanna Save Lots of Lives? Put (Imperfect) Self-Driving Cars on the Road, ASAP," WIRED, https://www.wired.com/story/self-driving-cars-rand-report/ //DF

Self-driving cars are obviously not perfect yet. In fact, we have a pretty clear sense of how not perfect they are. The 43 companies testing self-driving cars in California must submit public "disengagement reports," noting every time a human driver intervenes while behind the wheel of a self-driving car. Last year's reports show these cars are getting better, but aren't all the way there: Waymo's cars averaged 5,128 miles between disengagements—pretty good!—while Mercedes-Benz did 1.8—not so great. Today, autonomous vehicles are about as good as a standard crappy driver. "You're probably safer in a self-driving car than with a 16-year-old, or a 90-year-old," researcher Brandon Schoettle told WIREDin August. "But you're probably significantly safer with an alert, experienced, middle-aged driver than in a self-driving car." The researchers studied three basic scenarios. In one, autonomous vehicles get on the road when they're just a bit

better than the average human driver, about 10 percent safer. In another, AVs hit the streets later, when they're 75 percent safer. In the third, AVs arrive when they're nearly perfect, 90 percent better than human drivers. They found that, generally, the 10 percent safer scenario will save more human lives, faster—as many as 3,000 a year. Add in driverless cars' ability to improve as a fleet—when one makes a particular screw-up, all its brethren can learn to avoid it—and you get a robust argument for putting these vehicles on the road sooner rather than later. The researchers even built an online tool, so you can play with the scenarios yourself. But we don't live in a purely utilitarian world, and human beings are really not into certain risks. "Society tolerates a significant amount of human error on our roads," Gil Pratt, who heads up Toyota's research institute, said earlier this year. "We are, after all, only human. On the other hand, we expect machines to perform much better."