

**Resolved: The United States federal
government should impose price controls
on the Pharmaceutical industry**

Affirmation Blocks

POOR PEOPLE

The pharmaceutical industry is literally killing off poor people

Hartmann et. al 15 Thomas Carl "Thom" Hartmann is an American radio host, author, former psychotherapist, businessman, and progressive political commentator. Daily Take Team, 6-3-2015, "Big Pharma Is Killing Us," Truthout, <http://www.truth-out.org/opinion/item/31160-big-pharma-is-killing-us> //GF DDI 17

Drug company profits are literally killing people - and now even doctors are speaking out. Dr. Leonard Saltz, chief of gastrointestinal oncology at Memorial Sloan Kettering Cancer Center, rebuked the pharmaceutical industry for the sharp rise in cancer drug prices over the last decade. The **median monthly price for new cancer drugs nearly doubled between 2000 and 2014** - from a monthly cost of \$4,716 between 2000 and 2004 to a monthly cost of about \$9,900 between 2010 and 2014. Dr. Saltz explained part of the problem: "Cancer-drug **prices are not related to the value of the drug.** Prices are based on what has come before and what the seller believes the market will bear." See more news and opinion from Thom Hartmann at Truthout here. And that's a neat feature of our current patent system: **Drug companies don't have to worry about what people can afford to pay for a product. Because monopolies set their own prices.** And that's what a patent is: a state-backed monopoly on a product. Thomas Jefferson knew that monopolies would be a threat to the people and the people's government. Jefferson wrote to James Madison on December 20, 1787, expressing concern that the draft of the Constitution did not include a Bill of Rights "providing clearly [...] for freedom of religion, freedom of press, protection against standing armies, restriction of monopolies, the eternal and unremitting force of habeas corpus laws, and trials by jury..." Jefferson wanted safeguards from monopolies included in our Bill of Rights, but a patent gives a company the state-sponsored monopoly on a product for the term of the patent. And patents aren't inherently bad. It would be hugely discouraging to inventors and writers if any old troll can steal a novel idea and peddle it without crediting the inventor. That's why Article 1, Section 8 of the Constitution gives Congress the power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." And that's what the writers of our Constitution wanted **our patents** to do: **encourage innovations for the public good by allowing innovators exclusive rights to their inventions or writings for a limited time. But** as corporate power has taken hold of every aspect of our government, copyright and patent law in the US has changed dramatically. The 1790 Patent Act allowed patents to last for seven years with a one-time renewal offered in certain cases. Now patents last for 20 years after filing, and drug companies even enjoy special extensions to make up for delays in FDA approval. And that means **that drug companies don't have to worry about competitive pricing or creating demand because the consumer can only choose between treatment or misery and death.** So when a company develops a drug that treats a life-threatening illness, they can simply set their price: \$1,000 per pill for Hepatitis C treatment; **\$10,000 for a month of cancer treatment; \$300,000 for the year of treatment. Can't pay? Don't want to pay? Maybe you'd prefer to die. It's all the same to the companies.** Because the **companies that make our medicine don't do it for public health - they do it for profit.** Corporations like Walt Disney and Bristol Myer Squibb have lobbied to shape patent and copyright law to fill their corporate coffers instead of "promoting the progress of science and the useful arts."
As drug costs continue to climb, we're creating a two-tiered society: those who can afford to pay to stay alive, and those who can't. Public health is an issue of the commons, and it's time that we reform patent law to discourage monopolistic price-gouging on drugs that treat life-threatening illnesses.

Price Controls Good

Drug Price Controls Are Vital in a Market That's Not Free

Jared **Bernstein** (Senior fellow at the Center on Budget and Policy Priorities, former Chief economics for Joe Biden and executive director of the White House Task Force on the Middle Class), New York Times, "Drug Price Controls Are Vital in a Market That's Not Free - NYTimes.com", June 29, **2016**, <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-are-vital-in-a-market-thats-not-free>

If Charles Dickens were writing today and seeking a life model for one of his villains, he'd be pleased to find Martin Shkreli, the former hedge fund manager who, upon acquiring the rights to a critical drug for patients with life-threatening infections, raised its price to \$750 from \$13.50 per tablet. But the problem we face is less this particular individual than the fact that we're imposing a market structure on something that should be a public good. We wouldn't squirm watching this guy try to explain himself if he were selling yachts or high-end real estate. The challenge is finding the public policies that will take pharmaceuticals from what any objective person would view as a highly distorted market — prices don't rise 5,500 percent overnight in a functioning market — to a more rational one. Hillary Clinton just released a new proposal with various ideas that point in that direction: allowing Medicare to bargain for lower drug prices, a monthly cap of \$250 for patients with chronic conditions, research and development investment requirements for highly profitable drug companies, prohibition of delaying tactics that keep generics out of the market, and more. All good ideas that incrementally push in the right direction. But to go further will require two more aggressive steps: price controls and new incentives for drug research. Price controls for drugs, which are common in other advanced economies, increase affordability. But even when the mechanism is "cost-plus" pricing — the government allows drug companies some degree of markup — their profits will still decline from current levels. The producers argue that this will stifle their incentive to innovate. But the evidence is increasingly clear that we cannot count on the private sector to make necessary medicines affordable. In fact, given the incentive structure, neither can we count on private drug companies to develop the drugs we most need versus the ones that will be most profitable. In health economics, maximizing social benefits is often at odds with private benefits. The simplest solution is to take excessive profit out of the equation and ramp up what is already a robust public medical research infrastructure. This could take the form of an expanded National Institutes of Health, where researchers are employed by the government, or private research could be subsidized. Either way, the key outcome is that the patents themselves would be public goods in the public domain, meaning no more price gouging. But wouldn't this arrangement fail to inspire the most innovative researchers? To keep such competition alive, economist Joe Stiglitz recommends a prize fund, where those who developed the most beneficial medicines would get a windfall reward. The winners could get rich, but they could not restrict the benefits of their findings to extract more profits from sick people. It may take incremental steps like those offered by Hillary Clinton to start the ball rolling. If such steps prove insufficient — and if Dickensian stories still haunt the news — we'll need bolder steps. But the status quo cannot hold.

Price controls work to lower prices

Sara **Kliff**, May 10, **2018**, Vox, <https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained> The true story of America's sky-high prescription drug prices

What would happen if the United States started price-regulating drugs? For one thing, we'd spend less on prescription drugs. If the United States set up an agency that negotiated drug prices on behalf of the country's 319 million residents, it would likely be able to demand discounts similar to those of European countries. This would mean that health insurance premiums wouldn't go up nearly as quickly — they might even go down. There would be trade-offs. We'd likely have to give up some of the choice of drugs that our insurance plans cover. If a national board made decisions about what prices were appropriate for drugs, it would need to have the ability to reject the drugs that didn't make the cut. Consider the Veterans

Health Administration, which does negotiate drug prices. It gets drugs that are usually 40 percent cheaper than what Medicare pays. But it also covers fewer products. Margot Sanger-Katz recently reported for the New York Times that “many older patients who get their health insurance from the V.A. also sign up for Medicare drug plans to cover medicines that the V.A. won’t.” At the same time, **VA doctors do say their patients are generally able to obtain the medications they prescribe.**

Correct Market Failures

Pharmaceutical companies have enough market share generally that they have little incentive to make their products affordable.

Bennett, Sara, Jonathan D. Quick, and German Velasquez. "Public-private roles in the pharmaceutical sector: Implications for equitable access and rational drug use." **1997**.
<http://apps.who.int/medicinedocs/en/d/Jwhozip27e/6.3.html>

“When there are many buyers or sellers of a commodity the actions of any single actor do not affect anyone else. However, if there are few buyers or sellers then these few may be able to exercise market power. In the case of sellers this is called monopoly power, in the case of buyers it is known as monopsony power. Market power enables sellers to charge higher prices than they would in a situation of perfect competition. The extent of market failure Unlike the overall health care sector, the pharmaceutical sector suffers substantial problems related to the failure of competition. High initial investment costs mean that average production costs reduce only when a large quantity of a drug is produced. However, with international trade, it is rarely the case that a true monopoly of this sort exists. Instead market power is created through: - patent protection, which exists in order to encourage research and development; - brand loyalty created through marketing which generates market power even after patents expire; - market segmentation, especially by therapeutic subclass; - gaining control over key inputs, thus preventing other firms from competing effectively; - implicit collusion between firms through, for example, price-fixing. An alternative perspective suggests that, due to the special characteristics of drugs, competition takes undesirable forms. In particular, because of the life-saving nature of many drugs and the fact that patients do not pay for them directly in many countries, there is unlikely to be substantial price competition but rather competition in product quality, innovation and brand awareness.”

Pharmaceutical companies exist in a highly non-functional market that allows price gouging and unfair prices.

Jared Bernstein, NY Times, “Drug Price Controls Are Vital in a Market That’s Not Free”, June 29 2016,
<https://www.nytimes.com/roomfordebate/2015/09/23/shouldthe-government-impose-drug-price-controls/drug-price-controls-are-vital-in-a-market-thats-not-free>

“The challenge is finding the public policies that will take pharmaceuticals from what any objective person would view as a highly distorted market — prices don’t rise 5,500 percent overnight in a functioning market — to a more rational one. Hillary Clinton just released a new proposal with various ideas that point in that direction: allowing Medicare to bargain for lower drug prices, a monthly cap of \$250 for patients with chronic conditions, research and development investment requirements for highly profitable drug companies, prohibition of delaying tactics that keep generics out of the market, and more. All good ideas that incrementally push in the right direction. **But to go further will require two more aggressive steps: price controls and new incentives for drug research. Price controls for drugs, which are common in other advanced economies, increase affordability.** But even when the mechanism is “cost-plus” pricing — the government allows drug companies some degree of markup — their profits will still decline from current levels.”

Whenever one company chooses to gouge prices, other companies can follow suit due to the imbalanced nature of the market.

University of Pennsylvania Wharton. “Preventing Price Gouging in the Pharmaceutical Industry: A Comprehensive Policy Approach”. March 16 2018.
<https://publicpolicy.wharton.upenn.edu/live/news/2390-preventing-pricegouging-in-the-pharmaceutical/for-students/blog/news.php>

“A price hike occurs when a large biopharmaceutical company can increase prices either over a span of time, or in some cases, overnight, due to a single entity controlling much the market share. Soon after, other companies with similar drugs follow suit, creating a kind of “Shkreli effect,” named after the infamous CEO of Turing Pharmaceuticals, who was responsible for the Daraprim price increase. **Price gouging occurs because of pharmaceutical company abuse of patent laws and the current model for drug discovery and development previously mentioned.** Although patent protections were created to incentivize innovation, patents actually create “quasi-monopolies” in the pharmaceutical sector by allowing companies loopholes to delay selling to competitors that produce generic drugs. The prevalence of price hikes exemplifies the need to reform the biopharmaceutical market, without disincentivizing innovation or risk-taking in research.”

Consumers suffer and are exploited by producers due to this market failure, resulting in poor outcomes.

Berman, Aaron, et al. "Curbing unfair drug prices: A primer for states." (2017).

https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf

“The high cost of prescription drugs in the United States is unsustainable. Spending on prescription drugs is increasing at a faster rate than any other component of health care spending, and a growing number of Americans report difficulty affording their medications. High drug prices are forcing some patients to skip doses of critical medicines, and others to choose between their health and necessities like food and rent. Meanwhile, the pharmaceutical industry continues to launch new drugs at exorbitant prices, increase prices of many old drugs without justification, and reap record profits. Evidence has unequivocally shown that high drug prices are not linked to the actual costs of research, development and manufacturing. Instead, inflated drug prices are a result of drug manufacturers’ power to charge whatever price the market will bear. The need for legislative action is urgent.”

Market Manipulation

Market manipulation in the forms of pharmaceutical product hopping and evergreening prevent prices from dropping in a competitive market.

Scott **Morton** (BA from Yale & PhD from MIT, Professor of Economics at the Yale University School of Management) & Lysle Boller (Statistician at Yale's School of Management, M.Sc. in Economics from the London School of Economics, B.A. in Mathematics & Economics from the University of Virginia) write in **2017**

Despite the well-established regulatory framework governing the generic market, **pharmaceutical manufacturers** continue to **exploit aspects of the market to limit** effective generic **competition**. One issue of current concern to many observers is known as “**product hopping**” or “evergreening.” This **occurs when a branded manufacturer obtains** a new NDA or BLA **approval for a variant of its product** (for example, capsules instead of the existing tablets, an extended release version, or a new delivery device). **The branded manufacturer releases the new product and markets it heavily**, convincing physicians to switch their patients to the reformulated product. **After a period of time, the patent expires and an inexpensive generic** or biosimilar **version** of the first-generation drug or biologic **arrives on the market. By that time, a large fraction of consumers have been moved to the second generation product** which is not A-rated or interchangeable with the previous first generation. Thus, when prescriptions for the second generation product are submitted to the pharmacist, **that patient cannot be switched to the lower priced generic or biosimilar automatically without a new prescription from the physician**.⁷⁹ Estimates suggest that automatic substitution at the pharmacy is a critical element of the generic drug savings that has saved consumers hundreds of billions of dollars per year.⁸⁰ **This product hopping strategy slows the market penetration of generic or biosimilar versions of the older product. The result of the situation is that consumers pay higher prices.**

Price Controls Would Reduce Government Spending

Rising pharmaceutical expenditures put substantial pressures on public healthcare funds, causing a host of problems.

Bennett, Sara, Jonathan D. Quick, and German Velasquez. "Public-private roles in the pharmaceutical sector: Implications for equitable access and rational drug use." **1997**.
<http://apps.who.int/medicinedocs/en/d/Jwhozip27e/6.3.html>

"Americans spend a lot on prescription drugs, more per capita than any other country by far.

Pharmaceuticals represent a significant—and growing—share of the country's health spending, both because new, and often costly, drugs are emerging from the lab and because prices of many drugs are rising much faster than prices of other goods and services.

The Center for Medicare and Medicaid Services (CMS) estimates prescription drug spending will grow an average of 6.3% per year over the 2016-2025 period. Highly publicized cases of very expensive new drugs as well as sharp increases in the price of some older drugs has drawn widespread attention—and criticism—from the public, members of Congress and President Donald Trump. **Because the U.S. government pays more than 40% of the retail prescription drug tab, rising spending on drugs is putting pressure on the federal budget. It also contributes to rising health insurance premiums."**

Current government programs and insurance companies are unable to negotiate prices

Chris Lo, Pharmaceutical Technology, "Cost control: drug pricing policies around the world", 12 Feb **2018**, <https://www.pharmaceuticaltechnology.com/features/cost-control-drug-pricing-policies-around-world/>

"The US system of pharma reimbursement is multi-faceted and somewhat opaque, and often results in different prices for different buyers. **The US doesn't directly regulate drug prices, meaning that drug companies can set whatever sticker price they deem fit**, as Gilead did in 2013 when it set a price of \$84,000 for a 12-week course of its breakthrough hepatitis treatment Sovaldi, kicking off a sustained backlash on drug pricing that rages on today. Medicaid, the federal programme to cover the medical costs of low-income individuals, receives a mandated discount, but **Medicare** – which provides insurance for Americans over 65 and **is the pharma industry's biggest single customer, spending \$137bn on prescription drugs in 2015 – is not allowed to negotiate at the federal level**. Insurance companies that have been contracted to administer Medicare are able to negotiate, but with limitations such as having to cover all treatments across six broad drug categories. The private insurance system, which covers many Americans who are not on Medicare or Medicaid, is fragmented into hundreds of different employers and insurance providers, limiting their ability to negotiate steep discounts."

Health costs are compounded because patients who are unable to access the prescription drugs they need end up having other health complications, increasing medical spending.

Congressional Budget Office. "Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services". November **2012**.

<http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf>

"Prescription drugs affect people's health and their need for medical services.¹ Therefore, policy changes that influence Medicare beneficiaries' use of prescription drugs, such as those altering the cost-sharing structure of the Part D prescription drug benefit, **probably affect federal spending on their medical services.**² After reviewing recent research, the Congressional Budget Office (CBO) estimates that **a 1 percent increase in the number of**

prescriptions filled by beneficiaries would cause Medicare's spending on medical services to fall by roughly one-fifth of 1 percent. That estimate, which applies only to policies that directly affect the quantity of prescriptions filled, represents a change in the agency's estimating methodology, which until now has not incorporated such an effect. Previously, when estimating the budgetary effects of legislation regarding prescription drugs, CBO found insufficient evidence of an "offsetting" effect of prescription drug use on spending for medical services. But recently, more analysis has been published that demonstrates a link between changes in prescription drug use and changes in the use of and spending for medical services. This report provides background information about that relationship; reviews the literature on the size of the offset for the Medicare population; and describes how CBO synthesized the recent research.."

Reducing the price of pharmaceuticals would transfer money away from pharmaceutical companies and back toward consumers.

Alfred **Engelberg**, Health Affairs, "How Government Policy Promotes High Drug Prices", Oct 29 **2015**, <https://www.healthaffairs.org/doi/10.1377/hblog20151029.051488/full/>

"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.**"

Price Controls Protect the Uninsured

The uninsured population in America is large and continues to grow following actions by the Trump administration.

Tami **Luhby**. "Millions more Americans were uninsured in 2017." CNN Business. Jan 26 **2018**.

<https://money.cnn.com/2018/01/16/news/economy/uninsuredamericans/index.html>

"The uninsured rate rose 1.3 percentage points to 12.2% last year, according to the Gallup-Sharecare Well-Being Index. That represents an increase of roughly 3.2 million Americans.

Under Obamacare, the uninsured rate plummeted to a low of 10.9% at the end of 2016. Obamacare's exchanges opened in 2014, the same year Medicaid expansion began and the individual mandate -- which required nearly all Americans to have insurance or pay a penalty -- took effect. Those provisions helped reverse a soaring uninsured rate, which hit a peak of 18% in the fall of 2013, fueled in part by the aftermath of the Great Recession.

Several factors likely contributed to the increase last year. President Trump and congressional Republicans tried repeatedly, but unsuccessfully, to repeal the landmark health reform law. That may have led some Americans to question whether the administration would enforce the penalty for not having insurance, according to Gallup-Sharecare. Also, many insurers withdrew from the exchanges and the remaining carriers raised their rates, which may have prompted some consumers to forgo coverage. Some 500,000 fewer Americans signed up for 2017 coverage on the exchanges at the end of open enrollment a year ago. **The uninsured rate rose for all demographics last year, except for senior citizens, who all qualify for Medicare.** Young adults age 18 to 25 and Americans earning less than \$36,000 each saw a 2 percentage point increase. The rate for blacks soared 2.3 percentage points, while Hispanics saw a 2.2 percentage point jump. The annual increase is the largest single-year jump since Gallup and Sharecare began tracking the uninsured rate in 2008. **The trend will likely continue this year. The Trump administration pulled back on support and advertising for the 2018 open enrollment season, which ended last month with 500,000 fewer people signing up on the federal exchange."**

The uninsured are nearly twice as likely to underuse their prescription drugs due to cost concerns. Even among the insured, they often lack pharmaceutical drug benefits.

National Council on Patient Information and Education. "Understanding Prescription Assistance Programs (PAPS)". <http://www.bemedwise.org/documents/paps.pdf>

"Among those with health insurance, one out of 10 individuals 65 years old or younger and one in three persons over age 65 of age do not have prescription drug coverage. Not surprisingly, people with low incomes, older adults and those suffering with chronic conditions that require multiple medications face the greatest economic burden. These patients also tend to take less of their medication than has been prescribed due to cost concerns. In fact, **uninsured adults and their families are twice as likely as insured adults to underuse their medications in order to lower drug costs."**

This creates a cycle: the uninsured's inability to afford expensive pharmaceuticals cause prices of drugs for everyone to increase due to free-rider effects.

Dana **Sarnak**, "Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?" Oct 5 **2017**, The Commonwealth Fund,

<https://www.commonwealthfund.org/publications/issuebriefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier>

"Various factors contribute to high per capita drug spending in the U.S. While drug utilization appears to be similar in the U.S. and the nine other countries considered, **the prices at which drugs are sold in the U.S. are substantially**

higher. These price differences appear to at least partly explain current and historical disparities in spending on pharmaceutical drugs. U.S. consumers face particularly high out-of-pocket costs, both because the U.S. has a large uninsured population and because cost-sharing requirements for those with coverage are more burdensome than in other countries. Most Americans support reducing pharmaceutical costs. International experience demonstrates that policies like universal health coverage, insurance benefit design that restricts out-of-pocket spending, and certain price control strategies, like centralized price negotiations, can be effective."

The uninsured and poor engage in cost-cutting measures by opting for inferior or no pharmaceutical drugs, resulting in worse health outcomes.

Jeffrey Young, Health Affairs, "How Government Policy Promotes High Drug Prices", Oct 29 2015, <https://www.healthaffairs.org/doi/10.1377/hblog20151029.051488/full/>

"Uninsured people and those with low incomes are the most likely to go without prescription drugs they need because of cost — and it could be harming their health, according to survey results published by the Centers for Disease Control and Prevention Tuesday. The CDC found that one-fifth of American adults overall asked their doctors to prescribe a medicine cheaper than their first choice. Thirteen percent of adults 18-64 didn't take a prescribed drug because of cost compared to 6 percent of those over 65. Rising health care prices are a big reason why more Americans aren't getting treatments they need. But the 45 million or more without health insurance are most vulnerable to the high cost of prescription drugs in the United States. Nearly a quarter of people without health insurance said they didn't take a medicine their physicians prescribed, according to the survey. A slightly larger percentage asked for a lower-priced substitute. The poor and near-poor were much more apt than people with higher incomes to simply go without the prescription drug they needed because of the cost. This isn't merely an academic exercise, the CDC emphasizes in its report: Some cost-reduction strategies used by adults have been associated with negative health outcomes. For example, adults who do not take prescription medication as prescribed have been shown to have poorer health status and increased emergency room use, hospitalizations, and cardiovascular events."

Price Controls Help Stop Patent Monopolies

The current patent structure on pharmaceuticals is the most important factor keeping the prices of pharmaceuticals high.

Sydney **Lupkin**. "Government-Protected 'Monopolies' Drive Drug Prices Higher, Study Says" Kaiser Health News. August 23 **2016**. <https://khn.org/news/governmentprotected-monopolies-drive-drug-prices-higher-study-says/>

"The "most important factor" that drives prescription drug prices higher in the United States than anywhere else in the world is the existence of government-protected "monopoly" rights for drug manufacturers, researchers at Harvard Medical School report today. The researchers reviewed thousands of studies published from January 2005 through July 2016 in an attempt to simplify and explain what has caused America's drug price crisis and how to solve it. They found that the problem has deep and complicated roots and published their findings in JAMA, the journal of the American Medical Association. The study was funded by the Laura and John Arnold Foundation with additional support provided by the Engelberg Foundation."

The primary ways to oppose the patent monopolies in the status quo are through generic drugs and the power of the buyer, both of which have clear limitations.

Aaron **Kesselheim**. "The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform" JAMA Network. August 23/30 **2016**. <https://jamanetwork.com/journals/jama/article-abstract/2545691>

"Per capita prescription drug spending in the United States exceeds that in all other countries, largely driven by brand-name drug prices that have been increasing in recent years at rates far beyond the consumer price index. In 2013, per capita spending on prescription drugs was \$858 compared with an average of \$400 for 19 other industrialized nations. In the United States, prescription medications now comprise an estimated 17% of overall personal health care services. **The most important factor that allows manufacturers to set high drug prices is market exclusivity, protected by monopoly rights awarded upon Food and Drug Administration approval and by patents. The availability of generic drugs after this exclusivity period is the main means of reducing prices in the United States, but access to them may be delayed by numerous business and legal strategies.** The primary counterweight against excessive pricing during market exclusivity is the negotiating power of the payer, which is currently constrained by several factors, including the requirement that most government drug payment plans cover nearly all products. Another key contributor to drug spending is physician prescribing choices when comparable alternatives are available at different costs

Price controls would prevent powerful patent monopolies from exploiting their control over the market in a number of nefarious ways.

Henry **Mintzberg**, "Patent nonsense: Evidence tells of an industry out of social control" Aug 15 **2006**, US National Library of Medicine, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1534100/>

"Beyond these problems of promotion lie a litany of stories revealed in the press in recent years **about immoral and sometimes corrupt behaviours of pharmaceutical companies, including ostensibly the most reputable: about payoffs to generic producers not to rush in with cheaper drugs; about tactics used to delay the expiry of patents;** about lawsuits and convictions, criminal and otherwise, concerning marketing fraud and the overbilling of government agencies; about blatant misinformation; about the cooptation and sometimes downright bribery of physicians, researchers and politicians. Examples of these behaviours, from articles in the prominent press and some major medical journals, are provided in Appendix 1. Together, they tell a story of an industry that is out of social control. **The problem of high pharmaceutical prices is not without solutions. Many are obvious enough, and some have been implied in this article, including firmer regulation of pricing,** the use of independent clearinghouses for balanced information on products, research efforts more widely spread

across different types of institutions, and a stop to direct-to-consumer advertising. However, there is a lack of sufficient will to confront the problem directly, in part because of the power of the industry and its influence on political processes. The current situation in the patent-dependent pharmaceutical industry is not just unacceptable, it is shameful. It will remain so until concerned citizens gather the energy to change it."

This patent monopoly is unacceptable because it directly puts human lives at risk by allowing companies to charge unfairly high prices.

Robert **Pearl**, Forbes, "Why Patent Protection In The Drug Industry Is Out Of Control", Jan 19 **2017**, <https://www.forbes.com/sites/robertpearl/2017/01/19/whypatent-protection-in-the-drug-industry-is-out-of-control/#25a7a30478ca>

"Patent protection was never intended for use in a situation when human life would be endangered through its use. In other areas of society, broad legal prohibitions exist to protect human life and the well-being of citizens. For example, individuals are prohibited from yelling "Fire!" in a theater, and utility monopolies that control all of the electricity for a city are prohibited from price gouging. Patents make sense in a retail or manufacturing context. If you don't want to purchase Venetian glass, you can decide it's too expensive. In contrast, if your child is born with a genetic defect, you have no choice but to obtain the medication available for treatment regardless of price. Patent protection effectively grants the pharmaceutical industry a monopoly, regardless of the human consequences. For a patient with a particular disease and a single solution available in the form of a sole-source drug, allowing exorbitant pricing that prevents access for individuals to the medication runs counter to the expectation of Congress to protect the health of its citizens."

Price Controls Prevent Tradeoffs

Drug prices are increasing

Hackett, Brittany. "Prescription Drug Costs Continue to Skyrocket." AARP, 7 Dec. **2017**, www.aarp.org/health/drugs-supplements/info-2017/prescription-drug-costsfd.html.

Retail prices for prescription drugs continue to rise at significantly higher rates than inflation, which may make it difficult for many Americans, especially Medicare beneficiaries, to afford their medications, warns a new report from AARP's Public Policy Institute (PPI). **According to the report, retail prices for 768**

prescription drugs commonly used by older Americans rose by an average of 6.4 percent in 2015, the latest year for which data are available. The report also found that for 528 medications many older adults take every day to control chronic conditions like diabetes and high blood pressure, the average retail price was \$12,951 in 2015, more than three times the average price for such drugs in 2006. Most people do not pay the retail price for their medications because they either have private insurance or are covered by a government program such as Medicare, which pays most of a drug's costs. But there are a growing number of patients whose prescription plan requires them to pay a percentage of a medication's retail price, instead of a flat copay.

The amount of people using prescription drugs is only increasing

Iuga, Aurel O, and Maura J McGuire. "Adherence and Health Care Costs." Current Neurology and Neuroscience Reports., U.S. National Library of Medicine, **2014**, www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/.

In 2010 spending for prescription drugs in the US was US\$259 billion.²⁶ Considering the prevalent rates of nonadherence, drug-related expenses could increase substantially if adherence improved. Medication nonadherence is widespread and varied by disease, patient characteristics, and insurance coverage, with nonadherence rates ranging from 25% to 50%. **In the US, nearly half of all adults have at least one chronic disease²⁸ and the percentage of Americans taking at least one prescription drug increased from 38% in the period 1988–1994 to 49% in the period 2007–2010; during the same time the number of adults taking three or more prescription drugs doubled.**²⁶ prescription medication use will increase as the population ages. Based on these statistics, increasing adherence from current levels could increase medication expenses by billions of dollars. Strategies to enhance adherence should consider the impact on overall health care costs, weighing increased drug expenditures against savings from improved outcomes. The majority of the costs attributed to medication nonadherence result from avoidable hospitalization.

Medical care and prescription drugs are substitute products.

Santerre, Rexford E. and John A. Vernon. "Assessing Consumer Gains From A Drug Price Control Policy In The United States," Southern Economic Journal, **2006**, v73(1,Jul), 233-245.

The positive and statistically significant cross-price elasticity estimates suggest that medical care and prescription drugs are substitute products. For example, our results indicate that a 10 percent increase in the price of medical care is associated with a 4.5 to 5.6 percent increase in the quantity of prescription drugs demanded. **The direct relation between the price of medical care and the quantity of prescription drugs demanded suggests that decision-makers have some ability to substitute one good for the other in the production of good health when relative prices change. This finding is consistent with Lichtenberg's (1996) research, which found that increased expenditures on pharmaceuticals lead to reduced expenditures on hospitalizations, ambulatory care, and physician services.** Net income elasticity estimates are positive and statistically significant, indicating that pharmaceutical products can, collectively, be treated as normal goods. The income elasticities are fairly sizable and suggest that a 10 percent increase in real income per capita produces a 5 percentage increase in the quantity of drugs demanded. Studies tend to suggest that health care represents a normal good (Santerre and Neun, 2004).

High drug prices cause people to take unhealthy measures.

“Is There a Cure for High Drug Prices?” Product Reviews and Ratings - **Consumer Reports**, Consumer Reports, 29 July **2016**, www.consumerreports.org/drugs/cure-forhigh-drug-prices/.

The practice of raising drug prices on new—and old—medications is common and widespread. **From a nationally representative telephone poll conducted by Consumer Reports Best Buy Drugs in March, we learned that three in 10 Americans (about 32 million people) were hit with price hikes within the previous 12 months, costing them an average of \$63 more for a drug they routinely take—and a few paid \$500 or more.** We also found price increases on everything from longtime generics used to treat common conditions such as diabetes, high blood pressure, and high cholesterol to new treatments for diseases such as hepatitis C. **Our poll shows that when people were hit with higher drug costs, they were more likely to take unhealthy measures such as skipping doctor appointments, tests, or procedures, or not filling their prescriptions or taking them as directed.** Take the case of Marlene Condon, a nature writer living in Crozet, Va. Two years ago she paid about \$32 for 180 tablets of hydroxychloroquine (a generic available for almost two decades) to treat her rheumatoid arthritis. When the drug’s price more than doubled to \$75, Condon says she was annoyed but paid the bill anyway.

