Ready to Read

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. 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.

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.

Second, the nonadherence epidemic.

High drug prices hurts the poorest Americans the most, many of whom simply cannot afford to pay for them. Brenza reports in 2017: to save money, 1 in 7 People Don't Fill Their Prescriptions Because They Cost Too Much. The poorest adults were the most likely to not take medication as prescribed to save money.

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.

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

Case Cards

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.

Frontlines

R/T Generics Solve

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.

Engle p.76

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

2. 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

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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.

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.

Overdoses

R/T PC Increases Addiction

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.