Drugs are too expensive

Prescription Drug Costs are Rising - And Fast

Margot **Sanger-Katz**, New York Times, "Prescription Drug Costs Are Rising as a Campaign Issue - The New York Times", Sept. 21, **2015**, <https://www.nytimes.com/2015/09/22/upshot/prescription-drug-costs-are-rising-as-a-campaign-issue.html?rref=upshot>

Here's why prescription drugs are bubbling up to the top of the Democratic health care agenda: **Drug prices are bubbling up. Per capita drug spending increased by more than \$100 last year, a big jump. At the same time, a growing share of Americans are being asked to foot the bill for their medicines, even if they're insured.** The

Affordable Care Act, which has expanded insurance coverage, didn't do much to counteract those trends. Voters have clearly noticed the higher drug costs. This year, a survey from the Kaiser Family Foundation asked people to identify health issues that they thought should be top priorities for the president and Congress. The No. 1 issue was making drugs for serious diseases affordable. The No. 2 issue: lowering the cost of prescription drugs. A follow-up survey in August found that 24 percent of people said that they or a family member had declined to fill a prescription because of the cost. Mr. Sanders said that hearing about this difficulty in obtaining needed medicines motivated his proposal. "It is totally absurd that if somebody does have health insurance and they walk into a doctor's office and the doctor writes a prescription, they can't fill it," he said in an interview. "What sense is that?" Both candidates' proposals include provisions that would allow Americans to import drugs from Canada, and that would allow the Medicare program to negotiate with drug makers when purchasing medications for the program. The Sanders plan also would require companies to share more information about their research and development costs, and increase penalties on pharmaceutical companies found guilty of fraud. The Clinton plan would impose a requirement that drug companies spend a set percentage of their revenues on research and development, and would cap the amount insurance companies could ask customers to pay each month for their medications to \$250. **After years in which Americans' spending on drugs barely increased, last year they**

popped: Nationwide, spending on drugs increased by 12 percent when adjusted for inflation, according to federal government estimates. A lot of that increase came from the introduction of some very expensive and

popular new treatments for the chronic liver disease hepatitis C. But costly new drugs for cancer, multiple sclerosis and autoimmune disorders also explained the change, according to an analysis from the IMS Institute for Healthcare Informatics, which tracks the pharmaceutical industry. (The government numbers don't count all drugs — some cancer medications and other drugs given by doctors aren't included — but the number measures how much the country is paying for drugs sold through pharmacies, and that amount is rising.) **Just as the new and**

expensive treatments are entering the market, fewer older brand-name drugs are going generic. The process of going generic has historically led to lower prices. Industry analysts say that drug companies are also aggressively lifting their pricing. Sometimes, companies are putting in big price increases for long-established generic drugs, as my colleague Andrew Pollack recently wrote about. **Americans have long paid the highest prices for drugs. Because the United States gives drug makers long periods of patent**

exclusivity and lets a multitude of insurers each negotiate with drugmakers on price, drug spending here is, on a per capita average, roughly double the amount spent in many developed countries. That difference explains one of the planks of the candidates' drug proposals: to allow Americans to import Canadian drugs back into the United States. **Even Medicare, the government insurer for older Americans, doesn't negotiate on drug prices in**

a unified way; instead, individual private plans each haggle for separate discounts. Both Mr. Sanders and Mrs. Clinton have talked about shifting to a system where Medicare negotiates as a monolith. When drug costs go up, people tend to feel the change more acutely than they do increases in other parts of the health care system, even though prescription drug costs represent only a small portion of overall health care spending in the country. Government estimates suggest that prescription drug spending makes up only about 10 percent of federal spending on health care. There's even research suggesting that use of pharmaceuticals often lowers other kinds of health care spending. High drug costs are increasingly a problem even for the well insured. Most plans sold in the new Obamacare marketplaces include hefty deductibles for drugs of hundreds or even thousands of dollars a year. Even people who get their health insurance from large corporations, which tend to have the richest benefits, are expected to pay a growing share of their drug bill out of their pockets. Data from the Kaiser Family Foundation, which conducts a large survey of employers about their benefits, show the trend clearly. **More than 40 percent of employers now ask their workers to pay deductibles of \$1,000 or more. At small companies, more than 60 percent buy such plans. A few employees every year get sick enough that they spend their deductibles on doctor or hospital care. But many more take prescription drugs, meaning that the cost of medications is an expense they encounter every month.** A growing number of plans

are also adding special deductibles for drugs only. And insurance companies have been trying to discourage patients from choosing the most costly drugs by asking them to pay bigger co-payments even after they've used up their deductibles, meaning patients who need such drugs

may be paying a big bill all year long. "They are having to pay the full cost of their prescriptions, not just the co-payments; I think that's the thing that's changed," said Murray Aitken, the executive director of the IMS institute. "The very real explanation is people are having more exposure to the full cost."

Drug prices at highest in 13 years

Kimberly Leonard, 9-25, 15, <https://www.usnews.com/news/the-report/articles/2015/09/24/expensive-drugs-a-drag-on-consumers-and-government> Budget Breakers

PRESCRIPTION DRUGS ARE costly and most Americans agree that they pay too much for them. Recent headlines illustrate that point clearly – from presidential candidates' promising to tackle the issue, to a CEO initially announcing a jump in the cost of a parasitic-fighting medicine. And with **America's total spending on prescription medicine reaching its highest rate in 13 years**, policy groups are listening and are coming up with their own plans for reining in costs.

Costs of generic drugs is increasing

Kimberly Leonard, 9-25, 15, <https://www.usnews.com/news/the-report/articles/2015/09/24/expensive-drugs-a-drag-on-consumers-and-government> Budget Breakers

But even **the costs of generic medications are rising**. From July 2013 to July 2014, the **prices of more than 1,200 generic drugs increased by an average 448 percent**, according to the Centers for Medicare and Medicaid Services.

10% increase every year

Scott Atlas, March 21, 2018, <https://www.cnn.com/2018/03/21/opinions/the-overlooked-ingredient-to-lower-drug-prices-atlas/index.html> CNN Soaring drug prices? Here's how to control them

Even though prescription drugs constitute only 11% of US health expenditures, according to the Centers for Disease Control and Prevention and Centers for Medicare and Medicaid Services, and US drug spending ranks in the bottom one-third of comparison lists with other developed nations, **prices continue to increase rapidly here, with a year-over-year rise of almost 10% for drug list prices**, according to a 2017 Credit Suisse report.

Large price increase relative

Dana O. Sarnak, David Squires, and Shawn Bishop 2017, , <https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier> Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier? Former Senior Research Associate, International Program in Health Policy and Practice Innovations Former Senior Researcher to the President The Commonwealth Fund the Commonwealth Fund Vice President, Controlling Health Care Costs and Advancing Medicare The Commonwealth Fund, October 15, Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?

In the mid-2000s, spending growth slowed in all 10 countries, as fewer blockbuster drugs gained approval and many top-selling drugs, like Lipitor, came off patent.² **This slowdown ended** in striking fashion **in 2014 and 2015, as U.S. prescription spending spiked by approximately 20 percent over a period of two years.** This growth, like that experienced in the 1990s, was principally because of the introduction of several expensive specialty drugs to treat hepatitis C, cystic fibrosis, and other conditions.³ Also likely contributing to this growth in the U.S. was the increase in health insurance coverage following passage of the Affordable Care Act. While prescription spending also rose in 2014 and 2015 in several other countries (Germany, Norway, Switzerland, and the United Kingdom), the increases were not as large or abrupt as in the U.S. **The result is that by 2015, U.S. spending on pharmaceuticals exceeded \$1,000 per person and was 30 percent to 190 percent higher than in the other nine countries** (Exhibit 2).

Many Americans skip prescriptions because of the costs

Dana O. Sarnak, David Squires, and Shawn Bishop 2017, ,

<https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier> Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier? Former Senior Research Associate, International Program in Health Policy and Practice Innovations Former Senior Researcher to the President The Commonwealth Fund the Commonwealth Fund Vice President, Controlling Health Care Costs and Advancing Medicare The Commonwealth Fund, October 15, Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?

In a 2016 international survey of adults, **14 percent of insured Americans reported that, in the past year, they did not fill a prescription or skipped doses of medicine because of the cost, compared with 2 percent in the U.K. and 10 percent in Canada**, the nation with the highest rate after the U.S. (Exhibit 6).¹² Among Americans without continuous insurance coverage over the past year, the rate was twice as high: **one-third reported they did not fill a prescription for medicine, or skipped doses of medicine, because of the cost**. For **patients with chronic conditions**, cost barriers are particularly detrimental, as they can undermine adherence to highly effective medication regimens.¹³ The 2016 survey found that, in most countries, patients with two or more chronic conditions **were significantly more likely to skip medications because of costs than were healthier patients, with one-fourth of chronically ill adults in the U.S. reporting such a problem** (Exhibit 7). Notably, **the only countries where such patients were not significantly more likely to report cost barriers to prescription drugs were** France, Germany, and the U.K. — **countries that have instituted protections to reduce out-of-pocket charges for their** chronically ill **populations**.

Affordable Care Act has made medicines more affordable

Dana O. Sarnak, David Squires, and Shawn Bishop 2017, ,

<https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier> Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier? Former Senior Research Associate, International Program in Health Policy and Practice Innovations Former Senior Researcher to the President The Commonwealth Fund the Commonwealth Fund Vice President, Controlling Health Care Costs and Advancing Medicare The Commonwealth Fund, October 15, Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?

The Affordable Care Act, however, **implemented significant reforms to improve the affordability of health care, including prescription drugs**. Most notable were the insurance coverage expansions, through which more than 20 million low- and middle-income Americans gained coverage. **Data from the Commonwealth Fund's Biennial Health Insurance Surveys show that the percentage of low-income adults who reported not taking a prescribed drug because of the cost declined to 24 percent in 2016 from 39 percent in 2010** (Exhibit 8).

Lack of pricing drives up costs

Dana O. Sarnak, David Squires, and Shawn Bishop 2017, ,

<https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier> Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier? Former Senior Research Associate, International Program in Health Policy and Practice Innovations Former Senior Researcher to the President The Commonwealth Fund the Commonwealth Fund Vice President, Controlling Health Care Costs and Advancing Medicare The Commonwealth Fund, October 15, Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?

One reason U.S. prescription drug prices are higher may be the relative lack of price control strategies. Unlike the U.S., **many other countries employ centralized price negotiations, national formularies, and comparative and cost-effectiveness research for determining price ceilings.**¹⁴ **In the U.S., health care delivery and payment are fragmented, with numerous, separate negotiations between drug manufacturers and payers and complex arrangements for various federal and state health programs.**¹⁵ And, in general, the U.S. allows wider latitude for monopoly pricing of brand-name drugs than other countries are willing to accept.

Majority of voters support price controls

Karl **Lauterbach**, John McDonough, Elizabeth Seeley. "Germany's Model For Drug Price Regulation Could Work In The US, " Health Affairs Blog, December 29, **2016**. DOI: 10.1377/hblog20161229.058150, <https://www.healthaffairs.org/doi/10.1377/hblog20161229.058150/full/>

Donald **Trump** and Hillary **Clinton** **agreed on almost nothing during the 2016 presidential campaign – but they did agree that the U.S. needs to address unaffordable prescription drug prices.** And the public also supports this idea. A survey released in October 2016 showed that **64 percent of voters, including 52 percent of Republicans, believe that the federal government should place a “limit on how much pharmaceutical companies can increase prescription drug prices.”**

Increased Health Care Costs

High drug prices causing massive increase in overall health costs

Tanden & Calysen, 2015, Neera Tanden, right, is the president of the Center for American Progress and Maura Calsyn is its director of health policy. Ms. Tanden has advised Hillary Rodham Clinton's campaign on health issues. New York Times, Encourage Drug Research Over Profiteering

This week's news isn't unique; **drug companies commonly demand exorbitant prices for their medications, even when cheaper, equally effective options are available.** They can do this because drugs don't operate in a normal market. **Without reform, spending on prescription drugs, which totaled \$374 billion in the U.S. in 2014,** will continue to outpace the growth of other types of health care spending. In the next decade, federal health care programs and their beneficiaries will spend more than \$1.1 trillion on brand-name prescription drugs. In fact, rising drug prices are even affecting the overall rate of health care cost growth, driving up premiums for everyone and contributing to the squeeze on middle-class families' bottom lines.

Prescription drug costs are 17% of medical care costs

Michelle Mello, June 2018, Professor of Law, Stanford Law School, and Professor of Health Research and Policy, Department of Health Research and Policy, Stanford University School of Medicine; Ph.D., University of North Carolina at Chapel Hill; J.D., Yale Law School; M.Phil., University of Oxford; A.B., Stanford University., Minnesota Law Review, ARTICLE: What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?, http://www.minnesotalawreview.org/wp-content/uploads/2018/07/Mello_MLR.pdf p. 2277-8

Medicines now account for nearly seventeen percent of our total national healthcare expenditures. ¹⁸ **Except for 2016, they have been among the fastest-growing segments of healthcare costs.** ¹⁹ In a recent survey, **nearly one in four Americans reported that they or a family member had declined to fill a prescription, skipped doses, or reduced their dose in the past year because of concerns about cost.**

Lack of price controls mean the highest health care costs in the world

Michelle Mello, June 2018, Professor of Law, Stanford Law School, and Professor of Health Research and Policy, Department of Health Research and Policy, Stanford University School of Medicine; Ph.D., University of North Carolina at Chapel Hill; J.D., Yale Law School; M.Phil., University of Oxford; A.B., Stanford University., Minnesota Law Review, ARTICLE: What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?, http://www.minnesotalawreview.org/wp-content/uploads/2018/07/Mello_MLR.pdf

In all other developed countries, patients are protected by government authorities overseeing the market for prescription meds, ensuring that prices are reasonable while still allowing drug companies a fair profit. In the United States, profit comes before public interest. There are no limits to how much can be charged for a prescription drug, particularly specialty drugs intended for the costliest illnesses. As a result, **the U.S. is by far the world's biggest spender on pharmaceutical products, shelling out more than \$1,026 annually per person, according to a 2015 report from the Organization for Economic Cooperation and**

¹⁸ Id. at 24-25 (citing U.S. Dep't of Health & Human Servs., Observations on Trends in Prescription **Drug** Spending 7-8 (2016), <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf>) (discussing **drug** expenditures in the United States).

¹⁹ Id. at 5; US **Drug** 2016 Sales, at \$ 450 Billion, Moderate to Single-Digit Growth, Pharmaceutical Com. (May 4, 2017), <http://pharmaceuticalcommerce.com/latest-news/us-drug-2016-sales-450-billion-moderate-single-digit-growth>.

Development. That's double the OECD average of \$515 and considerably more than economic peers such as Germany (\$678), France (\$596) and Australia (\$590). Total U.S. spending on prescription drugs reached \$450 billion last year, according to the research firm QuintilesIMS. It could be as high as \$610 billion by 2021.

Hospitals

Price hikes hugely increase costs for hospitals – empirics

Saporito, Bill. [Writer/reporter for TIME Magazine]. “Hospitals Furious at Cancer-Drug Price Hikes”. TIME, **2014**. <http://time.com/3541484/cancer-drug-price-hikes/>

Some of the nation’s hospitals are seriously ticked off at **Genentech, the San Francisco biotech firm, for implementing a stealth price hike for three critical cancer drugs.** On September 16, Genentech told hospitals and oncology clinics that as of October 1, they can only buy Avastin, Herceptin and Rituxan—three of the biggest weapons in the cancer arsenal—through specialty distributors instead of general line wholesalers they’ve been using for years. **The shift means hospitals will lose out on standard industry discounts—which Genentech and its distributors will then pocket.** “Our blunt estimate: **It will cost \$300 million more in the U.S. overnight in what folks are paying for these lifesaving drugs.**” says Pete Allen, group senior vice president, sourcing operations, for Novation, a health care services company that negotiates drug contracts. **Novation estimates the hospitals it represents will take a \$50 million hit—and that’s before the costs of additional inventory, handling and paperwork the hospitals might also incur.** Sales of Avastin, used to treat colorectal, ovarian and other cancers, hit \$6.6 billion last year. Sales in what the company calls its HER2 breast cancer franchise—Herceptin, Perjeta and Kadcyla— rose 14% to nearly \$7 billion. “As a result of the decision to change its distribution system, Genentech’s use of specialty distributors is resulting in unprecedented price hikes, the results of which will harm the patients we serve,” said Dr. Roy Guharoy, chief pharmacy officer at Ascension Healthcare, a Catholic, nonprofit health system with some 1,500 locations, in a statement. Genentech—owned by Roche, which had \$50 billion in sales last year—says the switch to specialty wholesalers will improve the efficiency and security of the supply chain. The company says its newer cancer drugs, such as Perjeta, Kadcyla and Gazyva, are already supplied this way, which allowed it to reduce the number of distribution centers from 80 to five. “We do believe this is the best distribution model for these medicines,” said Charloëe Arnold, the company’s associate director of corporate relations. “We understand that there maybe a business impact on hospitals.” The company wouldn’t explain the specifics of why the specialty model is better. Hospitals aren’t buying the company’s rationale. “I haven’t talked to anyone who thought this was a safer way to distribute these drugs,” says Bill Woodward, senior director of contracting at Novation. **There is nothing about these drugs that would make them safer to be in the specialty channel.** Most of the major wholesalers, in fact, already have specialty distribution arms although one general firm, Morris & Dickson, had to create a specialty arm to remain a Genentech distributor. **It’s a difference without a distinction, say the hospitals, except that Genentech earns more money. The financial cost to the hospitals comes first through the loss of rebates from the big wholesalers. But more importantly, hospitals also lose to ability to negotiate what are called cost-minus discounts with their wholesalers that, depending on the cost of a drug, amounts to a 2%-to-5% price reduction.** The cost of this “back-end” funding had been borne by Genentech; now the hospitals will have eat it. Ascension says it is already seeing significant net price hikes. A 400 mg dose of Avastin jumped from \$2,382.28 on October 12 to \$2,511.36 on October 14, a nearly 8% increase. Similarly, a 500mg dose of Herceptin rose to \$3,878.89 from \$3,586.52. Even worse for the hospitals, they can’t pass this increase on to insurance companies—since the list price remained the same, as far as insurers are concerned there’s been no increase. Ascension has flatly alleged that Genentech is reclassifying Avastin, Herceptin and Rituxan as “specialty” drugs to enhance profits moreso than improve the supply chain. Specialty drugs usually fall under the FDA’s Risk Evaluation and Mitigation Strategy (REMS) program, established for compounds like the testosterone drug AndroGel that may have unusual side effects; or for drugs that are unusually expensive. According to Ascension, in 1990 only 10 specialty drugs existed. By 2012 that number jumped to nearly 300 compounds. “The end result is large price hikes unaccounted for in our 2015 budgets, and it will mean that already scarce resources will need to be stretched,” says Guharoy. The hospitals are already being forced to deal with rising prices for all kinds of drugs. According to Ascension, its drug costs have risen \$36 million in the past year. With 2015 pharmacy budgets already set, Genentech’s new distribution model threatens to bust hospital budgets before the year has even started. Genentech tried a similar switch in 2006, but outraged customers forced the company to rescind the program. This time Genentech seems like it’s digging in. “We understand there may be some adjustments,” said Arnold of Genentech’s testy customers, noting that the company was “working to educate them” about the benefits of the new system. Judging from the bile level, that could take awhile.

Drug prices are going up across the board at 10% per year – costs a ton to hospitals

Dennis, Brady. [Dennis is a writer for the Washington Post]. “Raïled by drug price increases, hospitals struggle with costs, care”. Chicago Tribune, **2016**. <http://www.chicagotribune.com/business/ct-hospitals-drug-price-increases-20160314-story.html>

Doctors at the University Hospitals of Cleveland see an immediately recognizable symbol pop up alongside certain drugs when they sign in online these days to prescribe medications for patients: \$\$\$\$\$. The **dollar signs, affixed by hospital administrators**, carry a not-so-subtle message: **Think twice before using this drug. Pick an alternative if possible.** The Zagat-like approach is just one of the strategies hospitals nationwide are using to try to counter drug costs. It was inspired in part by Shawn Osborne, the **University Hospitals** system's vice president of pharmacy services, who **saw unexpected price hikes wreak havoc on his budget last year.** The increases often involved brandname drugs with little or no competition as well as commonly used generics around for decades. Among those tagged were Nitropress and Isuprel, injectable heart medications that are a staple at many hospitals. Their 2015 list prices rose more than 200 percent and 500 percent, respectively, after both were acquired by Canadian-based Valeant Pharmaceuticals. Generic drugs: A bargain or sticker shock? **Hospital officials across the United States cite similar experiences, saying their predicament illustrates one dimension of a broken prescription-drug system.** "There's been a huge consolidation of these generic companies . . . everybody is buying everybody else," said Gerard Anderson, a professor at the Johns Hopkins Bloomberg School of Public Health. "If there's no competition, the prices go up. We are seeing a lot of [drug] shortages, and also price increases. That shouldn't happen, but it is." The problems, hospital administrators say, extend well beyond the increases that have grabbed headlines and caused public outrage, most notably the 5,000 percent spike by Turing Pharmaceuticals and its former chief executive, Martin Shkreli, in the list price of a drug to treat the parasitic infection toxoplasmosis. Pharmaceutical mergers and acquisitions, which can be beyond regulators' reach, are only part of the dynamic. Some companies have raised prices more modestly but repeatedly for a variety of medications old and new, and those increases add up over time. A recent Bloomberg Business survey of about 3,000 brand-name prescription drugs found that **prices had more than doubled for 60 medications since December 2014 and at least quadrupled for 20.** It found that **prices for many other drugs continued to rise at 10 percent or more annually, particularly as competition waned or patents neared expiration.** Special Report: Dangerous Doses — Pharmacies miss half of dangerous drug combinations A December report from the Department of Health and Human Services inspector general identified a similar trend. Prices rose faster than inflation for nearly a quarter of top generic drugs between 2005 and 2014, even as prices for many other generics remained low. "The challenge is, you don't have a crystal ball," said Jeff Rosner, senior director of pharmacy sourcing and purchasing at the Cleveland Clinic, which last year faced an unexpected increase of more than \$8 million after the prices of two heart therapies surged. Rosner said it's more and more difficult to anticipate how much the institution will spend on the myriad drugs it buys annually. But that hasn't stopped him and his counterparts from trying. Nationally, hospitals are aggressively pursuing efforts to anticipate and mitigate drug-cost pressures. "The target on my back has gotten much bigger, and it was pretty big before," said Osborne, who knows he must better predict drug spending this year after going roughly \$20 million over budget in 2015. That's a challenge, given the 6,000 medications the nonprofit system purchases. Hence the addition of "\$\$\$\$" in its electronic records to alert physicians about which are most expensive. Like other facilities, the system dropped multiple budget-busters from its formulary. Osborne said he now pays as much attention to news about pharmaceutical mergers and acquisitions each week as he does to academic articles about medicines. "Hospitals run on razor-thin margins. When you get surprises, it throws everything off," he said. "As they say, 'No margin, no mission.' "

Rising drug prices are unsustainable and force hospital closure – it's had a moderate to severe effect on costs for 90% of hospitals, data confirms prices are the key driver
Silverman, Ed. [Writer for PharmaLot]. "Rising drug prices are making hospitals feel ill". Stat News, 2016. <https://www.statnews.com/pharmalot/2016/10/11/hospitals-drugprices/>

The rising cost of medicines is making some hospitals feel ill. While much of the attention over prescription drug prices is focused on consumers, a survey released on Tuesday finds that hospitals are also spending much more than in the past. **Between 2013 and 2015, the average annual drug spending for patients who stay in community hospitals increased by of 23.4 percent, from \$5.2 million to \$6.5 million. And on a per admission basis, hospital spending on drugs jumped nearly 39 percent, to \$990.** Moreover, **the increase in prices outpaced reimbursement rates from payers, retail spending on medicines, and the pharmaceutical price inflation calculated by the US Bureau of Labor Statistics.** As a result, the survey found that more than 90 percent of the hospitals surveyed reported that recent price hikes for inpatient drugs had a moderate or severe effect on managing costs. **"With these drug prices so far outpacing the consumer price index, hospitals are struggling to come up with trade-offs to preserve access to affordable care for our patients,"** said Scoï Knoer, chief pharmacy officer at the Cleveland Clinic, who spoke at a press briefing held by the American Hospital Association and the Federation of American Hospitals, which conducted the survey. Last year, one hospital claimed that the price increases for four commonly used medications, which ranged between 479 and 1,261 percent, cost the same amount as the salaries of 55 full-time nurses, according to the trade groups, although they did not identify the hospital. But even 10 percent to 20 percent hikes on drugs that are widely used can have an impact, the survey noted. The survey, which last spring gathered pricing data from 712 US

community hospitals and two group purchasing organizations, adds to the growing chorus of anger and concern over increasing prescription drug costs. The issue, as noted previously, has become a talking point in the presidential campaign and prompted federal and state lawmakers to introduce bills designed to curb rising prices. Related: Most Americans believe prescription drug prices are unreasonable The furor has put the pharmaceutical industry on the defensive as many drug makers are scrambling to justify their price hikes. Some drug makers are pointing fingers at pharmacy benefits managers, and the convoluted pricing system in which rebates that are paid to win coveted placement on lists of drugs for which insurance coverage is provided. We asked the pharmaceutical industry trade group for a reply and will update you accordingly.

Hospitals generally pay for drugs that are administered and then look to get reimbursed for patient care that covers expenses. But the Bureau of Labor Statistics updates its pharmaceutical index every five to seven years, which means Medicare reimbursement rates cannot keep pace with large or unpredictable price hikes. And some commercial insurers also follow the Medicare payment method and rates.

Hospital concerns over rising drug costs are hardly new, though. Early last year, hospitals raised a ruckus after Valeant Pharmaceuticals bought the rights to a pair of lifesaving heart drugs, which are often used in emergency settings, and on the same day, raised their list prices by 525 percent and 212 percent, respectively. The episode triggered controversy as hospitals began pointing to similar instances, often noting that price hikes followed deals in which drugs changed hands, but little or no research was done to improve the value or effectiveness of the medications. In fact, the Valeant drugs — Nitropress and Isuprel — were cited in the survey as prime examples of the phenomenon. The survey found that growth in unit price — not increased volume — was primarily responsible for the rise in total inpatient drug spending. Many of the 28 medicines that were sampled for the survey were high volume drugs, but these also experienced what were described as “substantial” increases in unit prices. One example cited was calcitonin-sodium, a drug used to treat high levels of calcium in the blood or bone pain related to osteoporosis and other diseases. In 2013, the two group purchasing organizations reported they spent about \$2 million, but in 2015, spending climbed to \$55 million, mainly because the price per unit increased more than 3,000 percent. Among the drugs for which hospitals experienced the most significant price hikes was Daraprim, which is sold by Turing Pharmaceuticals. The company, which was run by Martin Shkreli, raised the price of the lifesaving parasitic medicine by 3,695 percent. “Hospitals are under incredible pressure to maintain or decrease drug spending, yet this is a virtually impossible task given the huge increase in prices of the most basic drugs,” said Erin R. Fox, director of the Drug Information Service at the University of Utah Health Care. “The drugs that are increasing in price generally are not new and are off patent. There is no competition, so hospitals are forced to pay in order to make the best patient care decisions,” she continued.

“These price increases are unsustainable for hospitals who are taking care of sicker and sicker patients

Specifically, rural hospitals are on the brink of closure now

SSI Group. “What is the Fate of Rural & Community Hospitals?”. SSI, 2017.

<http://thessigroup.com/fate-rural-community-hospitals/>

As **rural hospitals continue to close**, some health systems are making desperate attempts to address the problems of funding and the expanding number of patients during a simultaneous drop in the availability of physicians in rural areas. How are leaders dealing with these struggles? We take a look. **“Rural hospitals are especially vulnerable to closure due to payment cuts** because of their smaller operating margin. A recent report on indicators describing hospital performance shows **673 rural hospitals that are currently at risk for closure**, and of the 673 hospitals identified, **68 percent are critical access hospitals (CAHs)**.” — from “Facility Closure: How to Get In, Get Out, and Get What Is Important” published in Perspectives in Health Information Management a scholarly, peer-reviewed research journal by AIHMA.org. Last year, Becker’s Hospital Review gave a state by state breakdown of 77 closures for rural hospitals. According to that article, those states with the most closures are located in the south. Recently the total was updated to 80. You can see a map and get a complete list on this page at the Sheps Services for Health Services Research. **We counted 17 rural hospital closures in 2016 and 2017.**

Rural hospital closure damages the economy and hugely spikes food prices

Alemian, David. [Writer for MD Magazine]. “Rural Healthcare Is a Maker of National Security”. MD Magazine, **2016**. <https://www.mdmag.com/physicians-moneydigest/contributor/david-alemian-/2016/11/rural-healthcare-is-a-maker-of-nationalsecurity>

Rural health organizations are already struggling with enormous turnover rates and **costs that run up into the millions** of dollars each year. The additional financial burden of penalties from Medicare and Medicaid will put many rural health organizations at risk of going out of business. **If too many rural health organizations go out of business, it then becomes a maker of national security and here’s why:** In most rural communities, the healthcare organization is the largest employer. **When the largest employer goes out of business, the community collapses and people**

move away. What was once a thriving community then becomes a ghost town. **Rural America produces the food that feeds the rest of the country. What will happen when our amber waves of grain turn to desert wastelands because there is no one to work our great farmlands?** As the source of food dries up, and store shelves empty, the price of food will go through the roof. **As food prices go up,** hyperinflation will become a reality, and **our printed money will become worthless.** Almost overnight, **Americans will begin to go hungry** because they won't be able to afford to put food on the table. You may think it sounds like a really bad movie, but it should be food for thought.

Food price spikes cause refugee flows, instability, and Asian conflict

Natsios, Andrew. [Professor, George H.W. Bush School of Government at Texas A&M University].

“Modernizing Food Aid: Improving Effectiveness and Saving Lives.” Testimony to the House Committee on Foreign Affairs Hearing, February 14, **2018,**

<http://docs.house.gov/meetings/FA/FA00/20180214/106858/HHRG-115-FA00-WstateNatsiosA-20180214.pdf>

Since I last spoke to this committee in June 2013, we have witnessed the most massive refugee and internal displacement crisis in world history. The number of displaced persons reached a record high of 65.6 million people in 2016, and, while the UN High Commissioner for Refugees has not released 2017 figures, the famines in Nigeria, Somalia, South Sudan, and Yemen have likely made this number considerably higher still over the past year. The UN classifies the current situation as the worst humanitarian crisis since the institution's founding following WWII. Though this is a humanitarian crisis, it has substantial political implications as well. Individuals frequently cope with famine by migrating, either within their home country or outside its borders. **As a famine grows** more deadly, **refugee and internally displaced camps form and develop their own, often violent, systems of internal governance, and past experience shows us that allowing these camps to fester over time results in extremist groups taking root.** For example, **in Somalia** in 1992, famine and conflict forced families into displaced camps under the control of **warlords**, who actively **recruited unemployed, angry, and hungry young men for their militias.** Similarly, after **the Russian invasion of Afghanistan** in 1979 **drove** millions of Afghans to neighboring Pakistan, refugee camps formed which became the birthplace of **the Taliban.** We are all aware of how this led to the worst terrorist attack in U.S. history and the seventeen year effort by the United States government to stabilize Afghanistan. In histories such as these, we can see the unfolding of humanitarian crises that threaten not only human rights, millions of people's lives, but also United States national security. **Severe and prolonged food insecurity, particularly for great powers with large militaries, has a history of leading to wars among the great powers.** In the lead-up to World War II, Adolf Hitler executed a foreign policy that sought to overthrow the existing international order. One of his motivations for German expansionism was to secure land to cultivate food for the German population. He believed Germany lost WWI because it could not feed its own population from its own resources. Similarly, the Nazis carried out the horrors of the Holocaust and attempted the extermination of the urbanized Slavic peoples of central Europe to shrink these populations, which Hitler believed would ensure food for German Aryans by killing off what the Nazi regime called “useless eaters”. The Japanese suffered localized famines in the early and mid-1930s because they could not produce or import enough food to feed their growing population: the expansion of the Japanese empire that led to WWII in Asia was partially driven by this fear. Over the past decade, Asian powers, concerned by their rising food needs over the next century, are leasing hundreds of thousands of acres of land in Africa on ninety-nine year leases to grow food in the future because they believe themselves to be at risk of food crisis in the event of a break of the international food system. In nondemocratic countries lacking feedback and accountability mechanisms for citizens to express discontent to government in a peaceful manner, famines heighten the risk of conflict. For example, during the West African famine of 1968-1974, most governments in West Africa fell to coups or uprisings driven by the famine. In the mid-2000s, this pattern repeated itself when rising food prices caused riots in urban areas across the Arab world and Africa. One of the major factors driving the Arab uprisings of 2009 and 2010 were food insecurity caused by rapidly and steeply rising food prices. We are living with the ongoing chaos in the region driven by these uprisings nine years ago. While famines or severe food insecurity are not the sole reason for these upheavals, they can be the straw that breaks the camel's back in a context of popular discontentment with welfare and governance issues. Over the next century, food will become an increasingly important maker to people in poor countries across the globe. This will affect the national security of Great Powers such as the United States. Roger Thurow, who has written a great deal on modern famines, notes: **“After World War II, eliminating hunger was seen to be a bulwark against the extremism of the day: international communism. Today, eliminating hunger would be a bulwark against the extremism of the twenty-first century: global terrorism.” Food issues will determine war versus peace, and security and stability versus chaos.**

Food price spikes spill over globally and cause civil conflict

Jones, Aled W., and Phillips, Alexander. [Jones, Director, Global Sustainability Institute, Anglia Ruskin University; PhD, Cosmology, Cambridge. Phillips, Research Assistant, GSI]. “Historic Food Production Shocks: Quantifying the Extremes.” Sustainability 8: 427. **2016.**

Global food supply is now a complex system. **The interconnected nature of** intercountry **food dependence has increased dramatically over the last few decades** [8]. A globalised market can make the system itself more resilient to localised shocks when food can be sourced from alternative places not experiencing the particular shock. However, if there are systemic linked events in different regions or across a wide region, or an event is of sufficient size, then this system can be perversely more fragile [9,10]. In particular the tele-connected nature of extreme weather events is becoming an increasing focus of research [9] and while the short to medium term dynamics are not well understood at present it is important to develop methods that can use the outputs of these models to assess potential social impacts. These systemic risks involving significant global losses of food production could have major societal and economic impacts both through availability and price. Previous production shocks have been linked to major global events such as civil unrest and, in turn, major upheaval [11–13]. Understanding the historic causes and transmission of shock through to societal impact is key [14,15]. A recent study examining the evolution of trade networks over the period 1992–2009 concluded: **The global food system does exhibit characteristics consistent with a fragile one that is vulnerable to self-propagating disruptions.** That is, **in a setting where countries are increasingly interconnected and more food is traded globally** over the (last two decades), **a significant majority of countries are either dependent on imports for their staple food supply or would look to imports to meet any supply shortfalls.** [10] **A crop production shock results in a global food supply shock through trade and export restrictions** [16,17]. The responses of markets and governments to production shocks have been the subject of numerous studies since the 2007/08 price shocks [18–27] and range from short term speculation to more fundamental changes in policies. While food systems are both inherently local, particularly in the case of subsistence farming, and global a useful unit to explore production shocks is the country level. An extreme shock in food production will invariably involve a response by a government at country level [16,25] in an attempt to manage local price increases and the impact of the shock. Therefore, developing a detailed understanding of the impact of production shocks would initially necessitate an analysis at country level to allow a comparison across different studies. While it has been noted previously that the impact of food production shocks on an individual country do not seem to be correlated with whether that country is a net food importer or exporter [11] local infrastructure and processes will of course play an important part including transport, storage, policy responses and subsidies [9]. A common method to identify production shocks is therefore a first step in assessing whether an extreme loss constitutes a risk for a particular country or not.

Developing Countries

Current Pharmaceutical Prices prohibit developing countries from accessing medicine.

Pecoul et al 99 (Benard, Pierre Chirac, Patrice Trouiller, Jacques Pinel, "Access to Essential Drugs in Poor Countries A Lost Battle?"

Increasingly Prohibitive Prices? **A study sponsored by US pharmaceutical companies shows that granting drug patents does not tend to increase the price of drugs on the market.**³⁰ This study, however, **does not examine the prices of new innovative drugs and declares that, logically, the price of these new drugs should be higher.** Naturally, when the manufacturing company is assured that its product cannot be copied, it holds a stronger position to negotiate prices with public health authorities. Moreover, the liberalization of international pharmaceutical trade entails the development of parallel imports between countries where the same drug is sold at different prices. **Pharmaceutical companies, which are consequently less inclined to grant significantly lower prices to less developed countries, may instead set unique world- wide prices or delay marketing their drugs in developing countries.**²⁸ In either case, **access to drugs is jeopardized.** WHO's Revised Drug Strategy and the **essential drugs concept are still key strategies to help improve access to essential drugs and worldwide health.** The essential drugs concept is evidence based, is simple, promotes equity, and is rooted in firm public health principles. WHO's assistance to countries and advocacy work to promote the essential drugs concept and support countries in the formulation and implementation of national drug policies has resulted in change for the better. This strategy is a proven success but it needs to be continued and strengthened, and new ways of implementation have to be explored, given the changing context. In this spirit, **the following recommendations are made with respect to the 4 main issues that have been developed in this article. Procurement of Quality Drugs To improve the quality of existing drugs** and their procurement, it is important to develop a permanent "Observatory of Drug Quality," established by WHO in collaboration with organizations involved in the provision of essential drugs (eg, UNICEF, World Bank, the European Union, and nongovernmental organizations), that would oversee the implementation of adequate and effective control procedures. The practical knowledge acquired by international organizations to ensure the quality of generic drugs must be shared with health authorities in developing countries. Invitations to bid, required by big sponsors such as the World Bank, European Union, and the US Agency for International Development, must combine quality criteria and lower costs. Furthermore, **procurement of drugs should be centralized at a national level to rein- force the responsibility of governments to make procurement, quality control, stock management, and distribution of essential drugs a priority.**

Price Controls Exist in Other Countries

Prescription drugs are far cheaper in other countries

Jeanne **Whalen** (Jeanne Whalen writes and edits stories about health, science and the pharmaceutical industry in New York. She previously reported from the Journal's London and Moscow Bureaus. Jeanne Whalen is The Washington Post's global business reporter.), Wall Street Journal, "Why the U.S. Pays More Than Other Countries for Drugs - WSJ", December 1, **2015**, <https://www.wsj.com/articles/why-the-u-s-pays-more-than-other-countries-for-drugs-1448939481>

Norway, an oil producer with one of the world's richest economies, is an expensive place to live. A Big Mac costs \$5.65. A gallon of gasoline costs \$6. But **one thing is far cheaper than in the U.S.: prescription drugs. A vial of the cancer drug Rituxan cost Norway's taxpayer-funded health system \$1,527 in the third quarter of 2015, while the U.S. Medicare program paid \$3,678. An injection of the asthma drug Xolair cost Norway \$463, which was 46% less than Medicare paid for it.** Drug prices in the U.S. are shrouded in mystery, obscured by confidential rebates, multiple middlemen and the strict guarding of trade secrets. But for certain drugs—those paid for by Medicare Part B—prices are public. By stacking these against pricing in three foreign health systems, as discovered in nonpublic and public data, The Wall Street Journal was able to pinpoint international drug-cost differences and what lies behind them. What it found, **in the case of Norway**, was that **U.S. prices were higher for 93% of 40 top branded drugs available in both countries** in the third quarter. **Similar patterns appeared when U.S. prices were compared with those in England and Canada's Ontario province. Throughout the developed world, branded prescription drugs are generally cheaper than in the U.S.**

Countries with lower prices have one thing in common – Price Controls on the industry

Jeanne **Whalen** (Jeanne Whalen writes and edits stories about health, science and the pharmaceutical industry in New York. She previously reported from the Journal's London and Moscow Bureaus. Jeanne Whalen is The Washington Post's global business reporter.), Wall Street Journal, "Why the U.S. Pays More Than Other Countries for Drugs - WSJ", December 1, **2015**, <https://www.wsj.com/articles/why-the-u-s-pays-more-than-other-countries-for-drugs-1448939481>

This system automatically holds prices low because the countries consulted also have government-controlled prices. The Norwegian Medicines Agency, or NMA, then reviews patient data to decide whether a new drug is cost-effective. Its maker must request a reimbursement price at or under the maximum Norway has set and submit a detailed comparison of the drug's cost and benefits versus existing treatments. Companies have teams of number crunchers to produce these comparisons, which can also prove useful in pitching products in the U.S. **Norway recommends that companies describe a drug's cost per quality-adjusted life year, or QALY, a gauge used by many government health systems. Medicare is barred from using this gauge as a threshold to determining coverage.** Companies know Norway will sometimes deny coverage, and this threat is often "enough to get them to offer a discount," said Kristin Svanqvist, head of reimbursement at the NMA. If rejected, they can offer a lower price. When Amgen Inc. and GlaxoSmithKline PLC sought coverage of the osteoporosis injection Prolia for certain women, the NMA concluded it wasn't cost-effective compared with an existing infusion called Aclasta. Aclasta is a different type of drug, a bisphosphonate. These have an advantage in binding to the bone, the NMA said in a 2011 report on Prolia, and protect against fractures for a longer time after treatment stops. After Norway's rejection, Amgen and Glaxo lowered Prolia's price, according to Ms. Svanqvist. The NMA then ruled the health system would provide it for women 75 or older, for whom it appeared to work somewhat better, she said. A syringe of Prolia cost Norway \$260 in the third quarter. By the Journal analysis, that was 71% less than the \$893 paid by Medicare, which doesn't set an age test. Amgen said, "We partner with local payers in Europe to help ensure that all appropriate patients who could benefit will have access to an important new therapy." Glaxo referred questions to Amgen, to whom it sold Prolia's Norwegian marketing rights in 2014. If a manufacturer won't budge on price, Norway might refuse to cover a drug altogether. It did that with a brand of insulin called Tresiba. Producer Novo Nordisk A/S said Tresiba reduced nighttime dips in blood sugar better than other insulins and therefore was a good value. Ms. Svanqvist of the NMA called the documentation of this "quite lousy." "We think the reduction is actually quite low," she said, and not "worth paying 70% more for." A spokesman for Novo Nordisk said it believes the drug provides better outcomes and is therefore cost-effective. He also said Norway didn't ask the company to cut the price. The way things often work, said Ms. Svanqvist, is that when drug companies are told a product isn't cost-effective, they can provide more proof, and "if they don't

have better documentation they can only do something about the price. Very often they do something about the price.” Denying patients access to drugs can be contentious. When Norway last year declined to cover Roche’s injected breast-cancer drug Perjeta because of its cost, “patients and physicians were on television and demonstrating a lot,” Ms. Svanqvist said. Roche agreed to a discount provided the NMA kept the terms confidential, which it grudgingly agreed to do, according to Ms. Svanqvist. The agreement means Perjeta costs Norway less than the drug’s maximum allowed price in the country, which was \$3,579 for a vial in the third quarter. Medicare paid \$4,222. Roche said Perjeta has shown strong efficacy, and the firm and Norway reached an agreement to make it available. **While U.S. payers sound dire warnings of unsustainable drug pricing, the tone in Oslo is much calmer. “We have a system that has been working quite well,” said Helga Festoy, an economist at the NMA. Norway’s cost-effectiveness reviews sometimes cite[s] the work of England’s health-care cost watchdog, known as one of Europe’s toughest. England’s National Institute for Health and Care Excellence, or NICE, conducts extensive analyses and recommends that the taxpayer-funded health system not cover drugs providing low value. Sometimes after one is rejected, its maker offers a discount. England also controls prices by capping the level of National Health Service spending on drugs each year and requiring the pharmaceutical industry to reimburse the NHS for any spending over those limits. Of 40 branded drugs covered by Medicare Part B and also available in England in the third quarter, 98% were more expensive in the U.S., according to the Journal’s analysis of data from Medicare and the NHS’s Business Services Authority. For instance, two syringes of Cimzia, an anti-inflammatory for rheumatoid arthritis and other diseases, cost England’s health-care system \$1,117—less than half the \$2,357 Medicare paid, the Journal found. An NHS spokeswoman said prices it publishes are “indicative,” and vary in some situations. Cimzia is sold by Belgian company UCB SA. It didn’t respond to requests for comment. Canada doesn’t have a single large pharmaceutical payer, but drug prices are substantially lower nonetheless, held in check by regulation. A federal agency called the Patented Medicine Prices Review Board sets a maximum price for new drugs, based on factors including their therapeutic benefits and the prices in seven other countries—the U.S. and six European ones. Once a drug’s maximum price is set, the maker can’t raise it faster than the national inflation rate or above the highest price in the seven other countries. A separate body, the Canadian Agency for Drugs and Technologies in Health, recommends whether provincial and other government health programs should cover new drugs for the elderly or for low-income residents. Government agencies in Canada don’t cover most drug costs for most other people. One such program is run by Ontario’s Ministry of Health and Long-Term Care. Of 30 drugs that both it and Medicare Part B covered in the third quarter, 93% were more expensive in the U.S., according to the Journal’s analysis. Countries with national health systems tend to feel “we are all in this together” and “we can’t afford everything for everybody at any price,” said Steven Pearson, a physician who founded the Institute for Clinical and Economic Review, a Boston nonprofit that evaluates the cost-effectiveness of health care. “In America it’s more, ‘Well, I’ve paid my insurance premium and I don’t want anyone to tell me no. I don’t want anyone to get in the way of me and my doctor.’ ”**

Other countries have lower drug prices

David Lazarus, LA Times, "Yes, we can lower sky-high drug prices — other countries have done it - Los Angeles Times", July 25, 2017, <https://www.latimes.com/business/lazarus/la-fi-lazarus-drug-prices-20170725-story.html>

Scott Gottlieb, head of the Food and Drug Administration, wasted no time in his opening remarks at a forum last week on high drug prices. "The fact is that too many people can't afford the medicines that they need," he declared. On that, I hope, we can all agree. The trouble is doing something about it. **In all other developed countries, patients are protected by government authorities overseeing the market for prescription meds, ensuring that prices are reasonable while still allowing drug companies a fair profit. In the United States, profit comes before public interest.** There are no limits to how much can be charged for a prescription drug, particularly specialty drugs intended for the costliest illnesses. **As a result, the U.S. is by far the world's biggest spender on pharmaceutical products,** shelling out more than \$1,026 annually per person, according to a 2015 report from the Organization for Economic Cooperation and Development. That's **double the OECD average** of \$515 **and considerably more than economic peers** such as Germany (\$678), France (\$596) and Australia (\$590). Total U.S. spending on prescription drugs reached \$450 billion last year, according to the research firm QuintilesIMS. It could be as high as \$610 billion by 2021. The FDA has no power to dictate pricing to drug companies. So Gottlieb said last week that the agency will focus on speeding up the approval process for generic meds so consumers have cheaper alternatives to branded drugs. It also wants to encourage greater competition among

drug companies to lower prices. "These moves would help," said Peter Hilsenrath, a healthcare economist at the University of the Pacific. "But I wouldn't expect really big things to come of it." He pointed out to me that **generics already account for about 80% of U.S. drug sales, meaning that faster approval of generic meds wouldn't exactly be a game changer for the marketplace. "The big problem continues to be the prices of patented drugs,"** Hilsenrath said. Case in point: The same day that Gottlieb, a doctor when not running a federal agency, was calling for more affordable drug prices, the FDA gave its blessing to a new hepatitis C medication called Vosevi. It's the latest such drug from Gilead Sciences, which says Vosevi is for people who may not have seen strong results from the company's other blockbuster hepatitis C pills, Harvoni and Epclusa. The San Francisco Bay Area company plans to sell Vosevi for nearly \$25,000 a bottle, with three bottles required for 12 weeks of treatment — a total cost of about \$75,000. The company is no stranger to envelope pushing when it comes to the cost of its drugs. In 2013, it introduced its first hepatitis C drug, Sovaldi, at a price of \$1,000 a pill. Gilead execs argued at the time that the drug cured 98% of hep C patients who took it, so a thousand bucks a pill was still cheaper than treatment for expensive complications the virus can cause, such as liver failure and cancer. That may be true. But it's important to remember that Gilead didn't do the bulk of the research on Sovaldi. That was done by a pharmaceutical company called Pharmasset, which estimated in 2011 that a 12-week treatment regimen of its hep C drug would cost patients about \$36,000. Gilead paid \$11.2 billion to acquire Pharmasset in 2012 and immediately decided \$36,000 was much too cheap for a hepatitis cure. So it raised the price of a 12-week regimen to \$84,000.

That's the American way of drug pricing: Whatever the market will bear. Even if patients are treated as hostages. The International Federation of Health Plans said last year that a one-month supply of Gilead's Harvoni pill cost \$32,114 on average in the United States. The same amount of the same drug cost \$22,554 in Britain, \$18,165 in Spain and \$16,861 in Switzerland. How do other countries do it? Simple, said Jason Doctor, an associate professor at USC's School of Pharmacy. "**Developed countries keep their drug prices down through price controls,**" he said. First and foremost, other nations offer their citizens universal health coverage, achieved through variations of single-payer insurance systems. Basically, that's Medicare for everyone, not just seniors. This allows the government to keep rising drug prices in check by using its market clout as the biggest buyer of prescription meds. Incredibly, **Medicare has no such negotiating power. The government-run program is forbidden by law from haggling with drug companies over prices. Other nations also keep a close eye on what pharmaceutical companies charge in drugstores.** In **Canada**, for example, the Patented Medicine Prices Review Board **ensures that drug costs "are not excessive," which means companies can't gouge patients just because they can.** Canada also has a law requiring that breakthrough new drugs like Sovaldi can't be priced higher than the median price around the world, ensuring that the price for Canadians is fair relative to what people elsewhere are paying.

Money to Spare

In the US, profits typically are used for marketing – Not research

Jeanne **Whalen** (Jeanne Whalen writes and edits stories about health, science and the pharmaceutical industry in New York. She previously reported from the Journal's London and Moscow Bureaus. Jeanne Whalen is The Washington Post's global business reporter.), Wall Street Journal, "Why the U.S. Pays More Than Other Countries for Drugs - WSJ", December 1, **2015**, <https://www.wsj.com/articles/why-the-u-s-pays-more-than-other-countries-for-drugs-1448939481>

The higher U.S. prices also help drug makers afford hefty marketing budgets that in the U.S. include consumer advertising—something Europe doesn't allow. Pharmaceutical and biotechnology companies in the S&P 1500 earn an average net profit margin of 16%, compared with an average of about 7% for all companies in the index, according to S&P Capital IQ.

The industry focuses a lot of attention on advertisement

The Editorial Board (The editorial board is composed of journalists with wide-ranging areas of expertise. Their primary responsibility is to write The Times's editorials, which represent the voice of the board, its editor and the publisher. The board is part of the Opinion department, which is operated separately from The Times's newsroom, and includes the Letters to the Editor and Op-Ed sections. Michelle Cottle has covered Washington and national politics since the Clinton administration. She joined The Times in 2018 as the editorial board's national political writer after reporting on the nation's capital as a contributing editor for The Atlantic. Before that, Ms. Cottle was a senior writer at National Journal specializing in long-form profiles. From 2010 to 2014 she served as a Washington correspondent for Newsweek and the Daily Beast. Earlier, she was a longtime senior editor at The New Republic; some of her work there later appeared in "The Best American Political Writing of 2009." She also was an editor of The Washington Monthly magazine. Born and raised in the South, she has a B.A. in English from Vanderbilt University.), "Opinion | Turn the Volume Down on Drug Ads - The New York Times", November 27, **2015**, <https://www.nytimes.com/2015/11/27/opinion/turn-the-volume-down-on-drug-ads.html>

Watching television these days means sitting through ads for drugs to ease pain, induce sleep, overcome sexual dysfunction, alleviate depression, ease urinary tract symptoms and more. Some patients say the ads are helpful, but many **doctors warn that they are often misleading.** The American Medical Association's House of Delegates voted this month in favor of a ban on direct-to-consumer advertising of prescription drugs and medical devices. Its officers argued that **such advertising "inflates demand for new and more expensive drugs, even when these drugs may not be appropriate."** **Only two nations in the world, the United States and New Zealand, allow consumer drug ads.** A survey by the Kaiser Family Foundation published in late October found that a whopping **89 percent of the public favors requiring the Food and Drug Administration to review prescription-drug ads for accuracy before they are broadcast.** The F.D.A. currently does little to crack down on them, possibly fearing it would violate court rulings protecting commercial free-speech rights. **It has never imposed civil fines on a company for a misleading ad or promotion.** Supporters of the ads say they educate and inform patients about drugs their doctors might not mention, encourage discussions between doctors and patients, and can help patients take more responsibility for their own health care. But they can also lead to patients' demanding inappropriate drugs from their doctors. And they encourage the idea that there is a drug for every ill, even for conditions consumers might never have thought to treat. Decades ago, most drug ads appeared in medical journals, on the assumption that only medical professionals could weigh the risks, benefits and appropriate uses. In 1962, a law was passed that barred the F.D.A. from requiring prior approval for the content of drug ads. The agency concluded, after various court decisions, that it was also limited in its ability to crack down on ads already on the market. **By the mid-1990s, ads geared to consumers were on the rise.** Solutions other than an outright ban are being discussed, like proposals to tax the ads, which the courts might deem an infringement on commercial free speech. Another idea is to use public money to pay for evaluations by expert groups of the best ways to treat various conditions, which might emphasize dietary changes or exercise rather than drugs. That would provide unbiased information to counter the drug company ads. Or perhaps a television control device could allow consumers to block drug ads, if they want. David Vladeck, a law professor at Georgetown and former director of the Bureau of Consumer Protection at the Federal Trade Commission, believes Congress should ban direct-to-consumer advertising for two years after a drug has been approved and put on the market. That would allow a brief period for adverse effects to be observed and might pass constitutional muster as a limited restriction to protect public health. Meanwhile, **consumers need to be deeply skeptical of what they hear and read from drug companies.**

Companies are spending more on advertisement than they are on research – This completely negates their research argument

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Prescription drugs are a massive market: Americans spent \$329.2 billion on prescription drugs in 2013. That works out to about \$1,000 per person in the U.S., as John Oliver pointed out in his show on Sunday night. Oliver also mentioned that **nine out of 10 big pharmaceutical companies spend more on marketing than on research.** León Markovitz of Dadaviz found and graphed those figures from healthcare research firm GlobalData in the graphic below. The amounts spent on sales and marketing are shown in orange, while the amounts spent on research and development are in blue. The biggest spender, **Johnson & Johnson, shelled out \$17.5 billion on sales and marketing in 2013, compared with \$8.2 billion for R&D.** In the top 10, only Roche spent more on R&D than on sales and marketing. Most of this marketing money is directed at the physicians who do the prescribing, rather than consumers. As Oliver pointed out, **drug companies spent more than \$3 billion a year marketing to consumers in the U.S. in 2012, but an estimated \$24 billion marketing directly to health care professionals.** Oliver closed his segment with a hilarious spoof commercial that urges patients to ask their doctors how pharmaceutical marketing might be influencing them. "Ask your doctor today if he's taking pharmaceutical company money. Then ask your doctor what the money is for," the narrator says. **"Ask your doctor if he's taken any money from the companies who make the drugs he just prescribed for you. Then ask yourself if you're satisfied with that answer."**

Research doesn't play an effect on prices

An 18-month investigation found Sovaldi maximized revenue without concern for research, access, or affordability

Wyden-Grassley, (WYDEN, Ronald Lee, a Senator and a Representative from Oregon; born in Wichita, Sedgwick County, Kans., May 3, 1949; attended the public schools of Palo Alto, Calif.; A.B., Stanford University 1971; J.D., University of Oregon Law School in Eugene 1974; director, Oregon Legal Services for the Elderly 1977-1979; public member, Oregon State Board of Examiners of Nursing Home Administrators 1977-1979; elected as a Democrat to the Ninety-seventh and to the seven succeeding Congresses, and served from January 3, 1981, to February 5, 1996, when he resigned, having been elected to the Senate; elected to the Senate in a special election on January 30, 1996, to fill the unexpired portion of the term ending January 3, 1999, left vacant by the resignation of Robert W. Packwood, and began service on February 5, 1996; reelected in 1998, 2004, 2010, and again in 2016 for the term ending January 3, 2023; chair, Committee on Energy and Natural Resources (One Hundred Thirteenth Congress [January 3, 2013-February 12, 2014]), Committee on Finance (One Hundred Thirteenth Congress [February 12, 2014-January 3, 2015]), GRASSLEY, Education: B.A. 1955, M.A. 1956 Political Science, University of Northern Iowa; Ph.D. work, University of Iowa. Memberships: Farm Bureau, the Butler County and State of Iowa Historical Societies, Pi Gamma Mu, Kappa Delta Pi, International Association of Machinists 1962-71, Masons, Eagles, Baptist Church. Committees: Judiciary (Chairman), Finance, Budget, Agriculture, Joint Tax, Senate Caucus on International Narcotics Control (Chairman), Senate Caucus on Foster Youth (Co-Chair)). United States Senate Committee on Finance, "Ranking Member's News | Newsroom | The United States Senate Committee on Finance", December 1,

2015, <https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug>

WASHINGTON – Senate Finance Committee Ranking Member Ron Wyden, D-Ore., and senior committee member Chuck Grassley, R-Iowa, today released the results of an 18-month investigation into the pricing and marketing of Gilead Sciences' Hepatitis C drug Sovaldi and its second-wave successor, Harvoni. **Drawing from 20,000 pages of internal company documents, dozens of interviews with health care experts, and a trove of data from Medicaid programs in 50 states and the District of Columbia, the investigation found that [Gilead Science] the company pursued a marketing strategy and final wholesale price of Sovaldi – \$1,000 per pill, or \$84,000 for a single course of treatment – that it believed would maximize revenue. Building on that price, Harvoni was later introduced at \$94,500. Fostering broad, affordable access was not a key consideration in the process of setting the wholesale prices. In the 18 months following Sovaldi's approval, Medicare spent nearly \$8.2 billion before rebates on Sovaldi and Harvoni. Over that same span, Medicare's monthly spending on Hepatitis C treatments increased more than six-fold. In 2014 alone, Medicare and Medicaid combined to spend more than \$5 billion on Sovaldi and Harvoni before rebates.** That total is projected to climb in 2015. Gilead's recent financial statements show U.S. sales of Sovaldi and Harvoni, including through public programs and private payers, totaled \$20.6 billion after rebates in the 21 months following Sovaldi's introduction. Senators Wyden and Grassley will hold a press conference today at 11:15 a.m. in the Senate Radio/TV Gallery, S-325, to discuss the investigation. Details are below, including a streaming feed for media unable to attend in person. Further resources are also online and additional findings from the investigation are below. Video of the press conference can be found here.

"Gilead pursued a calculated scheme for pricing and marketing its Hepatitis C drug based on one primary goal, maximizing revenue, regardless of the human consequences. There was no concrete evidence in emails, meeting minutes or presentations that basic financial matters such as R&D costs or the multi-billion dollar acquisition of Pharmasset, the drug's first developer, factored into how Gilead set the price. Gilead knew these prices would put treatment out of the reach of millions and cause extraordinary problems for Medicare and Medicaid, but still the company went ahead. If Gilead's approach to pricing is the future of how blockbuster drugs are launched, it will cost billions and billions of dollars to treat just a fraction of patients," Senator Wyden said. **"America needs cures for cancer, Alzheimer's, diabetes and HIV. If those cures are unaffordable and out of reach to millions who need them, Congress will not have met its responsibilities to the American people. I reject the idea that America has to choose between soaring, out-of-reach drug prices and one-size-fits-all government policies. Solving this challenge will take fresh, bipartisan thinking and political independence to bring people together."**

R&D alone does not explain the elevated cost of drugs in the United States

Nancy L. **Yu**, Zachary **Helms** & Peter B. **Bach** (Nancy Yu, BA, MBA, is a financial and biopharma industry analyst at the Center for Health Policy and Outcomes at Memorial Sloan Kettering Cancer Center (MSKCC). Her work focuses on financial and policy analyses that support the value and accessibility of prescription drugs. Prior to joining MSKCC, Yu spent more than 10 years working in the health care investment industry, eight of which was in the equity research department at Morgan Stanley. In addition to her time as a sell-side analyst, Yu was the global pharmaceuticals analyst for a hedge fund and served as chief operating officer for a start-up health care investment firm. Zachary Helms is a project coordinator at the Center for Health Policy and Outcomes at Memorial Sloan Kettering Cancer Center in New York City. Peter B. Bach, MD, MAPP, director of Memorial Sloan Kettering's Center for Health Policy and Outcomes, is a physician, epidemiologist, researcher, and respected health care policy expert. Dr. Bach's work focuses on the cost and value of anticancer drugs, leading efforts to increase understanding of the US drug development process and develop new models for drug pricing that include value to patients. Dr. Bach's work in lung cancer screening has led to the development of several lung cancer screening guidelines and one of the first-ever risk-prediction models for this disease. He has also proposed a number of strategies for Medicare to link payment to the value of health care services delivered. Dr. Bach has been inducted into the National Academy of Medicine, the American Society of Clinical Investigators, and the Johns Hopkins University Society of Scholars. He served as a senior adviser for cancer policy at the Centers for Medicare and Medicaid Services in 2005 and 2006.), Health Affairs, "R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices", March 7, **2017**, <https://www.healthaffairs.org/doi/10.1377/hblog20170307.059036/full/>

That pharmaceutical companies charge much more for their drugs in the United States than they do in other Western countries has contributed to public and political distrust of their pricing practices.

When these higher US prices (which are sometimes cited as being two to five times the prices in Europe) are challenged, the pharmaceutical \$\$\$ industry often explains that the higher prices they charge in the US provide them with the funds \$\$ they need to conduct their high-risk research. This claim—that premiums earned from charging

US patients and taxpayers more for medications than other Western countries funds companies' research—**is empirically testable.**

Pharmaceutical companies report their Research and Development (R&D) expenses in public filings, and both they and numerous other sources report a mix of information on their drugs' prices and sales volumes in the US and other Western countries. These data allowed us to quantify both the premium companies earn and the amount they spend on research. We then assessed the relation between the two. Top-Selling Drugs

We focused our analysis on the 15 drug companies that manufactured the 20 top-selling drugs

globally for 2015. For each company individually and all companies collectively, we estimated how much excess revenue they generated as a result of the higher prices they charged for their products in the US compared to some referent European countries and Canada. For each of the manufacturers, we first derived a company level average by examining the US price premium for each drug in that company's portfolio that contributed 5 percent or more to US product sales, thus all of the top 20 drugs we had used to identify the companies in our sample were included in the calculation of each company's average. Once we calculated the average premium compared to the prices of those same products in the referent countries, we applied this premium percentage across each company's US pharmaceutical revenue base. This gave a proxy for the amount of total US revenue that resulted from US premium pricing. We then compared the amount of "excess revenue" to each company's worldwide spending on R&D. US prices came from July 2016 average sales price (ASP) files for physician administered drugs and the September wholesale acquisition costs (published in Truven Health's Redbook) for retail drugs, the latter of which was reduced by each company's reported average gross-to-net adjustment. This reduction incorporates in a pooled manner discounts and rebates the company provides to payers, Medicaid, 340B hospitals, and the Veterans Administration as well as other channel intermediaries. Non-US prices came from four countries with reliable and publicly available pricing: Canada, Denmark, Ireland, and the United Kingdom (UK). The British National Formulary was the primary source for UK drugs; the MIMS database for those that were not included. Canadian prices were pulled from both Quebec and Ontario, and we selected the higher in each case. Irish prices are published in the Irish Medicines Formulary, Danish prices from the Danish Medicine Agency's Medicinepriser. Rebates and discounts are also offered by drug companies in these other countries, but their magnitude is not published. Therefore, we used the drugs' list prices in these other countries, a conservative assumption that serves to lessen our estimate of the premium companies earn through charging higher prices to US patients (we did incorporate the estimate of rebates companies offer in US markets). An Outsized Premium List prices in other developed countries average 41 percent of US net drug prices (Exhibit 1) for the 15 companies that sell the 20 top-selling drugs in the US, with a range from 38 percent in the UK to 52 percent in Denmark. Overall in 2015 the premium earned by US net prices exceeding other countries' list prices generated \$116 billion, while that year the companies spent just 66 percent of that amount, or \$76 billion, on their global R&D. This relation between the level of global R&D spending and the excess revenues earned through premium pricing varied among the companies (Exhibit 1), but averaged 163 percent. The premium earned by Bristol-Myers equaled around 76 percent of its global R&D budget in 2015; it essentially matched global R&D spending for Novartis and Astra-Zeneca. By contrast, Amgen, Biogen, Pfizer, and Teva generated more than double their global R&D budgets, and three companies covered or nearly covered their research spending through premium pricing of just their top-selling product: AbbVie with Humira, Biogen with Tecfidera, and Teva with Copaxone. The magnitude by which the revenues earned through premium pricing exceeded global R&D spending appeared larger for US-based pharmaceutical companies than those based outside the US. However, the average ratio for companies domiciled both within and outside the US exceeded 1.0, as domestic companies generated 176 percent of their global R&D spending from US premium pricing; foreign companies generated 143 percent. This gap is mostly due to the fact that non-US companies generally earn a smaller fraction of their revenues

in the US than US-domiciled companies. The average differential between US and non-US prices was the same irrespective of domicile. Exhibit 1: Excess Revenues Earned Through Premium Pricing Of Products In The US As A Percentage Of The Company's Global Research And Development Expenditures, 2015 Comment **We found that the premiums pharmaceutical companies earn from charging substantially higher prices for their medications in the US** compared to other Western countries **generates substantially more than the companies spend globally on their research and development.** **This finding counters the claim that the higher prices paid by US patients and taxpayers are necessary to fund research and development. Rather, there are billions of dollars left over even after worldwide research budgets are covered.** To put the excess revenue in perspective, lowering the magnitude of the US premium to a level where it matches global R&D expenditures across the 15 companies we assessed would have saved US patients, businesses, and taxpayers approximately \$40 billion in 2015, a year for which the Centers for Medicare and Medicaid Services (CMS) reported that total US spending on pharmaceuticals was \$325 billion. Although **we can conclude that premium pricing exceeds what is needed to fund global R&D,** our analysis does not address whether prices in European countries or in the US are appropriate. We do know that all of the European countries included in our analysis use pharmacoeconomic analyses in their price negotiations, while this cannot be said of the US. Importantly, our analysis cannot inform the question whether or not it is appropriate for US patients, taxpayers, and businesses to bear the burden of funding pharmaceutical research for the world. Exhibit 2: Revenues Earned From US Premium Pricing And Global Spending On Research And Development Of The 15 Pharmaceutical Companies Responsible For The World's 20 Top-Selling Products In 2015 Author's Note Dr. Bach reports personal fees from Association of Community Cancer Centers, personal fees from America's Health Insurance Plans, personal fees from AIM Specialty Health, personal fees from AMERICAN COLLEGE OF CHEST PHYSICIANS, personal fees from American Society of Clinical Oncology, personal fees from BARCLAYS, personal fees from Defined Health, personal fees from EXPRESS SCRIPTS, personal fees from GENENTECH, personal fees from GOLDMAN SACHS, personal fees from McKinsey and Company, personal fees from MPM Capital, personal fees from National Comprehensive Cancer Network , personal fees from Biotechnology Industry Organization, personal fees from The American Journal of Managed Care., personal fees from The Boston Consulting Group, personal fees from Foundation Medicine, personal fees from Anthem Inc., personal fees from Novartis, personal fees from Excellus Health Plan, grants from NIH Core Grant P30 CA 008748 , grants from Kaiser Foundation Health Plan, grants from Laura and John Arnold Foundation, outside the submitted work.

Limit Political Power of Pharmaceutical Companies

Pharmaceutical companies put more money into influencing politics than any other industry.

Chris **McGreal**. "How big pharma's money – and its politicians – feed the US opioid crisis" The Guardian. 19 Oct **2017**. <https://www.theguardian.com/usnews/2017/oct/19/big-pharma-money-lobbying-us-opioid-crisis>

"Trump was right on both counts. Pharmaceutical companies spend far more than any other industry to influence politicians. Drugmakers have poured close to \$2.5bn into lobbying and funding members of Congress over the past decade. Hundreds of thousands of dollars have gone to McConnell – although he is hardly alone. Nine out of 10 members of the House of Representatives and all but three of the US's 100 senators have taken campaign contributions from pharmaceutical companies seeking to affect legislation on everything from the cost of drugs to how new medicines are approved. Trump's nominee for drug czar, the US congressman Tom Marino, was forced to withdraw after a report by the Washington Post and CBS's 60 Minutes highlighted his role in forging legislation that hinders the DEA's ability to move against drug distributors or pharmacies recklessly dispensing the opioid painkillers at the heart of the epidemic, which claims more than 100 lives a day."

The immense power of the pharmaceutical lobbying industry allows them to shut down virtually any attempt to reduce pharmaceutical prices

Henry **Mintzberg**, "Patent nonsense: Evidence tells of an industry out of social control" Aug 15 **2006**, US National Library of Medicine, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1534100/>

"Beyond these problems of promotion lie a litany of stories revealed in the press in recent years about immoral and sometimes corrupt behaviours of pharmaceutical companies, including ostensibly the most reputable: about payoffs to generic producers not to rush in with cheaper drugs; about tactics used to delay the expiry of patents; about lawsuits and convictions, criminal and otherwise, concerning marketing fraud and the overbilling of government agencies; about blatant misinformation; about the co-optation and sometimes downright bribery of physicians, researchers and politicians. Examples of these behaviours, from articles in the prominent press and some major medical journals, are provided in Appendix 1. Together, they tell a story of an industry that is out of social control. The problem of high pharmaceutical prices is not without solutions. Many are obvious enough, and some have been implied in this article, including firmer regulation of pricing, the use of independent clearinghouses for balanced information on products, research efforts more widely spread across different types of institutions, and a stop to direct-to-consumer advertising. However, there is a lack of sufficient will to confront the problem directly, in part because of the power of the industry and its influence on political processes. The current situation in the patent-dependent pharmaceutical industry is not just unacceptable, it is shameful. It will remain so until concerned citizens gather the energy to change it."

Price controls would cut into the profits of the pharmaceutical industry, reeling in their excessive political power.

Neeraj **Sood**, "The effect of regulation on pharmaceutical revenues: experience in nineteen countries", National Institute for Health, Dec 16 **2008**, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3829766/>

"Several important patterns emerge from our analysis. First, we find that a majority of regulations reduce pharmaceutical revenues significantly. Second, we find that most countries that adopted new regulations since 1994 already had some regulations in place for controlling costs. We find that such additional regulation had smaller impact on further controlling costs, though this is an average effect across all regulations introduced since 1994, including both enforced and poorly or un-enforced policies. However, we find that introducing new regulations in a largely unregulated market, for example the US, could reduce

pharmaceutical revenues significantly. Finally, we show that the effects of price controls increase over time – price controls not only reduce the level of pharmaceutical revenues but also reduce the rate of growth of pharmaceutical revenues.”

The pharmaceutical lobby’s immense power has contributed significantly to the opioid crisis in America.

Robert Pearl, Forbes, “Why Patent Protection In The Drug Industry Is Out Of Control”, Jan 19 2017, <https://www.forbes.com/sites/robertpearl/2017/01/19/whypatent-protection-in-the-drug-industry-is-out-of-control/#25a7a30478ca>

“For more than a decade, members of a little-known group called **the Pain Care Forum have blanketed Washington with messages touting prescription painkillers’ vital role in the lives of millions of Americans, creating an echo chamber that has quietly derailed efforts to curb U.S. consumption of the drugs**, which accounts for two-thirds of the world’s usage. **In 2012, drugmakers and their affiliates in the forum sent a letter to U.S. senators promoting a hearing about an influential report on a “crisis of epidemic proportions”: pain in America. Few knew the report stemmed from legislation drafted and pushed by forum members and that their experts had helped author it.** The report estimated more than 100 million Americans — roughly 40 percent of adults — suffered from chronic pain, an eye-popping statistic that some researchers call deeply problematic. **The letter made no reference to another health issue that had been declared an epidemic by federal authorities: drug overdoses tied to prescription painkillers. Deaths linked to addictive drugs like OxyContin, Vicodin and Percocet had increased more than fourfold since 1999, accounting for more fatal overdoses in 2012 than heroin and cocaine combined.”**

Pharmaceutical lobbying shapes government healthcare policy in negative ways to perpetuate pharmaceutical profits.

Laurie Powell, “The Danger Of Big Pharma ’s Silent Hold Over The US Government”, May 2 2016, Focus For Health, <https://www.focusforhealth.org/big-pharma-silenthhold-us-government/>

“Pharmaceutical companies are some of the richest, most profitable companies in the world. Besides using profits to advertise products and influence prescription-writing target markets, **Pharma spends extraordinary amounts of money on patents to protect their profit margins. Some cancer treatments can cost 600 times more in the U.S. than in other countries — and this form of price gouging remains legal in the U.S.**¹ Unfortunately for consumers, **the game is rigged in Pharma’s favour, as they buy this privilege by lobbying government representatives.** Lobbying expenditures by the pharmaceutical industry have been increasing every year and hit an all-time high of \$273 million in 2009. **Monies are used successfully to influence lawmakers and politicians and shape pending legislature. Since 2003, Medicare, the biggest drug purchaser in the US, cannot negotiate drug pricing. As a result, some of the most disenfranchised patients pay high co-pays, and tax payers are forced to cough up billions in taxes to subsidize Medicare drug spending. Another example of how pharmaceutical companies spend their money to influence government**, thanks to legislation passed in 1988. If a suit is won in the government-funded ‘vaccine court,’³ those cases are sealed so the public cannot see judgements or payouts to victims.⁴”

State Level Action

Several states have launched fair pricing bills

Berman, Aaron, Global Health Justice Partnership of the Yale Law School and the Yale School of Public Health, "Curbing Unfair Drug Prices - A Primer for States", **2017**, https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf

As an example of the first approach, **a recent bill passed in Maryland prohibits “unconscionable” price increases for essential generic drugs and drug-device combinations used to deliver generic drugs.**⁴³ **The Maryland bill requires manufacturers that impose significant price increases to provide a justification for such increases** to the Attorney General, **specifying an increase of over 50% in one year as a suggested benchmark for a significant increase.**⁴⁴ **The Attorney General**, in turn, **may** petition the Circuit Court to enjoin an “unconscionable” price increase, restore money to patients and third-party payers, and **impose a penalty on the manufacturer.**⁴⁵ **Similar bills have been proposed in Massachusetts, Montana, Oregon, Rhode Island, and Tennessee.**⁴⁶ A recent bill passed in **New York takes the second approach. It sets a Medicaid expenditure cap** by directing the state Department of Health to require manufacturer rebates for drugs which would otherwise exceed the Department’s projected spending targets.⁴⁷ **The bill instructs the state Department of Health to make annual projections for Medicaid drug spending, and to assess, on a quarterly basis, whether drug expenditures will exceed these targets.**⁴⁸ **If overall spending is anticipated to exceed these targets, the Department may negotiate additional supplemental Medicaid rebates for specific drugs from drug manufacturers.**⁴⁹ If an agreement cannot be reached, the drug may be referred to the state’s Drug Utilization Review Board for review, further manufacturer negotiations, and possibly formulary and prior authorization sanctions.⁵⁰ **These bills are very significant: they represent path-breaking efforts to address drug prices, and show that such laws can be enacted at the state level.** But they are also limited – Maryland by its focus on generic drug price increases and lack of public disclosure of information collected by the Attorney General, and New York by its limitation to Medicaid. In other states, such as Massachusetts and Oregon, ambitious bills targeting all prescription drugs, whether patented or generic, are still pending as of this writing.⁵¹

State Budgets

High drug prices force state tax increases and program cuts

Kimberly Leonard, 9-25, 15, <https://www.usnews.com/news/the-report/articles/2015/09/24/expensive-drugs-a-drag-on-consumers-and-government> Budget Breakers

While consumers are feeling the pinch of the prices of drugs, federal and state governments are struggling as well. Public payers like Medicare, Medicaid, the Department of Veteran's Affairs and state correctional facilities have all had challenges in handling the cost of drugs. **"It's unsustainable,"** says Gregg Gonsalves, co-director of the Global Health Justice Partnership at Yale Law School. **"Over time we are going to have to figure out a way through it and not put the burden on the taxpayer to funnel this back to the drug industry."** **To make room in the budget for needed drugs, states will either have to raise taxes or sacrifice other programs.** **"If your costs spike in one area you have to figure out where to tamp those costs elsewhere,"** says Mark Salo, executive director of the National Association of Medicaid Directors. **"That could mean less money for kids or seniors, or higher taxes or cutting from education**. None of those are ideal situations but that's what states struggle with."

Increases in state spending are massive

Kimberly Leonard, 9-25, 15, <https://www.usnews.com/news/the-report/articles/2015/09/24/expensive-drugs-a-drag-on-consumers-and-government> Budget Breakers

At the time the letter was written, several states reported that their first quarter 2014 prescription drug spending was two or three times more than their entire spending in 2013, largely because of the hepatitis C cures. NATIONAL ACADEMY FOR STATE HEALTH POLICY, OCTOBER 2016, States and the Rising Cost of Pharmaceuticals: A Call to Action <https://nashp.org/wp-content/uploads/2016/10/Rx-Paper.pdf> NASHP convened a Pharmacy Costs Work Group of state leaders from governors' staffs, state legislatures, Medicaid, public employees health insurance programs, offices of attorneys general, state-based insurance exchanges, comptrollers' offices and corrections departments. **"Your state taxes are underwriting state institutions that provide health care,"** Gonsalves says. **"Some of it goes toward paving the roads and making sure the buses are running, but part also goes to health care systems and to the drug companies themselves."** **States have a big stake in the rising costs of pharmaceuticals.** They have broad regulatory responsibilities for consumer protection and they are significant purchasers of pharmaceuticals for Medicaid, corrections, public employees, and higher education constituents. In 2013, the cost to insure 2.7 million public employees and their families was \$31 billion, including employee contributions. Assuming public employer plans reflect those in the private sector, **drug spending makes up 19 percent of health plan costs.** Medicaid now covers 70 million beneficiaries, making it the largest insurer in the country, and it spent \$27 billion in 2014 on outpatient drugs (state and federal share), including rebates and managed care plans. **After years of slow growth, spending on drugs increased 24.6 percent in states that expanded Medicaid and 14.1 percent in non-expansion states.** Drug coverage now represents 6 percent³ of total Medicaid spending, and this does not include the cost of physician-administered drugs.⁴ Additionally, **states face significant costs for prescription drugs used to treat inmates in state corrections institutions, accounting for nearly \$8 billion in spending 2011.**¹ This figure did not include new, costly drugs such as new Hepatitis C medications. States have worked hard to contain the cost of prescription medicines by employing strategies, summarized in an earlier National Academy for State Health Policy (NASHP) paper,⁶ such as negotiating supplemental rebates for Medicaid programs, implementing preferred drug lists (PDL) and utilizing pharmacy benefits managers and more.⁷ **Despite these efforts to maintain affordability, drug pricing and the unpredictability of price increases continues to vex state budgets.**

Depleted state budgets slow economic growth and ensure pension crisis

Donlan 17 [Thomas G. Donlan, editor at Barron's, "There's a Hole in State Pensions," Feb 11, 2017, <http://www.barrons.com/articles/theres-a-hole-in-state-pensions-1486794298>]

Turn away from the lurid deficit spectacles in Washington to **examine the declining state of the states**. In the eighth year of economic recovery, **23 states are still deep in the financial holes** they dug for themselves. **Economic growth and tax-revenue**

growth are slowing. Revenue growth from sales taxes—which are most sensitive to changing economic conditions—**have slowed the most**, according to the National Association of State Budget Officers. The executive director of that organization explains and complains that online sales across state lines—more popular every year—are often not taxed. Every state has a different tax system, a different tax base, and a different political inclination toward taxes and spending. But **slow growth in tax revenue in general has placed many under serious fiscal pressure**. In a report on states' fiscal health issued on Feb. 2, the Pew Charitable Trusts said that after adjusting for inflation, **23 states still have lower tax revenue than they did before the most recent recession, and 18 states have lower employment** than they did in 2007. Only 19 states have the kind of fiscal cushion—rainy-day funds and general fund surpluses—that they had in 2007.

Analysts at Pew and other watchdog groups are warning that the **states are clearly not ready for another recession**. MultiState Associates, a consulting firm, estimates **31 state legislatures will have revenue shortfalls to deal with before their next budgets go into effect**. The Cavalry Isn't Coming **The states may wish to call Washington for help**, but Congress and the White House are busy with their own fiscal quandaries. Newly empowered Republicans want to cut taxes, increase defense and infrastructure spending, and repeal Obamacare to replace it with something better—just to mention a few expensive proposals that nearly all Republicans agree on. All this and more, despite a \$559 billion deficit projected for fiscal 2017. **There's no room for helping out the states**, and plenty of reasons to say the states are getting more than enough help already. The federal government provides nearly a third of the states' total revenues, but the federal hand is far more important than direct grants, which totaled \$589 billion in 2014. The same year, the federal government paid out \$1.1 trillion in retirement benefits and \$895 billion in other benefits, chiefly medical, for individuals located in the 50 states. The U.S. government paid its own military and civilian employees \$305 billion, and it paid \$356 billion on federal contracts. Nearly all of that federal spending is subject to income tax in states that have income taxes, and the **recipients use federal money to buy things, generating revenue for states that have sales taxes**. Pension Panic Beyond the unfortunate short-term dependence of many states on money that falls from the federal heavens, there are the unfortunate longer-term policies of their own that have put many states in fiscal trouble. Chief among these is **the growing crisis in state and municipal pension funds**. Importantly, the condition of state and local pensions **is worse than officially reported**. Pension boards, their advisors, and their actuaries have been using unrealistic estimates of their investment returns that are left over from the years of higher inflation that ended in the 1990s. The National Association of State Retirement Administrators surveyed 132 big government pension plans last year and found the average estimate of future annual investment returns—the discount rate—to be 7.6%. Hard-nosed reformers say they should be using a Treasury rate around 3%, but only seven of the funds in the survey were using discount rates below 7%. The difference is powerful: **The funds pretend their investments are strong and that they are a mere \$1 trillion short of what they will need to pay benefits that workers have already earned. Cutting the 7.6% investment estimate back to 3% turns the \$1 trillion deficit into a \$3 trillion hole. Officials** around the country **are loath to acknowledge the mismatch**, and government plans aren't covered by federal pension law that would make them fess up.

Pension officials can use whatever discount rate suits their needs. **Excuses abound: Governments don't go out of business; they have taxing power; they can hold on for a long time before wolves chew their way through the door**. This is the Micawber theory of management. Wilkins Micawber, a colorful character in Charles Dickens' David Copperfield, is a grandiose optimist always flirting with poverty, whose financial maxim is "Something will turn up." Like the author's father, he spends some time in debtors' prison. But, being a charming Dickensian character, something does turn up for him eventually. **Actuaries should not be so sanguine**, but many know about getting by going along. They want to keep their jobs. The Montana pension systems spoke loudly in 2009 when they were looking for new actuaries. The invitation to actuaries said that a firm arguing for tougher standards "may be disqualified from further consideration."

Slow growth makes war more likely – drives tensions and hyper-nationalism

Landsay 17 Jonathan Landay, National Security Correspondent at Thomson Reuters. U.S. intelligence study warns of growing conflict risk <http://www.reuters.com/article/us-usa-intelligence-future/u-s-intelligence-study-warns-of-growing-conflict-risk-idUSKBN14T1J4>

The report also said that **while globalization** and technological advances **had "enriched the richest"** and raised billions from poverty, **they** had also **"hollowed out" Western middle classes and ignited backlashes against globalization. Those trends have been compounded by** the largest migrant flows in seven decades, which are stoking **"nativist, anti-elite impulses."** **"Slow growth** plus technology-induced disruptions in job markets **will** threaten poverty reduction and **drive tensions within countries in the years to come, fueling the very nationalism that contributes to tension between counties,"** it said.

Cuts undermine education reform and the economy

Leachman and Mai, '14 Michael (Director of State Fiscal Research with the State Fiscal Policy division of the Center on Budget and Policy Priorities) and Chris (Intern at the Center on Budget and Policy Priorities), "Most States Funding Schools Less Than Before the Recession", 5-20-14, Center on Budget and Policy Priorities, <http://www.cbpp.org/cms/?fa=view&id=4011>

The cuts undermine education reform and hinder school districts' ability to deliver high-quality education, with long-term negative consequences for the nation's economic competitiveness. Many states and school districts have undertaken important school reform initiatives to prepare children better for the future, but **deep funding cuts hamper their ability to implement many of these reforms.** At a time when producing workers with high-level technical and analytical skills is increasingly important to a country's prosperity, large cuts in funding for basic education threaten to undermine the nation's economic future.

Californian state budget crisis destroys industrial base and power projection

Gvosdev 3 (Nikolas, Editor – National Interest, The National Interest, Vol. 2, Issue 30, 8-13, <http://www.inthenationalinterest.com/Articles/Vol2Issue32/Vol2Issue32Realist.html>)

But the real issue is this: people "inside the Beltway" sometimes seem to forget that **there is no "United States" apart from the fifty states** (and associated territories and commonwealths). **A fiscal and economic crisis in California has a direct impact on the power of the United States,** since some 13 percent of the total U.S. output is produced by California. California on its own is the sixth largest economy in the world, worth some \$1.309 trillion--yet this represents a decline of approximately 2.3 percent from 2000, when California's economy outperformed that of France. **California represents a significant share of the country's technological base and of its human capital. The high-tech weaponry which led to a swift initial military victory in Iraq is in part a product of the technology and defense sectors of the California economy. A state budget crisis that significantly cuts back on everything from education** (including higher education, where so many innovative breakthroughs have taken place) **to health care has ramifications for how the United States projects its influence throughout the world.** In previous issues of *In the National Interest*, other authors have pointed out the dangerous implications of continued deficit spending by the federal government to support overseas operations, and this problem can only increase if a continuing crisis in the principal engine of America's economy continues. And, of course, California is the bellweather for the nation as a whole. Twenty-nine states have either passed or are considering tax hikes to close budget deficits. Several states--including Hawaii, Georgia and North Carolina--will call special fall sessions of their legislatures to deal with the fact that collected taxes have fallen short of budget projections. Yet the attitude is that the recall in California is amusing political comedy, nothing more. There seems to be almost no recognition of the fact that whoever sits in the governor's chair after October 7 --whether Grey Davis survives or is "terminated" --must work quickly to solve the problems that have led California into its current quagmire. Few other countries in the world would be so blasé if political turmoil and economic collapse threatened the welfare of a key component of its national power. The California crisis reminds us that there is no neat line dividing "domestic" and "foreign" policy. Ensuring that California survives its current crisis is no less a priority than stabilizing Iraq or containing North Korea

Neoliberalism Bad

Neoliberalism has negative results

Birch, Kean & Siemiatycki, Matti (Kean Birch has held the following positions: Editorial Positions 2018 - Editorial Board Member, *Science, Technology & Human Value* 2014 - Editorial Board Member, *OMICS: A Journal of Integrative Biology* 2007 - Co-Editor, *Science as Culture* (from 2018, previously Associate Editor, 2007-2018) Current Affiliations 2017 - Associate Professor, Department of Geography, York University, Canada (previously Assistant Professor & Associate Professor, Business & Society Program, Department of Social Science, York University) 2016 - Senior Associate, Innovation Policy Lab, Munk School of Global Affairs, Toronto University, Canada Previous Affiliations 2008 – 2017 Coordinator, Neoliberalism Working Group, International Initiative for Promoting Political Economy 2009 – 2011 Lecturer in Human Geography, School of Applied Social Sciences (formerly Department of Geography & Sociology), University of Strathclyde, Glasgow 2005-2009 Research Fellow, Centre for Public Policy for Regions, University of Glasgow 2002-2007 PhD, Department of Planning, Oxford Brookes University 1999-2000 MSc, Science Studies Unit, University of Edinburgh 1995-1999 MA (Hons), <https://docs.house.gov/meetings/PW/PW00/20140408/102097/HMTG-113-PW00-Bio-SiemiatyckiM-20140408.pdf>), Department of Sociology, University of Edinburgh, *Progress in Human Geography*, Vol. 40 Issue 2, "Neoliberalism and the geographies of marketization: EBSCOhost", April **2016**, <http://ezproxy.olympic.edu:2223/ehost/detail/detail?vid=0&sid=a686dc8b-f247-4d8c-b8e5-52ee22cd3bd8%40sessionmgr104&bdata=JnNpdGU9ZWwhvc3QtGIZZQ%3d%3d#AN=113948533&db=ap>h

Neoliberalism is conceived as the insertion or installation of markets as the underlying institution or mechanism for organizing society.

For example, David [37] : 3) characterizes neoliberalism as **the ascendance of a 'market ethic' in which 'contractual relations in the marketplace' are deemed the most efficient and most ethical means to organize**

society. This installation of markets as the organizing force in society entails a necessary role for the state. As [74] : 167–8) point out: 'More often than not, **the practice of neoliberalism has little to do with laissez-faire deregulation...but instead is associated with the extensive deconstruction and reconstruction of institutions, often in the name of or in the image of "markets"**.' This means that neoliberalization is better understood as the 'mobilization of state power in the contradictory extension and reproduction of market(-like) rule' (2003: 166, emphasis in original). **Consequently, neoliberalization**

has led to 'a tangled web of state-regulated oligopolies, profit-orientated enclaves and pseudo markets' (2003: 167). While several geographers have taken up the task of untangling this mess, as we will outline below, it is surprising that so few have sought to grapple conceptually with the diversity and variety of the processes, outcomes, forces and agents at work in this 'mobilization of state power' to extend markets, or marketization. In focusing on marketization – or, more accurately, marketizations – it is our intent to explore analytically the how and why of this 'state mobilization'.

Unregulated market competition makes economic collapse, inequality and extinction inevitable

Wise et al. 10 (Director of Doctoral Program in Migration Studies & Prof of Development Studies; Universidad Autónoma de Zacatecas, Mexico)

(Raúl Delgado Wise, Humberto Márquez Covarrubias, Rubén Puentes, Reframing the debate on migration, development and human rights: fundamental elements, October, 2010, www.migracionydesarrollo.org)

At the end of the first decade of the 21st century, a general crisis centered in the United States affected the global capitalist system on several levels (Márquez, 2009 and 2010). The consequences have been varied: Financial. **The overflowing of financial capital leads to speculative bubbles that affect the socioeconomic framework and result in global economic**

depressions. Speculative bubbles involve the bidding up of market prices of such commodities as real estate or electronic innovations far beyond their real value, leading inevitable to a subsequent slump

(Foster and Magdof, 2009; Bello, 2006). Overproduction. Overproduction crises emerge when the surplus capital in the global economy is not channeled into production processes due to a fall in profit margins and a slump in effective demand, the latter mainly a consequence of wage containment across all sectors of the population (Bello, 2006). Environmental. **Environmental degradation, climate change**

and a predatory approach to natural resources contribute to the destruction of the latter, along with a fundamental undermining of the material bases for production and human reproduction (Fola-dori and Pierri, 2005; Hinkelammert and Mora, 2008). Social. **Growing social inequalities**, the dismantling of the welfare state and dwindling means of subsistence **accentuate problems such as poverty, unemployment, violence, insecurity** and labor precariousness, increasing the pressure to emigrate (Harvey, 2007; Schierup, Hansen and Castles, 2006). **The crisis raises questions about the prevailing model of globalization and, in a deeper sense, the systemic global order, which currently undermines our main sources of wealth—labor and nature—and overexploits them to the extent that civilization itself is at risk.**

The responses to the crisis by the governments of developed countries and international agencies promoting globalization have been short-sighted and exclusivist. **Instead of addressing the root causes of the crisis, they have implemented limited**

strategies that seek to rescue financial and manufacturing corporations facing bankruptcy. In addition, government policies of labor flexibilization and fiscal adjustment have affected the living and working conditions of most of the population.

These measures are desperate attempts to prolong the privileges of ruling elites at the risk of

imminent and increasingly severe crises. In these conditions, **migrants have been made into scapegoats,**

leading to repressive anti-immigrant legislation and policies (Massey and Sánchez, 2006). A significant number of jobs have been lost while the conditions of remaining jobs deteriorate and deportations increase. Migrants' living standards have drastically deteriorated but, contrary to expectations, there have been neither massive return flows nor a collapse in remittances, though there is evidence that migrant worker flows have indeed diminished.

Regulatory Commission

Drug prices can be countered by a public utility-type system

Sheila **Tschinkel**, The Conversation, "Why the 'free market' for drugs doesn't work and what we can do about it", January 18, **2017**, <http://theconversation.com/why-the-free-market-for-drugs-doesnt-work-and-what-we-can-do-about-it-70007>

A proposed solution So what can be done to fix the problem? Allowing more government agencies to negotiate prices is one option. While this has lowered the prices paid by the Veterans Administration, it may not be the best way to go in a market like the one for many innovative new specialty drugs in which consumers have no good substitutes to choose from. Economists have shown that negotiated outcomes are not always the most efficient ones. As an example, if the government were to push drug producers too hard in negotiations, the public could get a great deal on prices in the short term but that could end up discouraging the development and testing of new drugs, which would hurt everyone in the long run. A better approach is to start with a public utilities method, which is frequently used when there is a natural monopoly in production, such as for water or power. In these cases, state and local governments typically allow a company to have a monopoly over the market but also establish regulatory commissions to determine "fair" prices. Such prices take into account current costs, the need for investment in production facilities and the need to earn a rate of return on capital invested. A wrinkle with drug developers is that they can incur substantial costs in their quest for new medications, including dead-end ideas and extensive testing. A 2014 report put the cost to develop a new drug at \$2.6 billion, while others put it at around half that. Under our proposal, an independent federal panel consisting of scientists, medical professionals, public health experts and economists – perhaps working as part of the FDA approval process and called on when the price of a drug is above a specific threshold – would determine the maximum price a government buyer such as Medicare or Medicaid could pay for a new drug. It could also do the same for existing treatments – for example, it could have turned down Turing's huge Daraprim price hike. A key element of this idea is that the panel would develop methods to identify and set maximum prices for existing and prospective drugs that cure a serious illness, improve the quality of life, limit contagion or otherwise provide large benefits to society. These procedures would need to make sure that producers of these important new drugs are sufficiently rewarded for those costly efforts.

Moral Obligation

Health care is a moral obligation because it is critical to human flourishing

Frank G. **Kirkpatrick**, Author, 'The Episcopal Church in Crisis: How Sex, the Bible and Authority are Dividing the Faithful, June 4, **2013**, Huffington Post, The Missing Moral Dimension in the Health Care Debate, http://www.huffingtonpost.com/frank-g-kirkpatrick/the-missing-moral-dimension-in-the-health-care-debate_b_3383194.html

Addressing health needs is a moral obligation because health is essential to the well-being and flourishing of all persons. And it is more than a personal good; it is a social good. The best health care possible should be provided to all members of any society that claims to be looking after the common good or the general welfare of the people. That is why its partial provision through a society-based program, Medicare, is called an entitlement. An entitlement, despite the bad odor the conservatives believe emanates from that word, is a moral term derived from a socially accepted moral obligation. As such, it ought not to be treated as a "discretionary" economic expenditure. It is shocking that a political party that has clothed itself in the mantle of morality has failed utterly to articulate the moral basis of health care or to offer any moral justification for overturning Obamacare or any alternative moral vision for what would replace it. Leaving millions uninsured, as the state of Texas continues to do, is a moral scandal. **A political party that cannot address the provision of health care in moral terms has forfeited its right to speak for moral values in America. Once our moral obligation to provide health care to all has been accepted the way will be clear to figuring out as realistically as possible how to provide it efficiently and effectively. But if the moral dimension of the debate is ignored, health care will be treated as having no more moral claim on our resources than does the demand that social taxes pay for my desire for a month's vacation in the Alps.**

Justice requires us to care about everyone's access to health care

Leonard M. **Fleck**, Ethics Professor, Michigan State University, **2009**, Just Caring: Health Care Rationing and Democratic Deliberation, p. viii-vix

We are too quick to blame overzealous lawyers, overpaid CEOs of health care institutions, and greedy insurance companies for the fiscal shortfalls in our health care system. Each of us should be "looking within" instead. We are very much of a divided mind in regard to our health care system. We want for our future possible selves as patients everything contemporary medical technology can offer that will improve the length or quality of our lives. But as presently healthy taxpayers/insurance premium payers we want health care costs controlled. We tell Congress that; we tell Aetna that. **We do not want "others" to be spending "our money" on these extremely expensive cancer drugs or other "last-chance therapies." We expect these "others" to be good citizens and good patients, accept their deaths with equanimity, and die cheaply.** These "others" have no right to waste "our money." Of course, what we avoid giving any thought to is the fact that **we are just another one of those "others" from the point of view of our fellow citizens. This captures in a nutshell the "Just Caring" problem: Why should anyone else pay attention to my demands for justice in meeting my health care needs when I refuse to pay attention to their demands for justice in meeting their health care needs.**

Ethical commitment to redistribute resources to cover health

Jennifer Prah **Ruger**, Law Professor-Yale, **2010**, Health and Social Justice, p. 5-6

Fifth, **because the achievement of equity in health requires social organization in the form of a redistribution of resources, and related legislation and regulation, this obligation requires an ethical commitment on the part of everyone,** those most fortunate and those in need, **to the end goal of providing health**

capability to all. Without this ethical commitment, redistributing resources from the wealthy to those less fortunate and from the well to the sick will not be possible, because the effort to do so must be voluntary, not coercive. As such, **individuals must internalize the public moral norm that health is worthy of social recognition**, investment and regulation to the point of successfully operationalizing it. **The ethical imperative of health equity provides strong grounding for individual and state action to respect, protect, and fulfill health equity through institutional change**. The primary means for achieving justice and actualizing a right to health are both legal and non-legal instruments. **This ethical commitment to health equity is an ethical claim, in this case on all individuals**, especially the wealthier, to redistribute some of their resources to help meet our own needs and those of others, today in the future.

Individuals in the original position (Rawls) would support access to health care

Han Hennenberger, Connecticut College, 2011, Health Care and Justice: A Moral Obligation? Philosophy Honors Papers, <http://digitalcommons.conncoll.edu/philhp/1> DOA: 6-16-16

In order to answer this question, I delve into the work of contemporary political philosopher John Rawls. His **book A Theory of Justice is the preeminent voice in the current conversation on justice**. From here I have borrowed Rawls' justice as fairness account, in which he imagines a hypothetical situation similar to the state of nature. These individuals in the original position exist behind what he calls the veil of ignorance; they have no knowledge of what their endowments, social status, or idea of the good will be in reality. Any guiding principles of justice which they agree to in this situation are thereby just. **Utilizing his conception of justice I explore what status universal healthcare should have. As it seems individuals in the original position would assent to principles of justice that guarantee access to healthcare I conclude that universal healthcare is necessary for justice. Therefore, as a society we are morally obligated to provide universal access to healthcare.**

Justice

Lack of health care undermines human capabilities, making a lack of access unjust

Han **Hennenberger**, Connecticut College, **2011**, Health Care and Justice: A Moral Obligation?

Philosophy Honors Papers, <http://digitalcommons.conncoll.edu/philhp/1> DOA: 6-16-16

Martha Nussbaum offers an alternative conception of justice which I also consider. The capabilities approach is founded on the idea that there are certain inalienable facets of human life that everyone should have access to. Some examples include living a life of normal length, bodily integrity, and the choice to participate in the various facets of society. It seems that justice is violated when one is denied access to any of these capabilities. Lack of healthcare seems to prevent the normal human functioning necessary for many of these experiences and therefore universal healthcare is necessary for justice. While I find this approach to have merit it is also problematic [Note: In this article, the author concludes that the justice as capabilities approach is not the best one and argues for the original position. This “straw person” argument is included so that you can consider it and access other resources to support it].

HIV/AIDS Epidemic

HIV infection rates are increasing among Latino and African-American gay men

Rae Ellen Bichell, journalist, February 25, **2016**, "The AIDS Crisis Hasn't Ended In The Black And Latino Communities," National Public Radio, <https://www.npr.org/sections/health-shots/2016/02/25/467968807/the-aids-crisis-hasnt-ended-in-the-black-and-latino-communities> (accessed 10/5/18)

But that leaves this bad part: **Rates are increasing in African-American and Hispanic men who have sex with men, according to data released Tuesday by the Centers for Disease Control and Prevention. At current rates, half of black and one quarter of Latino gay or bisexual men will be diagnosed with HIV in their lifetimes. In the last 10 years, diagnoses increased about 6 percent among all men who have sex with men, but rose 22 percent in black men and 24 percent in Latino men.** There were concerning increases over the decade among Asian American and American Indian/Alaska Native men who have sex with men, too, but the absolute numbers are tiny compared to those of other racial groups.

The most effective tool for ending the HIV epidemic is inaccessible due to cost

Shefali Luthra and Anna Gorman, journalists, June 30, **2018**, "Rising Cost Of PrEP To Prevent HIV Infection Pushes It Out Of Reach For Many," National Public Radio, <https://www.npr.org/sections/health-shots/2018/06/30/624045995/rising-cost-of-prep-a-pill-that-prevents-hiv-pushes-it-out-of-reach-for-many> (accessed 10/5/18)

Since brand-name Truvada was approved for HIV prevention six years ago, its average wholesale price has increased by about 45 percent. Now, the drug — which rakes in billions of dollars in annual global revenue for its manufacturer, Gilead Sciences — carries a list price of close to \$2,000 for a 30-day supply. Most insurers cover treatment with the pill, also known as pre-exposure prophylaxis, or PrEP. **It has been shown to be more than 90 percent effective in HIV prevention when the medicine is taken daily, according to the Centers for Disease Control and Prevention. But patients can get stuck with out-of-pocket costs that make the medicine unaffordable. "If there is any example of the dysfunction in the American pharmaceutical system, it is this case," says James Krellenstein, a member of the AIDS advocacy group ACT UP New York. "We have the most effective tool for ending the HIV epidemic, and one reason we're unable to scale up is because it costs so [much] unnecessarily."**

The state has a moral obligation to provide access to HIV treatment

Benjamin Mason Meier et al, researcher at the University of North Carolina Department of Public Health, **2015**, "Employing human rights frameworks to realize access to an HIV cure," Journal of the International AIDS Society, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4644771/>

As activists attacked global inequality in access to HIV treatment as a matter of social justice, international funding debates became central to human rights considerations under international law. The CESCR returned to the right to health in its 2006 General Comment, finding that states "have a duty to prevent unreasonably high costs for access to essential medicines ... from undermining the rights of large segments of the population to health" [24]. Recognizing the financial limitations of developing states in providing affordable medications, civil society advocates soon broadened their right to health advocacy (through public demonstration, government lobbying and legal action) to implicate international obligations on all manner of powerful states, organizations and corporations with the ability either to support or to impede access to ARVs in the developing world [25, 26]. Moved by the scale of the pandemic, wealthy nations came together to coordinate their financial allocations to secure "universal access," mobilizing unprecedented resources for global

health [27]. The UN Special Rapporteur on the right to health took up the global challenge of securing access to medicines, finding in 2006 that the “human right to medicines” is an “indispensable part” of the right to health and holding that “states have to do all they reasonably can to make sure that existing medicines are available in sufficient quantities”[28].

Specifically, the United States has a moral obligation to guarantee access to HIV treatment as a form of racial reparations

Salih Booker, executive director of Africa Action, June 19, **2003**, “Who owes whom? AIDS and reparations,” Christian Science Monitor, <https://www.csmonitor.com/2003/0619/p11s01-coop.html> (accessed 10/5/18)

The disproportionate impact of AIDS on blacks is closely related to the history of oppression and discrimination that people of African descent share. Vulnerability to AIDS is increased by impoverishment and marginalization, which remain the most important aspects of the continued legacy of slavery and colonialism. The same racist double standard that justified centuries of discrimination is visible today in the failure of Western policymakers to respond with the urgency that the AIDS pandemic requires. The AIDS crisis has become the deadliest manifestation of a system built upon the legacy of slavery, colonialism, and global racism. AIDS is the greatest challenge that people across the African diaspora share, and it makes plain the inseparable nature of the struggles for justice and reparations. While the debate over reparations continues, it must be an immediate priority to address the urgent crisis of HIV/AIDS, which has become the most serious threat to the survival of the black race since the transatlantic slave trade.

Insurance companies are too fractured to negotiate lower drug prices – price controls are needed

Chris Lo, journalist, February 12, **2018**, “Cost control: drug pricing policies around the world,” Pharmaceutical Technology, <https://www.pharmaceutical-technology.com/features/cost-control-drug-pricing-policies-around-world/> (accessed 10/4/18)

Medicaid, the federal programme to cover the medical costs of low-income individuals, receives a mandated discount, but Medicare – which provides insurance for Americans over 65 and is the pharma industry’s biggest single customer, spending \$137bn on prescription drugs in 2015 – is not allowed to negotiate at the federal level. Insurance companies that have been contracted to administer Medicare are able to negotiate, but with limitations such as having to cover all treatments across six broad drug categories. The private insurance system, which covers many Americans who are not on Medicare or Medicaid, is fragmented into hundreds of different employers and insurance providers, limiting their ability to negotiate steep discounts.

The end of HIV is within sight

Kent Sepkowitz, news analyst, February 22, **2016**, “Are We Creating Drug-Resistant HIV?” The Daily Beast, <http://www.thedailybeast.com/articles/2016/02/22/are-we-creating-drug-resistant-hiv.html> (accessed 10/5/18)

The 23rd Conference on Retroviruses and Opportunistic Infections (CROI) opens today in Boston. For the next few days, thousands of scientists will report on the latest trends, threats, and hopes. Much attention likely will be given to progress toward ending the HIV epidemic—a concept that no longer is a pipedream but now is an official government slogan. Also certain to be a hotspot, and in direct contrast with the ambient

optimism, will be discussion of the continued erosion of drug potency against the ever-mutable human immunodeficiency virus (HIV), the cause of AIDS. Charts and graphs and PowerPoint sleights of hand surely will be shown, fronted by sour 1950s faces, to demonstrate the doomsday scenario about to play out.

A cure for HIV is coming now

Stuary **Derbyshire**, October 14, **2016**, associate professor of psychology, “One day soon, humanity will triumph over HIV,” Spiked! <http://www.spiked-online.com/newsite/article/one-day-soon-humanity-will-triumph-over-hiv/18870#.WQNxT8a1tPY> (accessed 4/28/17)

Now, HIV scientists on the verge of an even bigger breakthrough: a complete cure for HIV, through a procedure dubbed ‘kick and kill’. It uses antiretrovirals to kill the virus, followed by a different drug to kick out the remaining HIV, which would otherwise lie dormant, so it can be eradicated. Fifty patients in the UK have received the treatment, and early tests on the first person to complete it show no signs of HIV in his blood. If that continues, he will be the first person to be completely cured of HIV using a drug regimen. It is too early to claim this as the ultimate breakthrough. There have been false dawns before. But even if ‘kick and kill’ is not the complete cure scientists hope for, it is getting awfully close. HIV patients who follow the regimen will be able to live their lives almost entirely virus-free, and the risk of them infecting others will become vanishingly small. A type of viral infection that was almost entirely unknown, actively misunderstood, and an almost guaranteed death sentence 25 years ago, may be about to be wiped out of existence. HIV, once touted as the virus that would drive humanity to extinction, now itself faces extinction at the hands of humanity.

Price controls lower drug costs by 22% - South Africa model

Chris Lo, journalist, February 12, **2018**, “Cost control: drug pricing policies around the world,” Pharmaceutical Technology, <https://www.pharmaceutical-technology.com/features/cost-control-drug-pricing-policies-around-world/> (accessed 10/4/18)

Just as in India, South Africa is working to improve access to effective medical treatments, with out-of-pocket costs high and medical schemes unaffordable for many citizens. The country has introduced price control measures such as capped annual price increases and mandatory generic substitution for branded drugs that have gone beyond patent protection. In 2004, South Africa introduced transparent drug pricing mechanisms, including a Single Exit Price (SEP). The SEP sets a price at which a prescription drug maker must sell to all pharmacies. The policy was designed to discourage the unnecessary prescribing of expensive drugs where alternatives are available, as pharmacies and doctors are able to add a small logistics fee, avoiding the informal arrangement of bonuses, incentives and rebates that can drive prices up for patients. Studies have shown that the SEP had an immediate effect on the price of medicines in South Africa, with a 22% reduction on prescription medicine prices in the first year after its introduction. But there remains a dearth of data on the long-term effectiveness of transparent pricing in the country.

Answers to Negation

Alternatives

The high cost of regulatory approval makes importing drugs a bad option

Pollack 2015 [Andrew; Price Increase Rescinded for a Tuberculosis Drug; The New York Times; 22 September 2015; Gale]

Amir Attaran, an expert on pharmaceutical access issues at the University of Ottawa, said it would have made much more sense to just import the drug from abroad, rather than have it produced in America for so few patients at such high cost. Mr. Hasler said this was probably not done because foreign manufacturers were not willing to bear the expense of applying for regulatory approval in the United States.

Easing restrictions on drug development is unlikely to reduce prices

Wapner 2017 [Jessica; Trump's Plan for Lowering Big Pharma Drug Prices Comes at a High Cost; Newsweek; 24 February 2017; Gale]

Take drug development. Trump said he will be "streamlining the process" so that companies do not have to wait years for a new product to be approved. Although he did not provide details, he hinted that his yet-to-be-named chief of the Food and Drug Administration has some plans. One leaked candidate for the post, Jim O'Neill, managing director of investment company Mithril Capital, publicly supports eliminating a large part of the drug approval process; namely, Phase II and III clinical trials, which test the effectiveness of new medications. The rationale is that easing FDA requirements would shave several years and millions of dollars off a company's investment in experimental products. But such an approach is unlikely to reduce prices, says James Love, director of Knowledge Ecology International, a nonprofit research organization focused on vulnerable populations. "Right now, the U.S. lets companies charge whatever they want here," says Love. In other words, the market price does not depend on the up-front investment. And the government lacks the means to force drug companies to lower prices in parallel with reduced development costs, says Winston Wong, who has worked in health care for more than 30 years and is a consultant to private insurers.

The cost of manufacturing a drug is not the cause of high prices; lowering the costs of manufacturing won't decrease drug prices

Wapner 2017 [Jessica; Trump's Plan for Lowering Big Pharma Drug Prices Comes at a High Cost; Newsweek; 24 February 2017; Gale]

The notion that lowering manufacturing costs would reduce drug costs is also misguided, says Mike Kelly, CEO of the Americas at Kantar Health, a pharmaceutical industry consulting company. "The cost of manufacturing a drug is infinitesimal compared to what it gets priced at." The dramatic price difference between branded and generic drugs underscores that point, says Love. The manufacturing process is the same, but branded drugs are, on average, 32 times more expensive than generics. "There's just no relationship between the price of a drug and what it costs to make," says Love.

Black Market

We have four responses to this.

First, this argument is NON-UNIQUE. There'll always be a reason to shift to a black market – This shift isn't contingent on the producer of the drug but rather on the consumer of the drug. In the world of the Aff the hypothetical impact of shortages could incentives a shift, yet in the Neg world the inflated cost of these drugs would cause the same shift to happen.

Second, you can de-link their argument because IMS Health in 2017 finds that 90% of drugs are already generics. This is important because at the point where we prove that the American people have access to cheaper alternatives away from brand name drugs, we prove that the incentive to shift towards a black market does not occur.

Third, you can turn the argument because the incentive to shift to black markets is accessibility. The Commonwealth Fund in 2017 found that 14% of insured Americans did not fill prescriptions due to high costs. The reason that this is important is that by my opponents logic these patients would have shifted to the black market right? Well, that isn't the case The New York Times furthers in 2017 that skipping medication or not filling prescriptions due to high costs has resulted in 125,000 deaths. People are not shifting to black markets, they are dying due to high drug costs

Finally, even if you don't buy that turn we've got another one - Patients are shifting to the Black Market in the status quo due to high drug prices. According to Orion College in 2017, prices for life-saving drugs have hit an all-time high, as a result of this, patients have already begun to seek black-market medications in their desperate attempts to stay healthy. My opponents have already caused this issue to manifest.

IMS Health

Forbes, Forbes Magazine, 12 Oct. 2017, www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduce-innovation-and-health-outcomes/#32f4201363a6.

"To start, the price controls would be irrelevant for most patients. Nearly 90 percent of all drugs dispensed in the U.S. in 2016 were generic medicines, according to IMS Health. Therefore, any price control scheme would not apply to the majority of patients who are using inexpensive generics, not more expensive patented products. It is also important to note that generic medicines are significantly cheaper in the U.S. compared to the other major industrialized countries. In fact, total pharmaceutical spending as a percentage of total health care spending is lower in the U.S. (12.2 percent) than the average for the 30 nations that comprise the Organization for Economic Cooperation and Development, or OECD, (16.9 percent). This is due to, in part, the prevalence of generic medicines that are more affordable here than in other OECD nations."

Commonwealth Fund

Sarnak, Dana O. "Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?" Prescription Drug Spending Why Is the U.S. an Outlier?, The Commonwealth Fund, 5 Oct. 2017, www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier.

Despite the differences among them, all countries do more than the U.S. does to limit patients' exposure to high out-of-pocket costs. While insured U.S. patients often pay little or nothing for generic prescriptions, they can be billed tens of thousands of dollars for certain high-priced medicines. Even Medicare's Part D prescription drug benefit has no out-of-pocket cap for beneficiaries. Only a handful of U.S. states have passed legislation to limit out-of-pocket spending for insurance sold within their borders; for example, Maryland has a \$150 monthly cap for specialty-tier drugs.¹¹ In a 2016 international survey of adults, **14 percent of insured Americans reported that, in the past year, they did not fill a prescription or skipped doses of medicine because of the cost**, compared with 2 percent in the U.K. and 10 percent in Canada, the nation with the highest rate after the U.S. (Exhibit 6).¹² Among Americans without continuous insurance coverage over the past year, the rate was twice as high: one-third reported they did not fill a prescription for medicine, or skipped doses of medicine, because of the cost.

New York Times

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

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.

Orion College

Edwards, Sam. "Interest in Black-Market Medications Climbs with Rising Pharmaceutical Prices." Online Allied Health and Medical School Education Courses by Orion College, 14 June 2017, <orioncollege.org/blog/interest-in-black-market-medications-climbs-with-rising-pharmaceutical-prices/>

"However, it's also more common than you probably think. **As prices for life-saving drugs hit an all-time high, patients have begun to seek black-market medications in their desperate attempts to stay healthy.** The risks of trading and buying drugs on the black market are pretty obvious. The FDA has no way to regulate these pharmaceuticals. There's also the risk of substance abuse. You could be trading with drug addicts, which is dangerous for you and for them. Thus, the practice is illegal and strongly ill-advised. The government has made some efforts to tighten the drug supply chain, but the solution is not necessarily simple. Making arrests and shutting down illicit online groups is often ineffective and consumes more resources than government institutions can spare. Most people who turn to the black market are fully aware of the risks, but do it anyway. They see no other option when drug prices are rising and health insurance doesn't cover what they need."

Bioterrorism

Our opponents are claiming that the Pharm industry is the key to stopping Bioterrorism but this argument is non-unique because there are so many alternate causes of bioterror happening. According to the U.S. International Trade Commission in 2007, countries like India and China are also major pharmaceutical giants. By my opponent's logic they could trigger these same impacts. At best we should prioritize happiness in the ST for American people.

U.S. International Trade Commission

William, U.S. International Trade Commission, 2007 "The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market", http://www.usitc.gov/publications/332/working_papers/EC200705A.pdf

There are approximately 34 foreign drug companies engaged in the Indian pharmaceutical market and among them are 15 of the world's 20 largest pharmaceutical companies. According to FICCI, although MNCs have not launched new products **they have invested in new production facilities and R&D centers and many are engaged in contract manufacturing, clinical trials, and other forms of outsourcing.**²⁵ In 2005-06, MNCs invested more than \$172 million in India's pharmaceutical industry and FDI has grown by a compound annual growth rate (CAGR) of 62 percent during 2002-06.²⁶ However, many industry experts believe that the return of the world's leading pharmaceutical companies will gradually erode India's cost advantages. According to the Organization of Pharmaceutical Producers of India, multinational drug companies currently command 24 percent of the domestic Indian market, through their share could rise to 40 percent by 2010.²⁷ GSK-India, a 51 percent subsidiary of GSK Plc (UK), is the largest foreign company in India's pharmaceutical market, its fourth largest pharmaceutical company, and leading prescription drug supplier. **GSK-India operates two Indian manufacturing plants and controls approximately 5.9 percent of the domestic Indian market.** GSK-India is among India's leading suppliers of anti-infective, anti-inflammatory, analgesic, gastroenterological, anti-allergic, and dermatological drugs. **GSK-India announced plans to extend its product line by launching several antibiotic, cancer, and cardiovascular products in India in the near term.** Likewise, MNCs dominate India's OTC (over the counter) drug market, with Pfizer accounting for 5.1 percent of the market, Sanofi-Aventis for 5.0 percent, and Johnson & Johnson for 4.8 percent. These companies offer analgesics, cough and cold preparations, indigestion medicines, skin care products, and vitamins and minerals. Other foreign multinationals active in India's pharmaceutical market include: Bristol-Myers Squibb, Eli Lilly, Boehringer, Bayer, Chiton Corp, Abbott, AstraZeneca, Janssen, and Roche. Recently, Teva Pharma (Israel), the world's leading generic drug manufacturing company, acquired a bulk drug manufacturing and intermediate facility in the State of Uttar Pradesh, announced plans to add two more units, and more than triple the value of its exports from India by the end of 2007. Teva also opened an R&D facility in India and announced plans to register between 10 and 15 bulk drugs per year in the United States from its Indian facilities. Mergers, acquisitions, and other alliances: The last 3 years have seen a significant rise in the number of consolidations, mergers & acquisitions, and other types of alliances and tie-ins in the Indian pharmaceutical industry. **Most of the acquisitions involve Indian companies searching for ways to penetrate overseas markets and widen their global footprint, diversify and enhance their product portfolios, offer their customers a 'nearshore-offshore' option, improve their custom manufacturing, packing, and R&D capabilities, acquire existing brands, and gain access to the highly regulated markets of Western Europe and the United States. Indian companies without significant R&D capabilities for drug discovery are also purchasing Western drug discovery companies. In 2005-06, 18 Indian companies spent approximately \$1.6 billion to acquire generic drug manufacturing firms in Europe, North America, and Mexico.**²⁹ These companies included Ranbaxy, Dr. Reddy's Labs, Nicholas Piramal, Sun Pharmaceutical, and Jubilant Organosys (table 5).³⁰ Although eleven of these transactions were for medium-and-small sized companies valued between \$5 million and \$30 million, several have been significant acquisitions valued in excess of \$500 million. To date, Dr. Reddy's purchase of Betapharm Arzneimittel of Germany for \$572 million is the industry's largest overseas acquisition.

Costs will go up

We have three responses

First, their own logic makes no sense. If price controls are instituted, the pharmaceutical industry is literally restricted from increasing the price on their product, whether that be in the U.S. or Internationally. Their argument lacks logical sense.

Even if you don't buy that, you can delink it because international countries are outpacing the U.S. in drug development and would solve for consumer costs in other nations. According to the U.S. International Trade Commission in 2007, India's pharmaceutical industry is quickly outpacing the U.S. and expanding investment. They further that 15 of the world's 20 largest pharmaceutical companies are Indian companies that also spent approximately \$1.6 billion to acquire generic drug manufacturing firms in Europe, North America, and Mexico. The Indian market is becoming the pharmaceutical leader of the world which means the cost of drugs would not be affected as global leaders would fill the void.

Finally, you can turn the argument because in the status quo, developing countries are struggling to afford pharmaceuticals due to high prices, this is uniquely true in the case of Ebola. The Independent furthers in 2014, that although Ebola was disastrous for humanity, there was no business case to make an Ebola vaccine for the people who needed it most. This is because Ebola affected people that were in some of the poorest countries in the world and couldn't afford to pay for a new vaccine. It's a market failure and price controls would take away the inherent barrier that market failure is a limiting factor in protecting lives. When these controls go into place, the pharmaceutical industry can no longer use profit mongering excuses for the deaths of those in developing countries.

U.S. International Trade Commission

William, U.S. International Trade Commission, 2007 "The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market", http://www.usitc.gov/publications/332/working_papers/EC200705A.pdf

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The Independent

Charlie Cooper, journalist for the Independent, 9-6-2014, "Ebola outbreak: 'Big Pharma' failed victims, says leading scientist," Independent, <http://www.independent.co.uk/life-style/health-and-families/health-news/ebola-outbreak-big-pharma-failed-victims-why-9716615.html>

The scientist leading Britain's response to the Ebola pandemic has launched a devastating attack on "Big Pharma", accusing drugs giants including GlaxoSmithKline (GSK), Sanofi, Merck and Pfizer of failing to manufacture a vaccine, not because it was impossible, but because there was "no business case". West Africa's Ebola outbreak, which has now claimed well over 2,000 lives, could have been "nipped in the bud", if a vaccine had been developed and stockpiled sooner – a feat that would likely have been "do-able", said Professor Adrian Hill of Oxford University. A team led by Professor Hill is to begin trials of an experimental Ebola vaccine fast-tracked into development in a desperate bid to slow the spread of the virus in Guinea, Sierra Leone and Liberia. If it passes safety and effectiveness trials, 10,000 doses of the vaccine – co-developed by the Britain's GSK and America's National Institutes of Health (NIH) – could be used to protect health workers in West Africa by December. However, Professor Hill said that **the fact that a vaccine had not been available to stop the disease when it emerged in Guinea six months ago represented a "market failure"** of the commercial system of vaccine production which is dominated by the pharmaceutical giants. The scale of the Ebola outbreak and the devastation it is causing in terms of lives lost and social breakdown had led the World Health Organisation (WHO) to order an unprecedented acceleration of normal drug development processes. Experts are looking at 10 different unlicensed and experimental Ebola therapy and vaccine candidates, of which the GSK/NIH vaccine is among the most promising. Regulatory processes that usually take up to 15 years have been abandoned, to fast-track drugs and vaccines into the field. Already, the experimental drug ZMapp, developed by Mapp, a small biopharmaceutical firm in the US, has been used to treat at least seven patients – four of them Westerners – and has shown promising results in trials on primates. Stocks have now run out, but Mapp has been handed \$25m (£15m) by the US government to scale up production. On Friday, the WHO met in Geneva to assess the options but concluded that despite the extraordinary measures, "new treatments or vaccines are not expected for widespread use before the end of 2014". As well as the GSK/NIH vaccine, to be tested in healthy volunteers in Oxford within two weeks, a Canadian vaccine has also shown promise and is being tested in the US. Professor Hill explained that the GSK/NIH vaccine, which is based on a strain of chimpanzee cold virus and known as ChAd3, was originally developed in the US for potential use against a bio-terror attack – and only existed because of high levels of funding allocated to vaccines designated for defence. **Asked why a fully tested and licensed vaccine had not been developed, Professor Hill said: "Well, who makes vaccines? Today, commercial vaccine supply is monopolised by four or five mega- companies – GSK, Sanofi, Merck, Pfizer – some of the biggest companies in the world. The problem with that is, even if you've got a way of making a vaccine, unless there's a big market, it's not worth the while of a mega-company There was no business case to make an Ebola vaccine for the people who needed it most:** first because of the nature of the outbreak; second, the number of people likely to be affected was, until now, thought to be very small; and third, **the fact that the people affected are in some of the poorest countries in the world and can't afford to pay for a new vaccine. It's a market failure."** He said that producing a vaccine for Ebola was "technically more doable" than making one for other challenging and more widespread diseases such as TB, HIV and malaria, which receive more funding. "There's a lesson here," he said. "If we had invested in an Ebola vaccine, had it sitting there as the outbreak comes, you could have nipped it in the bud, been able to vaccinate the region where it started.

Spending is low

Our opponents are saying that because drug spending is low we don't need price controls. We see two major problems with this.

First, drug spending being low isn't a reason to negate. Even if they prove that drugs are a minimal factor in overall healthcare spending, people are still dying. The New York Times in 2017 found that 125,000 patients have died as they skipped medication due to high costs. We outweigh on scope because saving lives is the most important impact in the round.

Second, this argument can be turned because prescription drug spending is high and increasing in the status quo. According to a study conducted by the Centers for Medicare and Medicaid Services in 2018, spending growth is projected to be fastest for prescription drugs, averaging an increase of 6.3 percent by 2026.

Centers for Medicare and Medicaid Services

"Press Release CMS Office of the Actuary Releases 2017-2026 Projections of National Health Expenditures." CMS Office of the Actuary Releases 2017-2026 Projections of National Health Expenditures | CMS, 14 Feb. 2018, www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2017-2026-projections-national-health-expenditures.

Personal healthcare spending: Over 2017-2026, growth in personal healthcare spending is projected to average 5.5 percent. Among the factors, personal healthcare price growth is anticipated to be the largest factor at 2.5 percentage points, growth in the use and intensity of goods and services is expected to contribute 1.7 percentage points of total growth, and population growth (0.9 percentage point) and changing demographics (0.5 percentage point) account for the remaining growth. Prescription drug spending: **Among the major sectors of healthcare, spending growth is projected to be fastest for prescription drugs, averaging 6.3 percent for 2017-2026.** This is due in part to faster projected drug price growth, particularly by the end of the period, influenced by trends in relatively costlier specialty drugs. Insured share of the population: The proportion of the population with health insurance is projected to decrease from 91.1 percent in 2016 to 89.3 percent in 2026, due in part to the elimination of the penalty payments associated with the individual mandate and also to a continuation of a downward trend in the offering and take-up of employer-sponsored health insurance.

Compensates for failed products

Our opponents say that the high cost of drugs in the status quo compensates for the number of failed drugs. We see two clear problems with this argument.

First, this argument is assuming that every drug that is ever developed is going to be successful. Unless they can prove to you that voting CON means that every drug they develop without price controls will be a success then they lose uniqueness and you flow the argument to our side.

Even if you don't buy that, though, you can turn it because right now drug companies are exploiting consumers to compensate themselves. This is inherently immoral because the New York Times finds in 2017 that a result of skipping medication due to high costs has resulted in a 10% increase in hospitalization. If you agree with the idea that we should overcharge and kill patients that need lifesaving medication just to compensate a drug company then by all means, negate the resolution. We reject these inherently corrupt and blatantly immoral standards at which consumers must be exploited for the mistakes of companies.

New York Times

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

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.

Drug Innovation

Our opponenets say that price controls will halt innovation, but we find four specific problems with this.

First, that argument is non-unique because innovation is failing now. Forbes in 2014 finds that the pharmaceutical industry has been scaling back R&D investment for the last 5 years and continues to do so. They further that \$12 billion has been undercut from investment.

Second, their link doesn't work because Dean Baker from the Center for Economic and Policy Research finds in 2018 that pharmaceutical revenue is not essential for research. He furthers, that we already spend more than \$30 billion a year financing research through the National Institutes of Health. This funding is, comparatively, more productive for R&D research than private revenue

Even if you don't buy that, AFF wins this argument because a lack of collaboration has made R&D stagnant and a failure. According to The Physician Payments Sunshine Act in 2017, a lack of collaboration between academia and the pharmaceutical corporations has stagnated growth in medical innovation.

Finally, R&D investment from the private sector empirically results in a massive reduction in financial returns. According to the Brookings Institution in 2018, adding a surplus of resources to innovation leads to an inevitable loss in breakthroughs. Even when these breakthroughs are met they are not affordable and cause financial damage.

Forbes

John LaMattina is an expert in the pharma industry and a writer for Forbes. "Pharma R&D Cuts Hurting U.S. Competitive Standing" Forbes. 1/3/14, <http://www.forbes.com/sites/johnlamattina/2014/01/03/pharma-rd-cuts-hurting-u-s-competitive-standing/>>)

A recent article in the New England Journal of Medicine (NEJM) should send warning signals to all interested in the state of the biopharmaceutical R&D in the U.S. The article, "Asia's Ascent – Global Trends in Biomedical R&D Expenditures", analyzes global biomedical R&D spending for the period between 2007 and 2012. While the article focuses on the relative rise in spending by Japan, China and India, **the eye-opening data for me are the numbers from the U.S. The authors point out that the U.S. share of this global spend has fallen from 51.2% in 2007 to 45.4% in 2012.** Europe's investment was essentially unchanged and Asia's increased from 18.1% to 23.8%. Further digging into the numbers revealed the following, **"The decline of \$12.0 billion in the inflation-adjusted U.S. expenditures from 2007 to 2012 was therefore driven by a \$12.9 billion reduction in industry's investment in R&D."** The U.S. share of global industry R&D expenditures decreased from 50.4% in 2007 to 42.3% in 2012. "The authors later say that "The decline is remarkable because the United States has provided a majority of the funding from biomedical R&D globally for the past two decades – a share that some previous analyses suggested was as high as 70 – 80%. Moreover, the decline was driven almost entirely by reduced investment by industry, not the public sector, between 2007 and 2012." Much of the news from **the pharmaceutical industry over the past five years has been about scaling back R&D.**

Dean Baker

Baker, Dean. (economist and the co-director of the Center for Economic and Policy Research), "Should the Government Impose Drug Price Controls?" The New York Times, The New York Times, 10 Jan. 2016, www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/end-patent-monopolies-on-drugs.

Drug companies also spend tens of millions on campaign contributions and lobbying to get every longer and stronger patent protection. The pharmaceutical industry is one of the main forces behind the Trans-Pacific Partnership, and its demands for stronger patent protections is one of the main obstacles to reaching an agreement with the other countries. We don't need patent monopolies to support research. **We already spend more than \$30 billion a year financing research through the National Institutes of Health. Everyone, including the drug companies, agrees that this money is very productive.** We could double or triple this spending and replace the patent supported research done by the drug companies. With the research costs paid upfront, most drugs would be available for the same price as a bottle of generic aspirin. While the measures being proposed by Hillary Clinton and earlier Bernie Sanders don't go this far, they are a big step in the right direction.

The Physician Payments Sunshine Act

Ginsburg, Paul. "Pharmaceutical Industry Profits And Research And Development." The Physician Payments Sunshine Act, 13 Nov. 2017, www.healthaffairs.org/doi/10.1377/hblog20171113.880918/full/.

It seems obvious that many of the obstacles to effective academic-pharmaceutical partnerships result from a fundamental lack of understanding by each party of the other's motivations and career pressures. Though, at least in principle, hypothesis generation and testing drive the research in both environments, the culture, goals, and guiding principles of the two sectors are fundamentally different. Investigators who have spent their careers in one ecosystem are generally unaware of the values and beliefs of their collaborators across the public-private divide. Unfortunately, academic scientists are also often blind to the constraints dictated by the need to fund and publish their own work, having lived with them so long that they are no longer noticeable. Perhaps the root of most of the differences in culture can be traced to the fundamental disparity in the commodity serving as the main internal and external measure of achievement. In the academic world, the immediate unit of success is the publication, whereas in preclinical research in the pharmaceutical sector it is a new chemical or biological entity that can be advanced safely into human trials to treat disease.

Brookings Institution

Frank, Richard, and Paul Ginsburg. "Pharmaceutical Industry Profits and Research and Development." Brookings, Brookings, 5 Mar. 2018, www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2017/11/17/pharmaceutical-industry-profits-and-research-and-development/.

When the challenge of affording prescription drugs is raised, pharmaceutical manufacturers often argue that steps to reduce prices will lead to less innovation in the future. This response presumably applies to policies that use the market, such as shortening periods of exclusivity and making approvals of generics more rapid, as well as regulatory tools such as price controls. The manufacturers' argument has validity in that expectations of lower revenues will lead to less investment in research and development (R&D). But we question the premise that more innovation is always a good thing. A central tenet of economics is the law of diminishing returns. In this case, additional resources going into innovation inevitably yield fewer important breakthroughs. At some point, perhaps already reached, the yield from additional resources going into R&D no longer justifies what society is paying in the form of higher prices to support this.

Drug companies not responsible for big innovations

David Lazarus, 2017, LA Times, July 26, <http://www.latimes.com/business/lazarus/la-fi-lazarus-drug-prices-20170725-story.html> Yes, we can lower sky-high drug prices — other countries have done it

There's something to that. Then again, how much innovation are big drug companies really responsible for? Pharmasset took most of the risk developing a promising hepatitis C drug. It was only after Gilead acquired the company that corporate greed became the driving force in pricing. Also, why should we rely so heavily on innovation by the private sector? Why not restore public-sector science to prominence with a boost in grant-making by the National Institutes of Health? Such grants could be funded via potentially billions of dollars in savings from allowing Medicare to negotiate public-sector drug prices. Consider this: The discovery of insulin in the early 20th century was one of the most important moments in modern medicine. It wasn't done by a private company. It was primarily the work of a Canadian scientist, Frederick Banting, who would go on to share the Nobel Prize in 1923. Banting and two colleagues subsequently sold the patent for insulin to the University of Toronto for just \$3. The university in turn allowed drug companies to manufacture insulin royalty-free. It wasn't about profit. It was about what was best for society. Today, drug companies see the global diabetes epidemic as an enormous business opportunity. Insulin prices have more than tripled in recent years. It's not about what's best for society. It's about profit.

High investment and high profits mean that drugs are created that no one can afford

Sara Kliff, May 10, 2018, Vox, <https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained> The true story of America's sky-high prescription drug prices

Right now America's high drug prices mean that investing in pharmaceuticals can generate a whole bunch of profits — and that drugs can be too expensive for Americans to afford.... CONTINUES.... At the same time, just because there are more drugs on the American market, that doesn't mean all patients can access them. "To think that patients have full access to a wide range of products isn't right," says Aaron Kesselheim, an associate professor of medicine at Harvard Medical School. "If the drugs are so expensive that you can't afford them, that's functionally

the same thing as not even having them on the market.”it also doesn't mean we're necessarily getting better treatment. **Other countries' regulatory agencies usually reject drugs when they don't think they provide enough benefit to justify the price that drugmakers want to charge. In the United States, those drugs come onto market — which means we get expensive drugs that offer little additional benefit but might be especially good at marketing. This happened in 2012 with a drug called Zaltrap, which treats colorectal cancer. The drug cost about \$11,000 per month — twice as much as its competitors — while, in the eyes of doctors, offering no additional benefit.** “In most industries something that offers no advantage of its competitors and yet sells for twice the price would never even get on the market,” Peter Bach, an oncologist at Sloan-Kettering Memorial Hospital, wrote in a New York Times op-ed. “But that is not how things work for drugs. The Food and Drug Administration approves drugs if they are shown to be ‘safe and effective.’ It does not consider what the relative costs might be.”

Private sector won't make the drugs we need

Bernstein, 2015, Jared Bernstein, a senior fellow at the Center on Budget and Policy Priorities, was the chief economist and economic adviser to Vice President Joe Biden and executive director of the White House Task Force on the Middle Class from 2009 to 2011., <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-are-vital-in-a-market-thats-not-free> Drug Controls are Vital in a Market that's not free,

The producers argue that this will stifle their incentive to innovate. But **the evidence is increasingly clear that we cannot count on the private sector to make necessary medicines affordable. In fact, given the incentive structure, neither can we count on private drug companies to develop the drugs we most need versus the ones that will be most profitable. In health economics, maximizing social benefits is often at odds with private benefits.**

Lack of industry transparency means no proof that price controls hurts research

Dylan **Scott**, research analyst, December 1, **2015**, “As outrage over prices grows, public sours on the drug industry,” STAT Plus, <https://www.statnews.com/2015/12/01/stat-harvard-drug-industry-poll/> (accessed 10/4/18)

Scott Ascher, a 41-year-old public works foreman from Sussex, Wis., said he thinks **it would be helpful if drug companies explained how much it costs for them to develop a drug.** Democratic presidential candidates Bernie Sanders and Hillary Clinton, as well as health insurers, support having drug makers disclose their research-and-development costs. “Who are we to go up against what they say? Do they open up their books to say, ‘This is what’s going on’? You can’t argue with one side of the story,” said Ascher, another Republican. **Drug companies could justify a price increase by showing their costs to produce a treatment, he continued. “Show me that in the numbers.”**

People don't believe that price controls hurts research

Dylan **Scott**, research analyst, December 1, **2015**, “As outrage over prices grows, public sours on the drug industry,” STAT Plus, <https://www.statnews.com/2015/12/01/stat-harvard-drug-industry-poll/> (accessed 10/4/18)

A new poll by STAT and the **Harvard** T.H. Chan School of Public Health **found significant skepticism about one of the drug industry's most prevalent talking points. Almost two-thirds of Americans said they did not believe that Medicare negotiating with drug companies to lower prices would lead to fewer medicines being developed. And a majority — 55 percent — believes that even outright price controls wouldn't slow the flow of new drugs.** Those are two specific examples, but the findings suggest that Americans reject a key counterargument the

industry makes whenever the specter of government action on drug costs comes up: **The current system, while imperfect, allows drug companies to create breakthrough lifesaving medications. They warn that any major changes, particularly more government involvement, could hamper that.**

Studies estimating decreases in R&D are statistically flawed – price controls have a very marginal effect

Scherer, F.M. [Professor emeritus of public policy and corporate management at the John F. Kennedy School of Government, Harvard University, in Cambridge, Massachusetts]. “Price Controls And Global Pharmaceutical Progress”. Health Affairs, **2009**.

<https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.28.1.w161>

My assignment was to comment on three papers in a Health Affairs Web-Exclusive package.¹ Because space is limited, I focus mainly on one: **the work by Darius Lakdawalla and colleagues** examining how U.S. price controls might affect pharmaceutical innovation and, ultimately, health in the United States and Europe.² Most major nations, many of whose policies are reviewed in the paper by Neeraj Sood and colleagues, enforce drug price controls.³ This means that the United States is the “honey pot” from which multinational pharmaceutical companies derive a lion’s share of their profits. I have no doubt that tough price controls in the United States would adversely affect incentives for innovation. The crucial questions are, how much, and on what kinds of drugs? The paper by Lakdawalla and colleagues **summarizes an** impressively rich and detailed **simulation analysis**, with commendable attention to the sensitivity of results to key assumptions. **My main quarrel with the paper entails its** so-called baseline-case “elasticity” **assumption that a 1 percent decrease in drug sales revenues would lead to a 3 percent decrease in the new product count.** (The assumption is stated most clearly in the authors’ technical appendix.) The conclusions by Lakdawalla and colleagues depend critically upon their baseline value of 3.0, as the sensitivity analysis in their Exhibit 6 reveals. An elasticity of 1.0 would yield a small positive increment to present value for the U.S. year 2060 cohort, given the other baseline assumptions; an elasticity of 2.0, a present value of –\$17,000, compared to the much larger effect of –\$51,000 for the elasticity of 3.0. **I was skeptical of the baseline 3.0 value for several reasons.** It is drawn from an econometric investigation by Daron Acemoglu and Joshua Linn.⁴ Their work uses state-of-the-art techniques to estimate how new Food and Drug Administration (FDA)–approved drugs respond to a variable that is predictable but largely unaffected by drug availability: the size of population cohorts susceptible to diverse diseases. My skepticism turns on several points. First, Acemoglu and Linn’s model addresses population counts (not revenues, as asserted by Lakdawalla and colleagues). **Correctly ascertaining the impact of price controls on new drug development requires a focus on revenues** (rising more rapidly than population) and research and development (R&D) costs (rising even more rapidly). Neither is explicitly used in Acemoglu and Linn’s analysis. Second, Acemoglu and Linn show no awareness that the number of new products and especially new chemical entities (NCEs) approved during the final decade of their 1965–2000 sample rose abruptly because of a reduced backlog of FDA applications (and possibly an altered bias favoring approval over rejection) imparted by the 1992 Prescription Drug User Fee Act (PDUFA). When I attempted a crude test (without the sophisticated cohort breakdowns used by Acemoglu and Linn) of how eliminating the backlog effect affected the response of the number of approved NCEs to the size of population cohorts ages 55–85, I obtained an elasticity of 2.61 with the unaltered NCE count data and 2.06 with data stripped of a three-year backlog effect. Ignoring PDUFA makes a difference. The motivational foundation for the analysis by Acemoglu and Linn was Jacob Schmookler’s seminal contributions on the importance of “demand-pull” to innovation.⁵ In Chapter 7 of his book, *Invention and Economic Growth*, Schmookler reported elasticities insignificantly different from 1.0. In the most extensive retest of the Schmookler hypotheses, covering patented inventions flowing to 214 capital goods–using industries, I estimated an elasticity of 0.686.⁶ Believing that drug development incentives depend upon revenues and production costs (which determine gross margins) and R&D outlays, I was also inclined toward skepticism of a 3.0 elasticity from my own analysis of R&D responses, published in an earlier issue of Health Affairs and in my industry case-study book.⁷ The analysis focused on deviations from trend, not absolute levels, because what price controls do is enforce a deviation from what otherwise would be trend values. The econometric version of my analysis suggests an R&D elasticity of approximately 0.6 with respect to gross margins. Because gross margins approximate 60 percent of sales revenues, this implies a sales revenue deviation elasticity of about 1.0. Lakdawalla and colleagues reject these results, arguing that “short-run deviations in profits have no bearing upon the long-term payoffs of investments.” They ignore the suggestion in my Health Affairs article that “managers’ expectations of future profit opportunities, which are tempered, inter alia, by contemporary market conditions, can exert a demand-pull influence on R&D investments.”⁸ To be sure, current profits are an imperfect predictor of future profits. But in a world of uncertainty and “bounded rationality,” Herbert Simon argued in his Nobel Prize–winning work, managers often seize upon imperfect observables in their decisions.⁹ An economic model I used to analyze how changes in third-world patent policy affect innovation also yielded modest new-drug elasticity estimates—on the order of 0.73.¹⁰ The model, however, was not calibrated from econometric estimates. Reconsidering it in the framework of Lakdawalla and colleagues’ paper, I recognized an important caveat. Lakdawalla and colleagues analyze the five top-selling drugs each of seven disease categories, which in their technical appendix they call “blockbusters.” In studies of three different new drug cohorts, Henry Grabowski and others have shown that the distribution of payoffs—technically, the discounted present value of gross margins—is highly skewed.¹¹ **Their three analyses show the discounted pay**

offs from top-decile blockbusters to be from 5.2 to 5.6 times commensurately capitalized R&D costs (including the costs of failed efforts). Suppose, then, that price controls reduce manufacturers' revenues by 20 percent and quasi-rents by 30 percent. The effect for the blockbusters will be to leave quasi-rents roughly 3.8 times R&D costs. Even in a highly uncertain world, this seems unlikely to discourage R&D investment for drugs expected to be top sellers.

Non-unique - Innovation is declining already – decades of data proves fewer drugs are getting approved by the FDA

Baker, Dean. [Economist and the Co-Director of the Center for Economic and Policy Research, in Washington, D.C.]. "Reducing Waste with an Efficient Medicare Prescription Drug Benefit". Center for Economic and Policy Research, **2013**. <http://cepr.net/documents/publications/medicare-drug-2012-12.pdf>

When Congress was debating the Medicare drug benefit in 2003, there were many who advocated that Medicare provide the benefit as part of the traditional hospital insurance program. This was expected to save money both due to lower administrative costs and also as result of Medicare's ability to use its market power to directly negotiate lower prices with the pharmaceutical industry. The plan that was passed instead required beneficiaries to purchase insurance from private insurers who would be subsidized by the government. It has been widely noted that the drug benefit has cost considerably less than expected. In 2004, the Medicare Trustees projected that the Part D benefit would cost \$131.4 billion in 2011, the most recent year for which data is available. In fact, the benefit cost \$67.4 billion in 2011, just 51.3 percent of the originally projected cost.¹ While advocates of using private insurers have claimed that lower than projected costs vindicate their design for the benefit, in fact the main reason that costs have been less than projected is that drug costs in general have risen much less rapidly than had been projected. In 2005, the Center for Medicare and Medicaid Services (CMS) projected that the country would spend \$403.7 billion on prescription drugs in 2014. ² (These were the first projections that incorporated the impact of the Medicare prescription drug benefit, and 2014 is chosen because the projections jump from 2006 to 2014.) The 2011 projections showed expenditures of \$308.7 billion for 2014, or 59.2 percent of the 2005 projection.³ While there are undoubtedly many factors underlying the slower than projected increase in drug costs, the main factor is a decline in the pace of innovation. The Food and Drug Administration (FDA) rates the importance of new drugs in their approval process. It fast tracks drugs that are considered "priority" drugs, meaning that they are potentially a qualitative improvement over existing drugs. In the 1990s, there was an average of 13.4 priority approvals a year of new molecular entities. This fell to 10.0 a year between 2004 and 2009, a 25 percent drop.⁴ Given the expected increase in expenditures on prescription drugs, and the increase in research spending claimed by the industry, it would have been expected that instead of falling, the number of priority approvals would have increased substantially. With fewer important new drugs being developed and patents expiring on many important existing drugs, it should not have been surprising that the increase in drug expenditures would slow. It is likely that this slower pace of innovation in the drug industry is a more important factor in explaining lower than projected costs than the role of private insurers in delivering the benefit.

No impact to innovation – new drugs that are only on the US market are just more expensive and do the same thing as existing ones – quality of care stays the same, especially because people can't even afford the newly innovated drugs

Kliff, Sarah. [Writer for Vox News]. "The true story of America's sky-high prescription drug prices". Vox News, May **2018**. <https://www.vox.com/science-andhealth/2016/11/30/12945756/prescription-drug-prices-explained>

Let's say you're a pharmaceutical executive and you've discovered a new drug. And you want to sell it in Australia. Or Canada. Or Britain. You're going to want to start setting up some meetings with agencies that make decisions about drug coverage and prices. These regulatory bodies generally evaluate two things: whether the country wants to buy your drug and, if so, how much they'll pay for it. These decisions are often related, as regulators evaluate whether your new drug is enough of an improvement on whatever is already on the market to warrant a higher price. So let's say you want to sell your drug in Australia. You'll have to submit an application to the Pharmaceutical Benefits Advisory Committee, where you'll attempt to prove that your drug is

more effective than whatever else is on the market right now. **The committee will then make a recommendation to the country's national health care system** of whether to buy the drug — and, if the recommendation is to buy it, the committee will suggest what price the health plan ought to pay. Australia's Pharmaceutical Benefits Advisory Committee is not easy to impress: It has rejected about half of the anti-cancer drug applications it received in the past decade because their benefits didn't seem worth the price. 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. At the same time, just because there are more drugs on the American market, that doesn't mean all patients can access them. **"To think that patients have full access to a wide range of products isn't right,"** says Aaron Kesselheim, an associate professor of medicine at Harvard Medical School. **"If the drugs are so expensive that you can't afford them, that's functionally the same thing as not even having them on the market."** It also doesn't mean we're necessarily getting better treatment. Other countries' regulatory agencies usually reject drugs when they don't think they provide enough benefit to justify the price that drugmakers want to charge. **In the United States, those drugs come onto market — which means we get expensive drugs that offer little additional benefit but might be especially good at marketing.** This happened in 2012 with a drug called Zaltrap, which treats colorectal cancer. The drug cost about \$11,000 per month — twice as much as its competitors — while, in the eyes of doctors, offering no additional benefit. "In most industries something that offers no advantage of its competitors and yet sells for twice the price would never even get on the market," Peter Bach, an oncologist at Sloan-Kettering Memorial Hospital, wrote in a New York Times op-ed. "But that is not how things work for drugs. **The Food and Drug Administration approves drugs if they are shown to be 'safe and effective.' It does not consider what the relative costs might be.**"

Trump solves – he's hollowing out the FDA, so costs/delays for getting a new drug to market will decrease

Johnson, Carolyn. [Reporter for the Washington Post]. "Trump calls for lower drug prices, fewer regulations in meeting with pharmaceutical executives". Washington Post, **2017**.

https://www.washingtonpost.com/news/wonk/wp/2017/01/31/trumpcalls-for-lower-drug-prices-fewer-regulations-in-meeting-with-pharmaceuticalexecutives/?utm_term=.ff8369bd58d7

Cutting regulations **Trump** made concessions to the industry as well, saying he **will ease regulations from the Food and Drug Administration to make it quicker to get drugs approved.** "We're also going to be streamlining the process, so that, from your standpoint, when you have a drug, you can actually get it approved if it works, instead of waiting for many, many years," Trump said. Trump's comments about speeding up drug approvals come as confusion swirls about how the FDA will be affected by recent executive orders, including one that imposed a federal hiring freeze. There are many empty positions at the FDA, said Diana Zuckerman, president of the National Center for Health Research. The recently enacted 21st Century Cures law provided for additional hiring authority. "But with the hiring freeze, will they be able to hire anyone?" she asked. Another executive order, issued on Monday, requires that agencies remove two regulations for each new rule that's promulgated. "That will cripple the FDA's ability to do anything other than regulate by nonbinding guidance documents," said David Vladeck, a professor at Georgetown University Law Center. "To hollow out the agency's authority by forbidding it from dealing with emerging issues through new regulations, and perhaps even giving guidance, will jeopardize consumers and threaten the reputation of the agency around the world." He also questioned Trump's comments Tuesday about slashing drug-approval times at the agency, asking whether consumers wanted the FDA to rely on "comic-book" versions of drug applications.

Pharmaceutical Companies Can Solve

Pharmaceutical companies won't solve – they're not economically inclined

Hoskins, Pennsylvania Hospital, ALS Center, Coordinator **10** [Katelin Hoskins, University of Pennsylvania, M.A. Science in Nursing, July 2010, vaccineethics.org, "Vaccines and Bioterrorism II. Obstacles to Bioterror Vaccine Development", http://www.vaccineethics.org/issue_briefs/bioterror_development.php, accessed, 7-12-13 AMS]

The Role of the Pharmaceutical Industry in Defense A group within the Department of Health and Human Services (HHS), the Biomedical Advanced Research and Development Authority (BARDA), manages the preparation and procurement of drugs, vaccines, and therapies for potential public health crises.⁸ In 2004 BARDA implemented Project BioShield, an initiative dedicated to advancing the development, production and purchase of "medical countermeasures" for chemical and biological threats.⁹ Though Congress allocated over \$5 billion to the project, **the world's major pharmaceutical companies have nonetheless largely eschewed government contracts for bioterror vaccine research and development. Such ventures promise little profit potential and present a major financial risk.**¹⁰ **Vaccines for bioterror threats occupy a limited market niche and their production involves substantial challenges such as establishing technical feasibility, constructing manufacturing facilities, assuring containment, and successfully conducting clinical testing.** Furthermore, **Project BioShield does not offer legal immunity to industry, and corporations are wary of potential litigation, particularly regarding vaccines.**¹¹⁻¹² **Major pharmaceutical companies are also often reluctant to agree to federal contracts for the exclusive development and purchase of drugs or vaccines.**¹³ **Government contracts typically yield low profit margins, as there is little or no market competition. There is also concern that security restrictions might severely limit information access and impede subsequent research and development.** In the past, production costs have also been vastly underestimated, leading to financing difficulties. In addition, **while the prospect of bioterrorism is deeply troubling, it is very likely that any particular threat will never materialize and that vaccines will go unused. While this is desirable from a security perspective, it provides no rationale for long-term corporate investment. Because of this, government contracts are generally awarded to smaller biotechnology companies eager for research subsidies and the possibility of large payments upon product delivery.**¹⁴ **These companies tend to be less established than larger corporations, with less product diversity and little record of developing and producing successful vaccines.**

Pharmaceutical companies won't solve pandemics – economic interest prevent vaccine dissemination to the poor

Shah, Global Issues, Editor, **2000** [Anup Shah, May 2000, "Pharmaceutical Corporations and Medical Research", <http://www.globalissues.org/article/52/pharmaceutical-corporations-and-medical-research>, accessed, 7-12-13 AMS]

Pharmaceutical companies have contributed to people's improved health and prolonged life, generally speaking. Research and development of drugs that are brought to market can be costly and there are strict regulations and requirements that companies must follow in most countries. But the details reveal further concerns. For example, **marketing practices and priorities of the pharmaceutical industry have come under scrutiny for many years.** It seems that there is increasing emphasis on drugs that fit scare-mongering and over-medicalized problems. **Testing and thorough clinical trials are fundamental to good medical drugs, but there are numerous accusations of shortcuts, including pressuring for favorable results, testing on people without their proper approval, using drugs for unapproved uses and much more. Ideologically, many drug companies support the position of less government involvement, yet in the developing world in**

particular, diseases and illnesses affect the poorest the most who cannot afford expensive (or even sometimes cheap) **treatments**. In the past decade or so, pharmaceutical companies have therefore also been criticized for ignoring this “market” because they can’t pay. **Public announcements of drug donations to poor countries are often welcome, but sometimes the details reveal murkier intentions; some of the drugs are close to, or even past, their expiry date** (and are expensive to dispose, adding more costs to recipient countries) for example. **Poorer countries encourage their drug companies to make cheaper generic alternatives to expensive branded ones or use other tools available at their disposal to help bring the price of medicines down to more affordable levels. But they face immense pressure from international institutions and multinational pharmaceutical corporations**, even when generics and other options pursued are legitimate under international rules. For these multinationals, they’ve poured billions into some of these drugs and therefore want a patent system that will protect their investments for as long as possible. **For the developing and poorer countries**, as remote as these issues may seem, patents and intellectual property rights **issues can mean life or death. (For example, at the end of the 1990s, the pharmaceutical industry lobbied the US government to threaten sanctions on South Africa for trying to produce generic drugs to fight its growing AIDS problem.** It took huge public outcry to get the case dropped some 2 years later.)

Obamacare Solves/People can buy drugs

Healthcare access has improved slightly, but nowhere near enough to be solved

Woolhandler, MD, MPH and Himmelstein, MD, professors CUNY School of Public Health, 2017

[Steffie Woolhandler, MD, MPH, and David U. Himmelstein, MD, both at CUNY School of Public Health, “The Obama Years: Tepid Palliation for America’s Health Scourges”, American Journal of Public Health 107, no. 1 (January 1, 2017): pp. 22-24. DOI: 10.2105/AJPH.2016.303531 accessed 7/22/17 TOG, * WAVE ONE*]

Access to care has improved, but remains abysmal, in part because many who gained coverage cannot afford to use it. In 2014, **66 million working-age adults skipped doctor visits, tests, or prescriptions because of costs**—down from 80 million in 2012—**while collection agencies dunned 37 million for medical debts, a reduction of 4 million.**³ **Post-ACA**, the Consumer Financial Protection Bureau reported that **medical debts still account for 52% of all bills sent to collection agencies.** **It is disturbing that the ACA has abetted**

corporate dominance in health care. The law funneled most of its trillion dollars in new federal spending through private insurers as payments for exchange coverage and Medicaid managed care plans, fortifying insurers’ bottom line and political clout. Meanwhile, insurers have skirted the law’s caps on overhead; Aetna’s overhead actually rose from an average of 17.0% in 2008 to 2010, to 19.5% in early 2016. Taken together, insurers’ added overhead and that of the new exchanges will consume 22.5% of the new federal spending.⁴ The ACA’s promise to cut overpayments to Medicare Advantage plans (estimated at \$1000 or more per enrollee) was also undermined, as the Centers for Medicare and Medicaid Services handed out “quality bonuses” to almost all of these private plans. **In both the Medicare**

Advantage program and the exchanges, insurers are abandoning unprofitable local markets while continuing to reap large profits from federal payments in others, essentially cherry-picking by county.

The **insurance giants, awash in cash, have gone on a shopping and merger spree that will shrink the number of major insurers** from five to three, unless two pending mergers are blocked on antitrust grounds. The ACA’s mandate that Medicare pay for “value not volume” through health maintenance organization—like entities called accountable care organizations has driven a wave of corporate takeovers. **The move from fee-for-service to quasi-capitation has not garnered the promised savings**⁵ (and its health impacts remain unknown) **but is driving small-scale providers from the market.** They lack the financial reserves to bear risk for high-cost patients or to invest in the information technology and administrative systems needed to manage

that risk or game the complex new payment incentives, as well as the market clout to bargain with suppliers and private payers. **Giant systems have been snapping up practices and hospitals, despite compelling evidence that such takeovers raise costs** (particularly when they create regionally dominant systems) and scant evidence that they improve care. The Medicare Access and CHIP Reauthorization Act of 2015 physician payment reform, which disproportionately penalizes small practices, promises to accelerate this trend. Although some credit the ACA with slowing health care cost growth, the slowdown began in 2005, well before the law was passed, and ended in 2014 when it was fully implemented. It is disturbing that the slowdown was only seen among low- and middle-

income Americans; health spending for the wealthiest 20% soared.⁶² **In 2015, there was an almost unprecedented increase in overall US death rates, while the poorest 20% of Americans**

have suffered rising mortality over the longer term. Some of this deterioration represents increasing rates of self-harm and fatal substance use, complex problems that cannot be blamed entirely on politicians. But politicians bear responsibility for the underfunding of mental health and addictions care, and for shrinking public health resources. **Congress and the president have also failed to pull policy levers—regulation, taxation, and social spending—that could ameliorate the market forces**

deepening the income divide and working-class despair. Between 2009 and 2015, the wealthiest 1% of Americans captured 52% of total income growth—continuing a decades-long trend—pushing the Gini index of income inequality up by 2.4%. Although median family income rose sharply in 2015 (with the poor enjoying the largest percentage gains), it remains 1.6% below the 2007 level.

Political Capital DA

National Institute of Health (NIH) solves

Dean **Baker** is an economist and the co-director of the Center for Economic and Policy Research. New York Times, End Patent Monopolies on Drugs,

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

We don't need patent monopolies to support research. We already spend more than \$30 billion a year financing research through the National Institutes of Health. Everyone, including the drug companies, agrees that this money is very productive. We could double or triple this spending and replace the patent supported research done by the drug companies. With the research costs paid upfront, most drugs would be available for the same price as a bottle of generic aspirin.

Bipartisan support for price controls

Michelle **Mello**, June 2018, Professor of Law, Stanford Law School, and Professor of Health Research and Policy, Department of Health Research and Policy, Stanford University School of Medicine; Ph.D., University of North Carolina at Chapel Hill; J.D., Yale Law School; M.Phil., University of Oxford; A.B., Stanford University., Minnesota Law Review, ARTICLE: What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?, http://www.minnesotalawreview.org/wp-content/uploads/2018/07/Mello_MLR.pdf p. 2278

Though it is difficult to find any issue today on which there is bipartisan agreement in Washington, even persons who cannot agree on whether or not the planet is warming agree that the problem of prescription drug costs requires action.

Drug Prices

Government controlled price negotiations lower drug prices – China case study

Chris **Lo**, journalist, February 12, **2018**, “Cost control: drug pricing policies around the world,” Pharmaceutical Technology, <https://www.pharmaceutical-technology.com/features/cost-control-drug-pricing-policies-around-world/> (accessed 10/4/18)

The new policy has been criticised by some as rather confused. “Some elements of the reform seem not to be well aligned or even contradictory, like introduction of the reimbursement standard and maintaining the tendering system,” wrote the authors of a 2016 Pfizer-sponsored study into the reforms. **“This indicates that, given complexity of the market, foreign pricing policies cannot be transferred to China without being properly adjusted for local healthcare specificities.”** **While the country is in the process of moving away from centralised drug price regulation, the government has shown its willingness to negotiate aggressively with companies, leveraging the size of state health insurance schemes (and its broader pharmaceutical market) to bring prices down. In early 2018, China reduced the prices of 36 drugs, predominantly branded medications developed by multinational pharma companies, by an average of 44% as a condition of being made reimbursable under government health insurance.**

Pharmaceutical price controls are popular – 7 out of 10 Americans support

David **Nather**, statistical analyst, December 1, **2015**, “STAT-Harvard poll: Dismayed by drug prices, public supports Democrats’ ideas,” STAT Plus, <https://www.statnews.com/2015/12/01/stat-harvard-drug-prices-poll/> (accessed 10/4/18)

Most Americans believe that the prices of brand-name prescription drugs have become unreasonable, and their dismay is leading to wide support for government action to keep costs down, including letting Medicare negotiate prices with drug companies, according to a new poll by STAT and the Harvard T.H. Chan School of Public Health. The poll found strong support across party lines for the Medicare negotiations idea, which is a centerpiece of all of the Democratic presidential candidates’ proposals to contain drug costs. **About 7 out of 10 Americans, including two-thirds of Republicans, said Medicare, the federal health insurance program for older and disabled Americans, should be able to negotiate lower prices for all prescription drugs.**

Another 13 percent support negotiations for just high-cost drugs for illnesses such as hepatitis C or cancer.

Price controls work and promote medical industry growth – India proves

Chris **Lo**, journalist, February 12, **2018**, “Cost control: drug pricing policies around the world,” Pharmaceutical Technology, <https://www.pharmaceutical-technology.com/features/cost-control-drug-pricing-policies-around-world/> (accessed 10/4/18)

Just as the US is well-known for its hands-off, free-market approach to drug price policy, India is famed for its hard-line stance on regulating drug prices and encouraging generic competition. Strict price controls and a permissive attitude to the development of generic versions of branded drugs for the domestic market – sometimes within a product’s patent period – has alienated big pharma and international trade partners to some extent, as well as transforming India’s generics industry into one of the world’s leading providers of low-cost medicines. India’s stance is understandable, given that the majority of prescription drug costs in the country are paid out-of-pocket, leaving many trapped in poverty by the weight of medical costs. Still, the Modi government is treading a tightrope as it pursues its goal of access to affordable drugs while promoting its ‘ease of doing business’ policy.

Generics

Our opponents say that we can fix prices by simply accessing more generic drugs. We see six specific issues with this argument

First - Just because generics make up 90% of the market does not mean we ignore the minority of the population. The point of the resolution is to debate in favor of the 10% of the population that does not use generics. Our opponents are basically telling you that 1/10 of American patients do not matter and we disagree

Second - Generics are subject to shortages. According to the Business Insider in 2017, companies are not incentivized to make generics because they are unable to keep up with demands. This is why generics are not dependable because they suffer from shortages. The Quartz in 2016 confirms this, finding that the Medicare Modernization Act passed in 2003 empirically triggered shortages on generics because the reimbursement on these drugs was restricted to the average selling price, taking away the financial incentive to meet demands

Third - Many doctors tend to prescribe brand name medication because large companies give them handouts. According to NPR in 2013, doctors who were surveyed said that they would prescribe brand name drugs even when generics were available. The NPR analysis furthers that these doctor's willingness was associated to their acceptance of free commodities or samples of brand name drugs from the same companies that were influencing their decision to prescribe expensive medication. Even if you don't buy any of those issues with generics specifically, this argument is nonunique because generic drugs do not go away in an AFF world. Unless they can uniquely prove why affirming would take away the access to these generics, this argument has no weight in the round.

Finally, you have to flow this argument over to AFF because we turn it in two ways. First, because generics are getting expensive. Harvard Medical School in 2015 found that 400 different generic drugs have been subject to price increases of over 1000%. The second way we can turn it is because generics are poor quality as observed in 2 instances. Harvard Medical School found in 2018, that the utilization of generics in emergency room visits resulted in an increase in future hospitalization. Harvard furthers that this is because generics are manufactured with different inactive ingredients and have variations in chemical formula that cause people to react differently. In addition, according to the Harvard Business Review in 2017. Over 260 generic drugs were recalled for being poor quality.

Business Insider

The ASHP cites a number of reasons for the shortages. Most are related to manufacturing problems. In the cases of saline and dextrose, Baxter's facilities in Puerto Rico were hit by the hurricanes, adding to existing drug shortages. In other cases, some of the companies which make large portions of the drug simply stop making it, or a drug is only being produced by a single manufacturer. **There simply are not enough companies making the drug to keep up with demand.** It's all part of a consolidation of the manufacturers who produce generic drugs. **US generic companies have had a harder time turning a profit on generic drugs** while competing with companies outside the US that are able to make the same drugs at a cheaper cost. **That's caused manufacturers to home in on certain generic drugs and discontinue others that don't make as much money. And if a generic manufacturer has a shortage,** there's no easy fix you can't just pass off the job to another company while the first fixes its problems, since getting approval to take on a new drug can take years. When it comes to this particular shortage, the AHA said in its letter that it would like the FDA to push manufacturers that make these drugs to invest in creating more supplies in the future, as well as find suppliers within the US that aren't as susceptible to natural disasters. The FDA said it will respond directly to the AHA regarding its letter. "However, in general the FDA has an important role to play in working with companies to address product shortages that disrupt patient access to medical products, and we have been closely working on a number of efforts related to the current IV fluids shortage, which actually dates back to 2014, but was recently worsened by Hurricane Maria's impact on Baxter manufacturing facilities in Puerto Rico," an FDA spokeswoman told Business Insider. "The FDA understands the concerns and importance of the ongoing shortages of IV solutions and we are actively working within our regulatory authority to address the shortage."

The Quartz

Chaggar, Anees. "America's Ongoing Lack of Generic Drugs Is a Matter of Life and Death." Quartz, Quartz, 3 Apr. 2016, qz.com/653136/americas-ongoing-lack-of-generic-drugs-is-a-matter-of-life-and-death/.

Some, like Owen's dad (cancer surgeon Kelly McMasters), believe that **generic manufacturers simply do not have a financial incentive to produce drugs like methotrexate. They cite as evidence the fact that we never seem to run out of the drugs that cost thousands of dollars, and that shortages increased after the 2003 Medicare Modernization Act restricted Medicare reimbursement on these drugs to the average selling price, plus a 6% administrative fee.** Others argue that increasing regulations imposed by the FDA have created more red tape and propagated shortages, a claim the FDA vigorously denies. Regardless of where the blame is laid, however, it seems clear that the current way of doing things is broken. A House of Representatives oversight committee found that in 2010, 90% of all oncology generic drugs were made by a handful of manufacturers in this country, meaning production disruptions at one factory can cause serious issues nationwide. It's time for a better system. In order to create a sort of emergency pipeline, the generic pharmaceutical industry has started what it calls the "Accelerated Recovery Initiative (ARI)," the goal of which is to limit the number of patients who cannot get a hold of drugs in critical shortage. While the process is long and complicated, it proves this is not an entirely unsolvable issue. Meanwhile, the FDA sent out a press release in February calling for increased modernization in the pharmaceutical industry, and vowing to help provide guidance to companies that are pursuing new technology.

NPR

Hensley, Scott. "Why Didn't Your Doctor Prescribe A Generic? Look In The Mirror." NPR, NPR, 7 Jan. 2013, www.npr.org/sections/health-shots/2013/01/07/168810473/why-didnt-your-doctor-prescribe-a-generic-look-in-the-mirror.

The generics are usually inexpensive. Think \$4 for a month's supply of the depression drug fluoxetine (or Prozac) at Wal-Mart. If you have insurance that covers pharmaceuticals, your copay will be lower with a generic than a brand-name drug, too. So when there's a generic available, why do doctors still write prescriptions for the brand? One reason: You asked for it. Some 37 percent of **doctors surveyed say they sometimes go ahead and prescribe a brand-name drug upon request, even when there's a generic available. The researchers found that doctors' willingness to prescribe a brand was associated with their acceptance of free food from drugmakers. They were also more likely to accept samples of brand-name drugs to hand out to their patients, too.** The findings were just published online by JAMA Internal Medicine. The researchers figure their estimates of doctors' willingness to prescribe a brand are at the low end of what happens in reality. Doctors surveyed (about 1,900 in this study) may not be inclined to fess up about going along with patients' requests. One limitation of this study is that the researchers can't be sure exactly which drugs patients got. Pharmacists in many states can substitute a generic, when it's available, to fill a doctor's prescription for a brand. An accompanying editorial calls for direct action to overcome prescriptions driven by "irrational cultural practices." Some health systems override physicians' prescriptions choices when there's a generic option. And the editorial says that measures like that "have immense potential to increase value in prescription medication use."

Harvard Medical School

Ameet Sarpatwari, Jd, PhD, 10-22-2015, "Why many generic drugs are becoming so expensive," Harvard Health Blog, <https://www.health.harvard.edu/blog/why-many-generic-drugs-are-becoming-so-expensive-201510228480>

The high cost of prescription drugs is big news. You hear about it on television, in your doctor's office, and even on the campaign trail. When you think about expensive drugs, you may think about novel therapies for lung cancer or hepatitis C. But in fact, prices are also skyrocketing for the generic versions of some commonly prescribed drugs. An article published last year in The New England Journal of Medicine reported that between 2012 and 2013, captopril — a generic drug used to treat high blood pressure and heart failure — increased in price from 1 cent to 40 cents per pill. During this same period, the cost of doxycycline, an older antibiotic, increased from 6 cents to \$3.36 per pill. Connecture, a health insurance information technology company, reports that while the price of most generic drugs remained constant between 2008 and 2015, **almost 400 generics saw price increases of more than 1,000%.** At a time when 18% of prescription drug costs are paid for out-of-pocket and 8% of Americans report not taking their medications in order to save money, such dramatic increases in generic drug prices place a heavy burden on public health. Why are generics going up in price? Most of us think of generics as the less expensive alternative to the brand-name version of a prescription drug — and that's often the case. **The pharmaceutical companies that make generics can sell them for lower prices** because they didn't have to pay for the research and development that brought the drug to market in the first place. **However, this cost advantage can take a back seat in situations such as the following, in which competition is reduced or delayed, enabling generic manufacturers to increase their prices:** The market for some generic drugs is so small that it does not attract multiple producers, as with pyrimethamine (Daraprim), a very old drug used to treat a parasitic infection called toxoplasmosis. GlaxoSmithKline had long been the only producer of pyrimethamine, but priced it modestly. This August, however, Turing Pharmaceuticals acquired rights to the drug and exploited its monopoly, raising the price 5,000% (from \$13.50 to \$750 a pill). In some cases, the number of producers of a generic drug decreases because of an ongoing wave of market consolidation within the pharmaceutical industry.

Harvard Medical School

Harvard Health Publishing. "Do Generic Drugs Compromise on Quality?" *Harvard Health*, Harvard Medical School, Jan. 2018, www.health.harvard.edu/staying-healthy/do-generic-drugs-compromise-on-quality.

This brings us to the Canadian study that seems to show differences between generic and brand-name medications. While it didn't examine how well these medications performed when it came to reducing blood pressure, it did raise the question of whether patients experienced more serious side effects from the generic medications than the original versions of the blood pressure drugs researchers looked at. The researchers looked at the numbers of emergency room visits and hospitalizations for 136,177 individuals ages 66 and over (60% of them women) who used any of three blood pressure medications: losartan (U.S. brand name Cozaar), valsartan (Diovan), and candesartan (Atacand). They examined data for the periods 24 months before and 12 months after the generic versions of these medications went on the market. **They found that before the generic versions became available, about one in 10 people taking the blood pressure drugs had to go to the emergency room or be hospitalized each month. In the month after each of the generics went into use, the rates of these adverse events went up: 8% for losartan, almost 12% for valsartan, and 14% for candesartan.** But the question is, did this increase result from problems with the generic versions of these medications? Or were there other factors that occurred in this time frame? "It is always possible, in fairness, that strange things happen," says Dr. Choudhry. **Maybe the generic form was manufactured with a different inactive ingredient that caused patients to have more side effects. Or maybe a slight variation in the chemical formula made people react differently.** But the increase in medication-associated events could have also been a result of problems with the study and the patient population researchers followed.

Harvard Business Review

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

"Although makers of a branded drug are using a variety of tactics to create barriers to healthy competition, generic drug companies are often not helping their own case. **In 2015, there were 267 recalls of generic drug products—more than one every other day. These recalls are for quality issues such as products not dissolving properly, becoming contaminated, or even being outright counterfeits.** A few high-profile recalls have shaken the belief that generic drugs are truly the same. In 2014, the FDA withdrew approval of Budeprion XL 300 — Teva's generic version of GlaxoSmithKline's Wellbutrin XL. Testing showed the drug did not properly release its key ingredient, substantiating consumers' claims that the generic was not equivalent. In addition, concerns about contaminated generic Lipitor caused the FDA to launch a \$20 million initiative to test generic products to ensure they are truly therapeutically equivalent."

Insurance Companies Pay For Drugs

You can delink this argument in two ways.

First, Chan from Boston University in 2016 found that as the cost of medication increases, health insurers look to shift the burden of expenses onto patients through higher deductibles or premiums. This is confirmed by the Healthline Board in 2018 when they find that an increase in drug prices greatly outpace healthcare inflation costs, which have been comparatively low in the past few years. These price increases increase insurance premiums

Second, This argument completely isolates low income individuals. The Kaiser Family Foundation in 2017 found that 45% of uninsured adults said that they remained uninsured because the cost of coverage was too high. Many people do not have access to coverage through a job, and some people remain ineligible for financial assistance for coverage. These are the patients that matter, by affirming these patients gain the access to drugs that their insurance blatantly denies them.

Chan

Chan, Kelvin. "Why We're All Talking about Drug Prices Inaccurately: The EpiPen Controversy." Medium, 26 Sept. 2016, <https://medium.com/unraveling-healthcare/why-were-all-talking-about-drug-prices-inaccurately-the-epipen-controversy-2d061689b904>.

Drugs feel more expensive when health insurers cover less of a drug. And as healthcare costs rise, health insurers look to shift the burden of expenses onto its patients through higher deductibles or premiums. Deductibles refer to the amount you have to pay before coverage kicks in. And since 2010, average deductibles have increased over 67%. As more Americans enroll in High-Deductible Health Plans (HDHP), so does the feeling of cost. Under an HDHP, EpiPen, which may have been previously covered by a health insurer for a \$50 co-pay, now costs \$600 until the deductible is met. Premiums or the monthly payments one makes to be covered are rising too, and have increased by about 27%. What's ultimately driving this feeling of "cost" boils down to rising healthcare costs and insurers counteracting those costs by covering less of it.

Healthline Board

Healthline Board. "Drug Price Increases and Your Health." Healthline, 18 July 2018, <https://www.healthline.com/health-news/rising-drug-prices-risk-to-your-health>.

Drug price increases also greatly outpace healthcare inflation costs, which have been comparatively low in the past few years. These price increases affect insurance premiums and out of pocket expenses, but it's hard to say exactly how much. However, Jonathan Gruber, a professor of economics at the Massachusetts Institute of Technology and president of the American Society of Health Economists, says the overall direction is clear. "Higher drug prices translate to higher health insurance costs for all of us," he says. He notes the convoluted system of rebates and discounts between pharmaceutical companies, pharmacy benefit managers, and insurance companies makes things even more murky. "Obviously, if they raise the price, that's going to pass through to some extent to consumers. Whether PBMs are helping or hurting is still unclear, it all depends on how these rebates play through," says Gruber. "We just don't know yet. When they raise the price, how much of that is actually making its way to consumers?"

Kaiser Family Foundation

Kaiser, Henry. Nov 29, Updated; et al. "Key Facts about the Uninsured Population." The Henry J. Kaiser Family Foundation, 19 Sept. 2017, <https://www.kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/>.

Even under the ACA, many uninsured people cite the high cost of insurance as the main reason they lack coverage. In 2016, 45% of uninsured adults said that they remained uninsured because the cost of coverage was too high. Many people do not have access to coverage through a job, and some people, particularly poor adults in states that did not expand Medicaid, remain ineligible for financial assistance for coverage. Some people who are eligible for financial assistance under the ACA may not know they can get help, and undocumented immigrants are ineligible for Medicaid or Marketplace coverage. Most uninsured people are in low-income families and have at least one worker in the family. Reflecting the more limited availability of public coverage in some states, adults are more likely to be uninsured than children. People of color are at higher risk of being uninsured than non-Hispanic Whites.

HIV can be solved without price controls

The HIV epidemic can be ended now, but drug prices are a barrier

Barbara Feder **Ostrov**, health journalist, December 23, **2015**, "It's Not Hard to Treat HIV—if You're Rich," Kaiser Health News, <http://www.thedailybeast.com/articles/2015/12/24/it-s-not-hard-to-treat-hiv-if-you-re-rich.html> (accessed 4/28/17)

HIV/AIDS advocates and physicians say that despite the significant medical advances in treating the disease, many patients are being left behind because of their life circumstances. Groups that once held angry demonstrations against government agencies and pharmaceutical companies to speed access to affordable, life-saving HIV medications now emphasize the socioeconomic barriers that keep some people living with HIV from consistently obtaining and using those drugs to remain healthy. "There is an extreme disparity when it comes to treating HIV and AIDS," said Anthony Hayes, managing director of public affairs and policy for GMHC, formerly Gay Men's Health Crisis. "It's critical, when we talk about ending the epidemic, to not just to talk about the science. These are people who are incredibly vulnerable as it relates to all aspects of society. In contrast, more-affluent HIV-positive people—specifically gay white men—are able to access care, they have jobs, they have homes, they have access to life's basic necessities that many do not. "It's very hard to talk about HIV prevention with someone who is homeless or someone who isn't sure where they're going to find their next meal." It's not a simple matter of financing care for those who can't afford it. Treatment and social services are currently available for low-income and uninsured or underinsured patients under the Ryan White Act. Once long waiting lists for free HIV medications have virtually been eliminated. But basic survival—money to live, a place to sleep—often takes precedence over seeking help and closely managing a disease that can be symptom-free in its early stages, doctors say.

Insurance companies are requiring patients to pay more for HIV medication

Shefali **Luthra** and Anna Gorman, journalists, June 30, **2018**, "Rising Cost Of PrEP To Prevent HIV Infection Pushes It Out Of Reach For Many," National Public Radio, <https://www.npr.org/sections/health-shots/2018/06/30/624045995/rising-cost-of-prep-a-pill-that-prevents-hiv-pushes-it-out-of-reach-for-many> (accessed 10/5/18)

As policymakers and the health system debate how to control ever-climbing drug prices, experts say this case underscores how patients are left holding the bag. Private health plans are making patients responsible for a larger share of drug costs. And more are restricting use of the copay coupons pharmaceutical companies have used to shield patients from out-of-pocket expenses. Insurers say the drug companies use coupons to steer consumers toward pricier meds. One way health plans are limiting their use is by no longer allowing them to count toward patients' deductibles. "This is one more thing that is going to push people off their medications," says Jim Pickett, a senior director at the AIDS Foundation of Chicago.

PrEP can cut new HIV infections in half by 2020, but cost is a barrier

Selena **Simmons-Duffin**, journalist, April 10, **2018**, "PrEP Campaign Aims To Block HIV Infection And Save Lives In D.C.," National Public Radio, <https://www.npr.org/sections/health-shots/2018/04/10/599606352/prep-campaign-aims-to-block-hiv-infection-and-saves-lives-in-d-c> (accessed 10/5/18)

A big part of Washington D.C.'s plan to get its HIV rate down is to get more uninfected people on PrEP, a two-medicine combination pill that's also sold under the brand name Truvada. When taken daily by people who are at high risk for contracting HIV via sex or shared needles with someone who is

infected, this pre-exposure prophylaxis can cut the risk of HIV infection by 92 percent, studies show. Most insurers cover treatment with the pill, also known as pre-exposure prophylaxis, or PrEP. It has been shown to be more than 90 percent effective in HIV prevention when the medicine is taken daily, according to the Centers for Disease Control and Prevention. **But patients can get stuck with out-of-pocket costs that make the medicine unaffordable. To cut new infections in half by 2020, D.C. health officials estimate it will need to more than quadruple the number of people in the District who are on PrEP.** The department of health and community groups are pulling out all the stops to raise awareness.

A cure for HIV is coming now

Elianna **Bar-El**, contributing reporter, May 24, **2017**, “A Breakthrough Cure for AIDS May Be on the Horizon,” Goodnet, <https://www.goodnet.org/articles/breakthrough-cure-for-aids-may-be-on-horizon> (accessed 10/5/18)

For those who have spent the majority of close to the last four decades with bated breath for a cure to one of the world's most devastating viruses, you may just be able to expel a sigh of relief. **Scientists at New York's Rockefeller University recently released significant research supporting the fact that a heady combination of three antibody drugs have the revolutionary potential of suppressing HIV in infected mice. The remarkable discovery of isolated antibodies was culled from a patient who displayed an unusually effective response against the virus - leading researchers to believe that they have hit the nail on the head they've been seeking for the last ten years.** This patient is part of a small group of infected individuals - called elite controllers - who possess immune systems capable of defeating the virus by manufacturing broadly neutralizing antibodies, which can take down multiple forms of HIV. **The patient lending his blood to science was infected at least three decades ago and has developed at least three different types of broadly neutralizing antibodies that bind to three different sites on the virus. The remarkable thing about his antibodies is that they seem to complement each other's activity, completely shutting down HIV.**

A cure for HIV will be developed within a year

Jonathan **Leitman**, journalist, October 27, **2016**, “A Cure on the Horizon?” Roosevelt Institute at Cornell College, <https://www.cornellrooseveltinstitute.org/health/a-cure-on-the-horizon> (accessed 10/5/18)

For millions of people around the world suffering from HIV, there is now hope after an experimental vaccine has left a 44-year-old, unnamed British man with no detectable levels of the virus. The new treatment, along with a high dosage of the antiretroviral drug Vorinostat, is the culmination of a joint effort by the National Health Service of the United Kingdom and five British institutions: Oxford, Cambridge, Imperial College, King's College, and University College. **It works by causing HIV-infected cells to produce more proteins, allowing the immune system to detect and destroy them. The treatment goes a step further than past efforts, because not only does it suppress the virus, but destroys dormant cells that carry the virus.** While many doctors and medical experts are wary to say that this treatment is a cure, it is evident that this vaccine is a triumphant breakthrough in HIV treatment, and within the next decade we may see the end of HIV infection.

Life-saving HIV medication prices are increasing

Rebecca **Robbins**, health reporter, July 1, **2016**, “Gilead hikes price of HIV therapies, other drugs by up to 10 percent,” Stat News, <https://www.statnews.com/pharmalot/2016/07/01/gilead-hikes-prices-six-drugs-7-10-percent/> (accessed 10/5/18)

Gilead raised the price of its hypertension drug Letairis and of its HIV regimens Complera and Stribild by 7 percent each. The HIV treatment hikes come on top of increases in the prices of both of those

drugs just six months ago, by 7 and 5 percent, respectively. Gilead's moves come amid ongoing uproar over the rising cost of medicines — and on the heels of a series of price hikes by other big drug companies. Pfizer several weeks ago raised its US drug prices by an average of nearly 9 percent. And in recent months Mylan has raised prices by more than 20 percent on two dozen products, including several increases of more than 400 percent.

Long-Term Cost Increases

We see three main concerns with this argument.

Logically, it makes no sense. The long-term cost of drugs cannot increase more than the price control enforced by the USFG

Even if you think there's some weird type of logic to it, it's non-unique because their link to the cost of drugs is innovation which exists in either world. According to the UCLA in 2008, there are existing federal policies that incentivize drug innovation through tax credits.

Finally, you can turn the argument because in the status quo, the cost of drugs is already at an all-time high. According to the Washington Post in 2015, as long as there is R&D investment, drug companies will keep their prices high. Voting for the CON in today's round ensures that the LT price of these drugs increase because there is a lack of federal regulation. On the contrary, imposing price controls through the PRO world would regulate these companies and keep prices affordable for consumers

UCLA

Yin, Wesley. "Market Incentives and Pharmaceutical Innovation." Science Direct, 2008. https://luskin.ucla.edu/sites/default/files/download-pdfs/ODA_innovation.pdf

I study the impact of the Orphan Drug Act (ODA), which established tax incentives for rare disease drug development. I examine the flow of new clinical drug trials for a large set of rare diseases. Among more prevalent rare diseases, the ODA led to a significant and sustained increase in new trials. The impact for less prevalent rare diseases was limited to an increase in the stock of drugs. **Tax credits can stimulate R&D;** yet because they leave revenue margins unaffected, tax credits appear to have a more limited impact on private innovation in markets with smaller revenue potential. This paper studies the impact of public policy on private innovation. Policy intervention is normatively justified when market failures lead to inefficient allocation of R&D investments. Whether public policies can improve welfare in these cases depends in large part on whether they are able to stimulate innovation.

The Washington Post

Angell, Marica. "Why Do Drug Companies Charge so Much? Because They Can." The Washington Post, WP Company, 25 Sept. 2015, www.washingtonpost.com/opinions/why-do-drug-companies-charge-so-much-because-they-can/2015/09/25/967d3df4-6266-11e5-b38e-06883aacba64_story.html?utm_term=.af0856bca6a3.

Drug companies say high prices are necessary to cover their research and development costs, enabling them to discover innovative new medicines. Turing says it planned to use the profits from Daraprim's higher price to fund research into better treatments for toxoplasmosis. But in fact, Daraprim illustrates the way most drugs are priced: They are invented not by the companies that sell them now but by someone else. Then, like big fish swallowing little fish, larger companies either buy small firms outright or license promising drugs from them. Very often, the original discovery occurs in a university lab with public funding from the National Institutes of Health (NIH), then licensed to a start-up company partly owned by the university and then to a large company. There is very little innovation at the big drug firms. Instead, their major creative output is trivial variations of top-selling medications that are already on the market (called "me-too drugs"), to cash in with treatments just different enough to justify new patents.

Free Market Good

Health care is not simply another commodity, it is something we have a moral obligation to provide

Frank G. **Kirkpatrick** Author, 'The Episcopal Church in Crisis: How Sex, the Bible and Authority are Dividing the Faithful, June 4, **2013**, Huffington Post, The Missing Moral Dimension in the Health Care Debate, http://www.huffingtonpost.com/frank-g-kirkpatrick/the-missing-moral-dimension-in-the-health-care-debate_b_3383194.html

This is good news for those concerned about the costs of providing all Americans with access to quality health care. But it also obscures an element that has been sadly and surprisingly missing from recent health care debates, especially among those vehemently opposed to the Affordable Care Act (Obamacare). That missing element is the moral basis for health care. The political debate has become focused almost entirely on costs rather than on the services those costs help to pay for. By concentrating on costs to the virtual exclusion of everything else, the **opponents of providing universal health care want us to believe that health care is an optional consumer commodity**, one that consumers can freely choose to obtain or not to obtain depending on their preferences. Among people committed to the libertarian principle that all choices are essentially economic and are to be made by individuals pursuing their own self-interests, it is almost inevitable that everything with a cost attached to it is a commodity, to be chosen or not chosen as one sees fit. **But to treat health care as an optional commodity, which should compete in the market place alongside the option of choosing a large flat-screen TV, fundamentally misunderstands what health care is and why its provision is a moral imperative in a society that claims**, however confusingly, to be a moral society. **In a family, the health of the members is not normally treated as a commodity whose purchase is optional and whose importance is to be weighed alongside the purchase of a new car or a club membership. When a child is dying of a disease that can be treated, the family does not seriously ask whether it should seek the treatment and forgo the vacation. It places the health of the sick child above everything else. In a family context most people know that the health of those they love is an essential moral necessity not to be compared with truly discretionary options.** (As a nation we used to think of national defense in the same way: It was a moral necessity and should be funded by taxes at whatever level was necessary to make it reliable.)

Government is already the largest health care provider

Leo **Chan**, Assistant Professor of Finance Department of Finance and Economics Woodbury School of Business, Utah Valley University, September **2010**, It is the moral obligation of the state to provide basic health care for its citizens, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1578548 DOA: 6-26-16

Some of those opposing health care reform would argue that the government is not in the business of meddling with people's health care. But the government is already the largest health care and health care insurance provider in the US! If we don't do anything about the health care system now, the government's Medicare and Medicaid commitment will bankrupt the government in 20 years. If there is universal health care, Medicare and Medicaid will be part of it, and I can assure you that the cost for the government will be much, much less than 30% of tax revenue. The future Medicare and Medicaid unfunded liabilities of \$50 trillion will be off the books. So, the government's financial commitment will be smaller, not bigger with a universal health care system. Further people will actually make their own choice whether to have private insurance or not.

Government health care can't be dissolved

Leo **Chan**, Assistant Professor of Finance Department of Finance and Economics Woodbury School of Business, Utah Valley University, September **2010**, It is the moral obligation of the state to provide basic health care for its citizens, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1578548 DOA: 6-26-16

The current system is so full of subsidies and loopholes that would be impossible to untangle. It would be impossible to dissolve the current system when the government has already made commitments to millions of retirees. If you think deeply about the nature of health care, you can argue that the health of its citizens in any particular country is a public good. All public good should be provided, in some form, by the government under classical economic theory.

Health care is a basic public good

Leo **Chan**, Assistant Professor of Finance Department of Finance and Economics Woodbury School of Business, Utah Valley University, September **2010**, It is the moral obligation of the state to provide basic health care for its citizens, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1578548 DOA: 6-26-16

In economics, a public good is a good that is non-rivalrous and non-excludable. This means that consumption of the good by one individual does not reduce availability of the good for consumption by others; and that no one can be effectively excluded from using the good. Of course, no real world example can be classified a true public good. The two most common public goods are basic education and national defense. The similarities of basic education and basic health care are many. **For a nation to prosper, it must have a well educated and a healthy workforce.** One can argue that the benefits of education are largely captured by the person receiving the education. But a higher educated individual, with a high income, contributes far more tax revenue than a person with low level of education and who works for a low wage. Thus, the benefit of someone became highly educated is not fully excludable or rivalrous. **The same can be said about the health of the workforce of a nation. A country whose citizens have limited access to health care usually has low GDP per capita. The reason is that productivity will be limited as people get sick more often. Preventive medicines and early treatments are not easily obtainable in these countries. As a result, people usually wait until they get really sick before they get medical care (if they can get any). A healthy workforce (particularly for those who work for low income jobs) will ensure that basic services to those who are highly trained are uninterrupted. Imagine the economic losses if the baby sitter or nanny of a top executive of a Fortune 500 company got sick, and the executive has to take a day off to take care of the kids. Or imagine if the millions of college educated female members of the workforce were forced to do all the household tasks their grandmother's generation were expected to do because there were no healthy low-income workforce to shoulder those responsibilities (dinning out, lawn care, etc) for them?** The economic consequence of these two examples is not a small sum.

Health care needs inconsistent with the free market

Leo **Chan**, Assistant Professor of Finance Department of Finance and Economics Woodbury School of Business, Utah Valley University, September **2010**, It is the moral obligation of the state to provide basic health care for its citizens, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1578548 DOA: 6-26-16

A universal health care system is also fair and more efficient. An individual's income profile over the life time is a hump-shape. However, our need for medical care is a V-shape. So, there is a mismatch of income and the ability to afford medical care. Imagine if all babies had to come up the cost needed to get them delivered. Unless there is a market in which we can borrow our future income to get health care when we need it at a younger age, poor babies would suffer. Universal health care is the only way in which a person would be able to afford health care when born into a poor family. A person who is born into a poor family who gets good basic education and basic health care would be able to increase his/her income potential, and thus increase his/her ability to pay higher taxes in the future and repay the medical expenses the government lend them when they were young. In essence, this is

how the free K-12 education supposes to work. The same can be applied to basic health care. If the government is benefitting from the hard work provided by low-income family, it has a moral obligation to provide basic health care to them to ensure a fair playing field for all.

Free market destroying the health care system

Annalisa Merelli, 2015, Quartz, <https://qz.com/509344/the-way-to-fix-outrageous-drug-pricing-in-the-us-is-simply-to-do-what-all-other-rich-countries-do/> The way to fix outrageous drug pricing in the US is simply to do what all other rich countries do

Yes, we can lower sky-high drug prices — other countries have done it. Finally, **pharmaceutical companies can count on tens of billions of dollars in revenue, at higher margins than most other sectors (with the sole exception of software). So they make the most of the opportunity to advertise directly to the customer in the world's only rich market that's unregulated. With more advertising come more requests of specific brand names, which in turn can cause higher volumes of prescriptions, overmedication, and price hikes.** This doesn't in any way mean that other countries are immune to high drug prices. A recent Guardian article, for instance, exposed the struggles of the UK's National Health System (NHS), one of the biggest in the world, in supplying British patients with expensive cancer drugs. Yet drug prices that are too high for the NHS, or other publicly funded systems, are a fraction of what US citizens pay. Let's take Daraprim as an extreme case: the same drug (pyrimethamine, Daraprim's main ingredient) that could be priced \$750 a pill in the US is currently available in India for ₹7, or \$0.10. Beyond drug pricing. The Daraprim case should make clear why 61 prominent US economists are among the 267 signatories of the Economists' Declaration on Universal Health Care, a statement led by Larry Summers and subscribed to by economists Joseph Stiglitz and Thomas Piketty, presented in New York ahead of the United Nations General Assembly, on Sept. 18. **Healthcare expenditure in the US far outpaces other rich countries** and represents the first cause of individual bankruptcy. In the declaration, the **economists "call on global policymakers to prioritize a pro-poor pathway to universal health coverage as an essential pillar of development."** The document also focuses on the **individual human right to high-quality, accessible health care, which, if administered through universal coverage has "accompanying benefits in both health and in protection from health-related financial risks."** Publicly funded healthcare is not simply good for citizens but also for the economy on the whole. As Yates told Quartz, "these [economists] aren't people who have vested interests, but who recognize that [universal health coverage] is good for society." Indeed, despite the US adversity to publicly funded, socialized healthcare (where citizens contribute to health coverage according to their income), the current system has proved ineffective not only in providing access to affordable care, but also in saving public resources. Although the Affordable Care Act might help in reducing costs for the government, the US government is currently in the paradoxical position of spending more in healthcare than any other in terms of GDP percentage, while covering a much smaller percentage of the overall health costs. "One of every four dollars we pay in the US [for healthcare] are used for administrative expenses," William Hsiao, professor of economics at Harvard Public Health School, told Quartz. Because there are so many insurers, each with their own sets of rules, there is a large amount of resources wasted purely in dealing with the system. To explain it, Hsiao provides the example of an independent medical practice. The average US independent doctor, Hsiao says, deals with an average of six different insurance companies, each providing several products with specific rules in terms of reimbursement and co-pay, so the practice has to deal with an estimated 30 different plans. This becomes so complicated that the doctor has to hire a dedicated person to deal with it, and on top of it 25% of the nurses' weekly time, and eight hours of the doctor's, are dedicated to administrative tasks. If, instead, there were a single, publicly funded payer—not necessarily through taxation, but with a social insurance fund based on income, that covered everyone—these costs would be eliminated. **"My very rough guess would be that we could reduce US healthcare cost of 30%," Hsiao told Quartz. It would mean going from a 17.5% GDP spending in health to about 12%—which could save the average American \$2,500 a year.** But what would happen to all those administrative jobs that would become obsolete? "To be realistic about it, the savings of the initial years would have to be spent re-training the people for some other occupations," Hsiao told Quartz. This would, however, only be an issue for the very short-term, since people would spend the savings they make on healthcare in other sectors, creating new, different jobs. The American exception Then there is the cultural issue, well expressed a few years ago by Megan McArdle in The Atlantic: "Once the government gets into the business of providing our health care, the government gets into the business of deciding whose life matters, and how much." That is a concern that sits at the core of the American belief that no good comes of government's involvement in the life of the individual—in any sphere. It's something that profoundly differentiates the US from other Western countries, and is embodied in the country's welfare state (or lack of thereof). The economists directly address this in their declaration, stating that "resource constraints require individual countries to determine their own definition of 'essential.'" They, however, believe having a public entity, rather than private capital, decide what is "essential," (what needs to be covered, and in which order of priority) is the better option. "You never get perfect universal health care," Yates told Quartz, "it's always a process." **Defenders**

of private healthcare think it offers choice and access to the best services. But the reality is that such services remain a privilege of the rich, who face a proportionally lower cost since insurance premiums, whether provided through an employer or independently purchased, do not vary according to the insured's income level. The system doesn't appear to be working, and the poor performance of America in terms of health parameters such as life expectancy, infant mortality rates, maternal deaths are proof. But while many agree that the system needs to change, not everyone is convinced publicly funded health care is the way to go, or that it would even be feasible, in the US. "You have to have a solution that fits your culture," said Ondra, who proposes an approach to healthcare that would leverage the private entrepreneurial spirit as a driver to lower costs. "If you can find a non-governmental solution, a rational middle ground that fits more with our dynamics," Ondra told Quartz, that would be "more efficient and creative." Yates, on the other hand, thinks America might not be that far from implementing publicly funded health care. The Affordable Care Act, he says, was the first step in that direction, and now some states "are debating [adopting] health care [plans] that are socially and publicly funded." The power is often in people's hands on this and, Yates believes, can move the electoral needle in the US as it has in other countries. Healthcare is a campaign issue, and not only for the left: "Donald Trump has been on the record as believing in universal health care," Yates told Quartz, and in case a Republican won, "it wouldn't be without precedent that a rightwing government introduces universal health care." As the US struggles with the dilemma, middle- (and sometimes low-) income countries the world over are adopting publicly funded systems. Sri Lanka, Brazil, Turkey, Indonesia are just some of the countries making steps toward universal health care. Paradoxically, America's wealth might be what makes it harder to transition. For all its wastage, the current system has "built up very powerful and wealthy stakeholders," Hsiao told Quartz. What he calls a "rampant insurance industry" is worth about \$1 trillion—a size large enough that even a 1% investment in lobbying and advertising could stall attempts at substantial reforms at the federal level. These vested interest groups aren't, however, as powerful at the state level, where perhaps lies the real hope for the American system to finally follow the rest of the world's lead.

Moral status of health care justifies government involvement

Leonard M. **Fleck**, Ethics Professor, Michigan State University, **2009**, Just Caring: Health Care Rationing and Democratic Deliberation, p. 103

When the question is raised as to whether or not health care resources are morally special, the intent is to suggest that health care ought to be distributed in accord with norms of justice as opposed to market norms (i.e., ability to pay). Two preliminary considerations would suggest that health care ought to be distributed in accord with norms of justice: its effectiveness in matters of life and death, and the massive public investments that yielded effectiveness.

Moral significance of health care means it can't be left to the market

Leonard M. **Fleck**, Ethics Professor, Michigan State University, **2009**, Just Caring: Health Care Rationing and Democratic Deliberation, p. 103

Health care today is often very effective in reversing or substantially ameliorating the effects of illness or accident. That is, needed health care can often make the difference between life and a very premature death, or between a serious temporary injury and a serious permanently disabling injury. These are morally significant outcomes. It is hard to imagine any consumer good or service distributed on the basis of the ability to pay that has comparable consequences. Further, what would seem to be a related and relevant moral norm would be a "duty to rescue."

State Level Action Better

State level legislation won't pass

Kimberly **Leonard**, 9-25, **15**, <https://www.usnews.com/news/the-report/articles/2015/09/24/expensive-drugs-a-drag-on-consumers-and-government> Budget Breakers

At the state level, legislation has centered on improving transparency so drugmakers can justify their prices to public agencies. **Bills have been introduced in several states requiring drug makers to disclose costs for research, development, manufacturing and marketing, as well as the profits, for costly drugs or in some cases for all drugs. Passage, however, appears unlikely. "The pharmaceutical industry is the third rail of politics and if you go against them they will cut you off at the knees,"** Salo says.

PBM Takes Cut

PBMs take the smallest slice of the pie

Sarah **Owermohle** & Sarah **Karlin-Smith**, Aug 6 **2018**. Politico. “Reality check on PBMs and drug costs” <https://www.politico.com/newsletters/prescriptionpulse/2018/08/06/reality-check-on-pbms-and-drug-costs-306265>

Because the PBMs can retain a portion of the rebate as profit, they may have a perverse incentive to favor higher-cost medicines with larger rebates in their insurance plan formularies, leading drugmakers to raise prices on brand medicines, HHS Secretary Alex Azar has said. But **a new analysis sheds light into how little of U.S. drug spending might be addressed by overhauling rebates. That’s because most of the money spent on pharmaceuticals in this country goes to drug companies — not middlemen like PBMs**, wholesalers, pharmacies, insurers or doctors. **The U.S. spent an estimated \$480 billion on prescription medicines in 2016**, including the gross profits of all intermediaries, according to an analysis last week on the Health Affairs blog. Memorial Sloan Kettering Cancer’s Nancy Yu, Preston Atteberry and Peter Bach found that **\$323 billion of that was drugmakers’ net revenue** excluding rebates, discounts and other price concessions like copay coupons — but not accounting for manufacturing expenses. In comparison, **PBMs captured only 4 percent of the pie** — or \$23 billion in gross profits. That’s less than the profits taken by other players in the supply chain like pharmacies (\$73 billion), providers (\$35 billion) and wholesalers (\$18 billion).

Political Backlash

This is ridiculous. By their logic we should never impose price controls on industries that exploit their consumers because they can just use lobbying power to get out of regulation. Remember that the resolution says “should” – We aren’t discussing the political feasibility, we’re discussing the substance of the resolution itself.

Besides, this argument is non-unique in two ways. First, there is always going to be political backlash. Either pharmaceutical companies are lobbying to stop price controls from happening or they are pushing for general drug regulation to be halted after the resolution is affirmed. Moreover, there has never been a time where the House or Senate have made an amicable agreement on policy making without having conflict. This means that their advocacy is only possible in utopia.

The second way it’s non-unique is that pharmaceutical companies have been lobbying since around the early 90’s so by their logic political backlash has been happening for over 20 years. Judge, you need to make them prove that price controls would all of a sudden fire up congressional leaders and cause more backlash.

Rare/Orphan Diseases

First, you can delink their argument because The Orphan Drug Act has made substantial progress to making breakthroughs in rare orphan diseases. The National Organization for Rare Disorders found that as of 2017, the FDA has approved 600 orphan drugs. These advancements are not related to the private sector but are rather coming from federal organization funding.

Second, even if you don't buy that delink, I got a second one free. The FDA decides what orphan drugs are approved and what rate they are licensed at. In fact, under Section 529 to the FD&C Act, the FDA awards priority review to rare orphan diseases. Under this program, a drug sponsor who receives priority approval may qualify to receive a priority review, expediting the licensing procedure and making it top priority. This means that the private sector has nothing to do with how these drugs get to the people

Finally, you can turn this argument because the investment that goes to these orphan diseases come from the Orphan Drug Act and not the private sector, reducing the cost of these drugs has no correlation with taking away investment. The reason that this is important is because we increase access to orphan drugs by capping the price at which they are sold, without touching the federal investment that is making the breakthroughs for these rare diseases. Voting for the PRO is a win-win situation.

National Organization for Rare Disorders

National Organization for Rare Disorders, "Trends in Orphan Drug Costs and Expenditures Do Not Support Revisions in the Orphan Drug Act: Background and History", https://rarediseases.org/wp-content/uploads/2017/10/NORD-IMS-Report_FNL.pdf

The success of the ODA in the U.S. has been widely recognized over the years and helped to encourage similar legislation in other parts of the world. Japan adopted orphan drug legislation in 1993, Australia in 1998, and the European Union in 2000. **As of January 2017, FDA had approved almost 600 orphan drugs** and granted nearly 4,000 orphan drug designations since 1983. The orphan designation requests include new molecular entities, original biological products and new orphan uses of previously approved drugs and biologics.⁸ Over the years, the ODA has resulted in many treatments, such as zinc acetate for Wilson's disease, that have provided valuable treatment for patients but which had little prospect of commercial return. It has also made possible treatments that have resulted in cost savings. For instance, a treatment for infant botulism developed by California Public Health officials and made possible by the ODA and the orphan grants program, used to date to treat more than 1,500 patients, has resulted in more than 90 years of avoided hospital stay and more than \$130 million of avoided hospital costs.⁹ The need for safe, effective treatments for children has been widely documented, and a 10-year analysis of the ODA concluded that from 2000 through 2009 pediatric products increased from 17.5% to 30.8% of total orphan approvals. These products were for diseases on the rare end of the spectrum, with a median prevalence of 8,972.¹⁰ The ODA has been credited with helping drive innovation in cancer treatment,¹¹ and it has resulted in life-saving enzyme replacement therapies for children and adults with metabolic diseases for which there was previously no treatment. From the patient perspective, the Orphan Drug Act has been extremely successful, encouraging research and development of products for diseases that would otherwise have no treatment.

FDA

U.S. Food and Drug Administration, "Rare Pediatric Disease Priority Review Voucher Program", 11/02/17, <https://www.fda.gov/forindustry/developingproductsforrareediseasesconditions/rarepediatricdiseasepriorityvoucherprogram/default.htm>

Under Section 529 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), **FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. Under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product.** On September 30, 2016, the Advancing Hope Act of 2016 (Public Law No: 114-229) amended Section 529 of the FD&C Act. Among the changes, the term "rare pediatric disease" now means a disease that meets each of the following criteria: A. The disease is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents. B. The disease is rare disease or conditions, within the meaning of Section 526. The Act changed the language of Subsection (A) from, "The disease primarily affects individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents." The full text of the Advancing Hope Act is available at:

<https://www.gpo.gov/fdsys/pkg/BILLS-114s1878enr/pdf/BILLS-114s1878enr.pdf> Effective 90 days after the enactment of the Advancing Hope Act of 2016, the sponsor of a rare pediatric disease product application that intends to request a priority review voucher must submit such request in a cover letter to their NDA/BLA submission.

Shortages/Supply & Demand

First, you can delink their argument because Forbes in 2017 finds that 90% medication is cheap and affordable already and are not suffering from shortages. Just because you enforce price controls on the drugs that are not generic, does not mean they will be subject to special consequences. This is important because unless they can prove that generics, which are already cheap, are suffering from shortages, then there is no link to why other drugs would be affected. Empirically their claims are false.

Second, you can delink it again because Harvard Medical School in 2012 found that the FDA often addresses and solves drug shortages in 2 ways: Either a) The FDA can ramp up production of hard-to-get drugs by expediting approval of materials that have already gone through licensing procedures. Or b) The FDA can look for international sources for specific drugs. They review the safety of such supplies and allows temporary imports to ensure that critical patient needs are met

Even if you don't buy the delinks the argument was non-unique to begin with. According to the AMA, or American Medical Association in 2018, there are current efforts to reform drug shortage policy. in order to respond to shortages occurring in the status quo, the AMA adopted policy declaring drug shortages an urgent public health crisis and have urged the Department of Health and Human Services to examine drug shortages as a national security initiative. Even if they prove that shortages are a bad thing, there are current efforts in action to solve them.

Forbes

Winegarden, Wayne. "Price Controls Will Reduce Innovation and Health Outcomes." Forbes, Forbes Magazine, 12 Oct. 2017, www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduce-innovation-and-health-outcomes/#32f4201363a6.

"To start, the price controls would be irrelevant for most patients. Nearly 90 percent of all drugs dispensed in the U.S. in 2016 were generic medicines, according to IMS Health. Therefore, any price control scheme would not apply to the majority of patients who are using inexpensive generics, not more expensive patented products. It is also important to note that generic medicines are significantly cheaper in the U.S. compared to the other major industrialized countries. In fact, total pharmaceutical spending as a percentage of total health care spending is lower in the U.S. (12.2 percent) than the average for the 30 nations that comprise the Organization for Economic Cooperation and Development, or OECD, (16.9 percent). This is due to, in part, the prevalence of generic medicines that are more affordable here than in other OECD nations."

Harvard Medical School

Ferrari, Nancy. "How Drug Shortages Happen." Harvard Health Blog, Harvard Medical School, 23 Feb. 2012, www.health.harvard.edu/blog/how-drug-shortages-happen-201202174276.

A drug shortage can occur because of increased demand. It can also happen when a pharmaceutical company discontinues a drug or takes a manufacturing facility offline—which companies can do at any time. What can be done? **The FDA can sometimes help ease a drug shortage.** When a drug is in short supply but the manufacturer has some in stock that has expired or is close to expiring, the FDA can review whether extending the expiration date is safe. If so, it can free those supplies to be used. **The FDA can also help ramp up production of hard-to-get drugs by expediting approval of new production lines or new materials that can be used to make the drug.** In some cases, **the FDA may look for overseas sources for specific drugs. It reviews the safety of such supplies and allows temporary import to ensure that critical patient needs are met.** Within the FDA, the Center for Drug Evaluation and Research maintains a Drug Shortage Action Plan. Its goal is to help prevent and address drug shortages. You can read the specifics of the plan here.

American Medical Association

Mills, Robert. "New AMA Policy Reflects Frustration over Ongoing Drug Shortages." New AMA Policy Reflects Frustration over Ongoing Drug Shortages | American Medical Association, The American Medical Association, 12 June 2018, www.ama-assn.org/new-ama-policy-reflects-frustration-over-ongoing-drug-shortages.

Responding to ongoing national drug shortages that threaten patient care and safety, physicians gathered at the Annual Meeting of the American Medical Association (AMA) today adopted policy declaring drug shortages an urgent public health crisis. The new declaration strengthens existing AMA policy outlining the physician prescription for a comprehensive solution to ongoing drug shortages. Many of the drugs currently in shortage are everyday products required for patient care in all medical settings, such as sterile intravenous products containing saline or other fluids. Shortages of these basic products, and their containers, increased following hurricane damage to production facilities in Puerto Rico, leaving the health care system scrambling for options that were either limited or risky. In response to hazards that pose a threat to the resilience of drug production, **the AMA will urge the Department of Health and Human Services and the Department of Homeland Security to examine drug shortages as a national security initiative.** This would result in drug manufacturing sites being designated as critical infrastructure with vital importance to the nation's public health. "Physicians strive to provide the best possible care to their patients, which means being able to obtain the right drugs at the right time," said AMA Board Member William E. Kobler, M.D. "The fact that drug shortages worsened when major hurricanes struck drug production facilities on Puerto Rico highlights the need to evaluate and plan for hazards that pose a threat to critical infrastructure for manufacturing pharmaceutical and medical products." Managing risk to enhance the security and resilience of drug manufacturing sites needs to be a shared priority for the industry and government. However, many manufacturers are unwilling to share production locations for drugs and other medical products, even though information shared with officials at Health and Human Services and Homeland Security is protected by law from public disclosure and used only in the context of preparedness planning and response.

Vaccines

Basically what the NEG is saying is that in a world with price controls, vaccine research slows or even stops. There's a lot wrong with this argument, though. In the span of about 45 seconds, we're gonna delink it, non-unique it, and turn it.

First, the delink. Private sector development is not where vaccines are researched and developed. There are two main sources of vaccine research. Caceres in 2018 finds that most vaccine research is done in universities like Harvard, UCLA, and the University of Washington. If you don't buy that study, Hinman from Clinical Infectious Disease in 2004 found that 57% of immunizations do not come from the private sector. The private sector won't magically start providing vaccine research in the status quo, and public research won't be affected by price controls.

Second, the argument is non-unique because Tate from the Healthcare Institute of New Jersey in 2002 found that vaccine prices already have price regulations and have been stagnant since 1994. This has been an issue for over 20 years, voting for them on this reason literally does nothing.

Finally, you can turn the argument because even if the private sector was making vaccines, research on new vaccines is useless if people cannot afford them. According to the New York Times in 2014, 1/3 of doctors considered giving up immunizations because they were so expensive, and patients could not afford them. Dumping more research into vaccines would be useless as consumers are unable to financially access them in the status quo.

Caceres

Caceres, Marco. "Big Pharma Pays Universities for Most Medical Research in U.S. Today." The Vaccine Reaction, 15 Apr. 2018, <https://thevaccinereaction.org/2018/04/big-pharma-pays-universities-for-most-medical-research-in-u-s-today/>.

In the past, collaboration between scientists in academia and pharmaceutical companies was relatively uncommon. However, lately there has been a growing interest in developing financial partnerships between these two sectors. The drug industry's funding patterns for academic research has shifted from handpicked projects on investigation of the biology of disease to large integrated programs, with an emphasis on the development of therapeutic drugs and vaccines. In the last few years, pharmaceutical companies have also formed "science hubs" in bigger academic institutions to promote biomedical innovation.¹ Some of these partnerships include GlaxoSmithKline at Harvard University, Pfizer at University of California, and AstraZeneca at University of Washington, etc.¹ In fact, with the increasing financial ties between academia and the pharmaceutical industry, many drug companies have formed specialized divisions that are solely responsible for seeking research and development relationships with academic institutions.

Hinman

Hinman, Alan R., et al. "Financing Immunizations in the United States." Clinical Infectious Diseases, vol. 38, no. 10, May 2004, pp. 1440–46. academic.oup.com, doi:10.1086/420748.

Children in the United States receive immunizations through both private and public sectors. The federal government has supported childhood immunization since 1963 through the Vaccination Assistance Act (Section 317 of the Public Health Service Act). Since 1994, the Vaccines for Children (VFC) program has provided additional support for childhood vaccines. In 2002, 41% of childhood vaccines were purchased through VFC, 11% through Section 317, 5% through state and/or local governments, and 43% through the private sector. The recent introduction of more-expensive vaccines, such as pneumococcal conjugate vaccine, has highlighted weaknesses in the current system. Adult immunization is primarily performed in the private sector. Until 1981, there was no federal support for adult immunization. Since 1981, Medicare has reimbursed the cost of pneumococcal vaccine for its beneficiaries; influenza vaccine was added in 1993.

Tate

Tate, Edward. Government Price Controls on Prescription Drugs May Be More than Patients Bargain For - HealthCare Institute of New Jersey. 7 Oct. 2002, <http://hinj.org/government-price-controls-on-prescription-drugs-may-be-more-than-patients-bargain-for/>.

Consider the recent flu vaccine shortage. The largest purchaser of the vaccine is the federal Vaccines for Children Program. The program buys up nearly 70 percent of all childhood vaccines at government-set prices and then distributes them to states according to a federally-set formula. The end result is that vaccines have been distributed to states where there is no epidemic often leaving a shortage where it is needed. **Because the government controls the price, the vaccine makers are discouraged from producing more than what the government orders. Vaccine prices have remained stagnant since 1994. Thanks to these price controls, there now are only four developers of childhood vaccines. That's down from 20 companies just a few years ago.** Even the U.S. Department of Health and Human Services recognizes the consequences to medical innovation if the federal government should choose to impose price controls. In a recent study the Department stated, **"There are potentially serious consequences to medical innovation with the implementation of government controls that are inevitably arbitrary and out of touch with the diversity of patients needs and consequences."**

New York Times

Rosenthal, Elisabeth. "The Price of Prevention: Vaccine Costs Are Soaring." The New York Times, 2 July 2014. NYTimes.com, <https://www.nytimes.com/2014/07/03/health/Vaccine-Costs-Soaring-Paying-Till-It-Hurts.html>.

To deal with the rising prices, some doctors, who say they lose money on every vaccination, reserve their shots for longstanding patients. A survey of family-practice doctors, who along with pediatricians are among the lowest-earning physicians, found that about one-third were considering giving up immunizations because of the expense. Another survey found that 40 percent do not offer at least some required childhood immunizations. That is why Breanna Farris, a San Antonio mother, had to call 10 pediatricians in April before she found Dr. Irvin to vaccinate her son, Traven, who is entering kindergarten this fall. The family's usual doctors do not offer vaccinations, and referred Ms. Farris to local pharmacies (which do not vaccinate children) or the city health clinic (which would not take Traven's insurance).

Negation Blocks

Case Destroyer

They have no solvency because high costs in the status quo are a direct result of price controls in other countries – Implementing more won't fix that

Darius **Lakdawalla**, PhD, Dana P. Goldman, PhD, Pierre-Carl Michaud, PhD, Neeraj Sood, PhD, Robert Lempert, PhD, Ze Cong, PhD, MPhil, Han de Vries, MPhil, and Italo Gutierrez, HHS, (Darius Lakdawalla is an economist. He is the Quintiles Chair in Pharmaceutical Development and Regulatory Innovation at the School of Pharmacy at the Leonard D. Schaeffer Center for Health Policy and Economics at the University of Southern California and co-founder and Chief Scientific Officer of Precision Health Economics, a health care consulting firm. Dr. Lakdawalla also serves as the Executive Director of the "Innovation and Value Initiative", a multi-stakeholder scientific initiative that aims to improve the way value is measured and rewarded in the healthcare marketplace. Dr. Goldman holds the Leonard D. Schaeffer Director's Chair at the University of Southern California and is the founding director of the Schaeffer Center for Health Policy and Economics. He is a Distinguished Professor of public policy, pharmacy, and economics at USC. Pierre-Carl Michaud is Professor of Economics at HEC Montreal and Industrielle Alliance Research Chair on the Economic Consequences of Demographic Change. Neeraj Sood, Ph.D., is the Vice Dean for Research at the USC Price School of Public Policy. In addition, he currently serves as the Director of Research at the Leonard D. Schaeffer Center for Health Policy & Economics, and is a Professor at the Price School's Department of Health Policy and Management and the School of Pharmacy's Department of Pharmaceutical and Health Economics. Robert Lempert is a principal researcher at the RAND Corporation and director of the Frederick S. Pardee Center for Longer Range Global Policy and the Future Human Condition. His research focuses on decisionmaking under conditions of deep uncertainty, with an emphasis on climate change, energy, and the environment. Senior Director, Health Economics and Outcomes Research at Global Blood Therapeutics. Italo Gutierrez is an economist at RAND and a member of the Pardee RAND Graduate

School faculty.) "U.S. pharmaceutical policy in a global marketplace", December 16, **2008**, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804349/>

Markets for innovative goods involve significant spillovers in a global economy. **When US consumers pay higher prices for drugs, this stimulates innovation that benefits consumers all over the world. Conversely, when large European markets restrict prices and profits, foreign consumers bear some of the long-run cost in the form of less innovation.** The result is a free-riding problem at a global level. These incentives are particularly strong for smaller markets, whose policies have relatively little impact on global innovation, but can have relatively large impacts on national pharmaceutical budgets. The result is a system in which the largest countries bear disproportionate burdens for stimulating innovation. Using a microsimulation approach, we estimate the impact of these incentive effects. The model's baseline estimates demonstrates that **the US adoption of European-style price controls would harm consumers in the US and Europe; over a 50-year period, it would cost \$8 trillion in the US, and \$5 trillion in Europe. Similarly, repealing European price controls would add \$10 trillion to the wealth of US society, and \$6 trillion to wealth in Europe. Even under the most conservative assumptions, adopting price controls generates at best a small benefit, but risks a large cost. On the other hand, reducing pharmaceutical copayments would increase wealth in both societies, a result which is robust to a wide variety of parameter values.**

The adoption of price controls in the United States would lower global life expectancy

Darius **Lakdawalla**, PhD, Dana P. Goldman, PhD, Pierre-Carl Michaud, PhD, Neeraj Sood, PhD, Robert Lempert, PhD, Ze Cong, PhD, MPhil, Han de Vries, MPhil, and Italo Gutierrez, HHS, (Darius Lakdawalla is an economist. He is the Quintiles Chair in Pharmaceutical Development and Regulatory Innovation at the School of Pharmacy at the Leonard D. Schaeffer Center for Health Policy and Economics at the University of Southern California and co-founder and Chief Scientific Officer of Precision Health Economics, a health care consulting firm. Dr. Lakdawalla also serves as the Executive Director of the "Innovation and Value Initiative", a multi-stakeholder scientific initiative that aims to improve the way value is measured and rewarded in the healthcare marketplace. Dr. Goldman holds the Leonard D. Schaeffer Director's Chair at the University of Southern California and is the founding director of the Schaeffer Center for Health Policy and Economics. He is a Distinguished Professor of public policy, pharmacy, and economics at USC. Pierre-Carl Michaud is Professor of Economics at HEC Montreal and Industrielle Alliance Research Chair on the Economic Consequences of Demographic Change. Neeraj Sood, Ph.D., is the Vice Dean for Research at the USC Price School of Public Policy. In addition, he currently serves as the Director of Research at the Leonard D. Schaeffer Center for Health Policy & Economics, and is a Professor at the Price School's Department of Health Policy and Management and the School of Pharmacy's Department of Pharmaceutical and Health Economics. Robert Lempert is a principal researcher at the RAND Corporation and director of the Frederick S. Pardee Center for Longer Range Global Policy and the Future Human Condition. His research focuses on decisionmaking under conditions of deep uncertainty, with an emphasis on climate change, energy, and the environment. Senior Director, Health Economics and Outcomes Research at Global Blood Therapeutics. Italo Gutierrez is an economist at RAND and a member of the Pardee RAND Graduate

School faculty.) "U.S. pharmaceutical policy in a global marketplace", December 16, **2008**, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804349/>

A rough comparison of these numbers with the **changes in life expectancy suggest: that the reduction in life expectancy will outweigh the health care savings, even at very low values of life.** If one were to transform the change in raw life expectancy into a change in discounted life-years, this would reduce the life expectancy costs by about one-third. Even after this adjustment, and even using a \$50,000 value of a statistical life-year, it is clear that **the reductions in longevity will be costly, on balance.** Figure 4 demonstrates this reasoning. **The figure shows that US price controls are costly, imposing net present per capita costs of \$3000 and \$6000 on the 2010 cohorts of Americans and Europeans, respectively.** The cohorts exposed for longer periods to the effects on innovation suffer even larger costs. **Each 55–59 year-old alive in 2060 can expect to face a cost of \$44,000 and \$34,000 in the US and Europe, respectively.**

Free Market Good

Maintaining a pharmaceutical free market in the US is specifically key

Bandow 5 (Doug, senior fellow at the Cato Institute and a former special assistant to President Reagan, 3/27/05, U-T San Diego website, "A strong pharmaceutical industry is the best defense against pandemics", http://www.utsandiego.com/uniontrib/20050327/news_lz1e27bandow.html, accessed 7/1/13, JZ)

The United States is essentially the last pharmaceutical free market among leading industrialized states. Price and use controls pervade Europe and other industrialized states, including Canada and Japan.

In Europe, observed Wall Street Journal reporter Stephen D. Moore, "Innovative cancer drugs have gotten bogged down even earlier in the system." He adds: "Many European countries also attempt to restrict demand after new medicines reach pharmacy shelves. Drugs can be saddled with tight prescribing rules to limit consumption. Patients across Europe are fighting for improved access to older drugs such as Taxol, the world's top-selling anticancer drug." **Thus, the vast majority of drug innovation derives from the American**

market. That will end, however, if government arbitrarily seizes – directly, through domestic restrictions, or indirectly, through "reimportation" of American drugs from countries with price controls – the fruit of industry R&D, thereby cutting industry prices and profits. Investment will fall. Which will mean less research and development. And fewer life-saving products. Life is uncertain and arbitrary; SARS

demonstrated that flying on the wrong plane and sitting next to the wrong person could become a death sentence. And **potentially many more people will die if new, even deadlier infectious diseases emerge, whether avian flu or**

something else. Yet the resources are available to prevent or ameliorate any such outbreak. Writes Dr. Joseph DiMasi of Tufts University: "a rapid expansion of scientific discoveries and technologic advances has given the pharmaceutical industry unprecedented opportunities to innovate. Combinatorial chemistry, high-throughput screening and genomics have provided a technologic platform that is highly conducive to growth in innovation. However, given typical lengths for the drug discovery and development processes, most of the fruits of these efforts will likely not be realized for years to come." **Reaping those long-term benefits to protect people worldwide will**

require the aid of America's much-vilified pharmaceutical industry. If critics succeed in disabling the drugmakers, we will all be at risk. It's time those who benefit from industry research stopped treating drugmakers as the enemy.

Drug Innovation

Price controls restrict drug innovation needed to cure global diseases, including *DRUG RESISTANT BACTERIAL AND VIRAL INFECTIONS*

Robert Easton, 1-22, 18, <https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/> RST OPINION Price controls would stifle innovation in the pharmaceutical industry

Consumer access to affordable and effective medicines is an important issue. As the cost of many drugs continues to rise, sometimes astronomically, **some have suggested imposing price controls on the U.S. pharmaceutical industry. Doing that risks crippling our only hope of curing the many serious diseases that still plague us. The global pharmaceutical industry is among the most profitable, driven by its ability to price to value, especially in the United States.** High profits attract investors and generate money for research. The global pharmaceutical industry's investment in research and development is second, barely, to the computer and electronics industry and well beyond that of most other industries. For comparison, **the top 10 pharmaceutical companies spend five times more on research and development as a percent of sales than do the top 18 U.S. chemical companies. The pharma industry's efforts have been quite productive in attacking some of the most vexing problems in medicine. Cardiovascular mortality in the U.S. has declined more than 50 percent since the introduction of propranolol, the first beta blocker, in 1964. Many cancers, such as childhood leukemia, have almost been cured. AIDS is now a chronic disease, as the death rate has declined from near 100 percent to near 0 percent. Hepatitis C is now curable. Even metastatic melanoma, formerly a death sentence for 95 percent of its victims, is now curable for many. Lung cancer may be next.** All these miracles have been brought through the clinic and into the market by commercial pharmaceutical companies. ADVERTISEMENT **Yet there remain huge unmet needs for new and better treatments for most cancers; all neurological problems, especially Alzheimer's disease; most autoimmune diseases; most major gastrointestinal disorders; macular degeneration; and diabetes – not to mention the global scourge of drug-resistant bacterial and viral infections. Advances in these areas will come if money continues flowing to pharmaceutical companies and their primary sources of innovation, biotechnology startups.** Related: At \$850,000, price for new childhood blindness gene therapy four times too high, analysis says But if U.S. drug prices come under bureaucratic control, as they have in most of Europe and Japan, it will be a different story. Little pharmaceutical innovation occurs in price-control jurisdictions. The United States has always, by a large margin, led the world as a source of new drugs, and that lead has widened as Japan and Germany have imposed price controls over the past few decades. All major international pharmaceutical companies, without exception, have instituted R&D and commercial operations in the U.S. to take advantage of its pricing environment. **If price controls pressure the U.S. industry into a more conventional process industry model, like that of the chemical industry, pharmaceutical R&D budgets would be slashed.** To achieve the chemical industry's rate of R&D spending, as would be required to achieve profitability competitive with the chemical industry, top pharmaceutical companies would have to reduce their R&D budgets by 80 percent — almost \$50 billion in total. This reduction in spending would take a few years to realize, but would be completely evident by 2023 or earlier. An important corollary is that, if profitability and value creation opportunities for new drugs declined, the appetite of the venture community for risky, long-term biopharmaceutical investments would shrink exponentially. Price controls on drugs would have the surprising effect of accelerating the flow of investment into high technology, where timelines to market are shorter, less regulated, and less risky. The venture capital community is flush with cash and anxious to invest where high returns can be achieved — ideally within a much shorter time than is typically possible in the realm of drug R&D. **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.**

California drug price controls failed

Gleason, 2017, Gleason Patrick Gleason is vice president of state affairs at Americans for Tax Reform, and a senior fellow at the Beacon Center of Tennessee,

<https://www.forbes.com/sites/patrickgleason/2017/02/21/states-consider-imposing-drug-price-controls/#4fedc887639b> States Consider Imposing Drug Price Controls

This state legislative activity represents the continuation of a debate that featured prominently in the 2016 election cycle on two fronts. In addition to Bernie Sanders and Hillary Clinton touting their proposals for drug price controls throughout the primary and general election campaigns, **there was an initiative on the California ballot, one of the most expensive ballot measure fights of 2016, which would've imposed drug price controls in the most populous state in the country. While both Clinton & Sanders were unsuccessful, and the California ballot measure was rejected by voters, the debate over drug price controls carries on in at least eight 2017 state legislative fights.**

Spending on drugs relatively insignificant

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<https://www.forbes.com/sites/patrickgleason/2017/02/21/states-consider-imposing-drug-price-controls/#4fedc887639b> States Consider Imposing Drug Price Controls

For starters, the justification for price controls on prescription drugs is based in myth. **The claim that U.S. drug spending is growing out of control is simply not true. Spending on prescription drugs as a share of all health care spending in the U.S. is the same as it was 60 years ago.** As the Manhattan Institute pointed out in a 2015 report, **spending in the U.S. on drugs accounts for about 10% of total health care spending.** In fact, drugs account for a lower percentage of total health care spending in the U.S. than in Europe, where drug price controls have been on the books for decades. Upon further investigation, it becomes clear **pharmaceutical price controls – like those now being debated in eight state capitals – are misguided solutions in search of a problem, and are a red herring when it comes to the effort to bend the overall health care cost curve.**

Price drives innovation

George A. **Chressanthis** is Principal Scientist at Axtria, USA. This article was co-published with Axtria, a big data and analytics company, November **2016**, <https://themedicinemaker.com/issues/1016/the-potential-pitfalls-of-price-controls/> The Potential Pitfalls of Price Controls

Price incentives do matter. **Empirical research shows that the shift in pharma R&D to focus on specialty medicines has been driven partly by the greater freedom companies have to price these medicines, particularly when there are few, if any, competing products** (11). In addition, **there is much evidence to show that a country's pricing environment impacts the diffusion of new drug technologies. The IMS Institute for Healthcare Informatics has forecast that "in 2020 the use of new medicines, introduced in the prior 10 years, will represent 0.1 percent of volumes in 'pharmerging' markets, compared to 2–3 percent in developed markets"** (12). The difference in drug utilization will likely result from a combination of both relative price and income effects across markets. Naturally, however, **pharma companies will seek diffusion of new drug technology in countries where they can reap higher prices to help pay for R&D** (13), (14). For example, companies often choose to avoid countries in Europe with lower prices and stringent price controls, and introduce fewer new drugs after entering a price-controlled market (15). The existence of parallel imports further delays new product launches, meaning that price control policies in one country can have spillover effects in other countries (15). Another large study across 15 countries found negative new drug price elasticities in the -0.75 to -1.1 range, as well as positive (but small) cross-price new drug quantity effects with respect to old drug pricing (16). (Drug price elasticity estimates into the elastic range – greater than 1 in absolute value – suggests that the diffusion of new drug technology will be hampered by an environment that creates higher price sensitivity.) This study is unique and interesting as it also captured the effects that promoting older drugs have on new drugs – promoting older drugs can have a significant negative impact on new drug market share. A second study examining 642 new drugs in 76 countries, from 1983 to 2002, found a robust relationship between patent and price regulation effects, and the diffusion of new drugs – in the manner predicted by economic theory (17). That is to say, patents and price controls create a balancing act of conflicting forces. On one hand, patents create government-protected IP monopoly power, thereby rewarding companies taking risks – though at the

expense of higher prices. On the other hand, **direct price controls lower drug prices but also reduce rewards for innovation. There is no “right” answer here, but rather which trade-off society wishes to accept. The policy path chosen in the US on this issue is one that tries to balance the trade-off between providing incentives needed for innovation, while at the same time minimizing the negative effects patents create for society – through the creation of patents of limited duration** (to make it easier for generic and biosimilar drugs to enter the market) and government subsidies that protect drug access for at-risk groups (Medicare Part D and Medicaid, for example). Whether this approach is better than the more direct approach of regulating drug pricing as done throughout much of Western Europe or Canada depends on the criteria used to evaluate the outcome. Lastly, **another large study done over time and across selected Organization for Economic Cooperation and Development countries found that higher US brand prices relative to other countries contributed to faster diffusion of new drug technologies – but also higher spending per capita on prescription drugs** (18).

Innovation key to improving health outcomes

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What about the more complicated relationship of price controls and pharmaceutical R&D? This is a more indirect relationship and involves a chain of effects. The first link in the chain is the relationship between drug pricing and pharma R&D investment – and a long line of research has shown that drug pricing does impact R&D. The second link is the relationship between R&D and patient health outcomes. Pharma companies are increasingly focusing on high-cost, specialty medicines – especially those classified as orphan drugs (19) – which require higher incentives to compensate for the added cost and risk involved in development (20). **Evidence of the impact of the US’s Orphan Drug Act of 1983 suggests that the incentives enacted through this legislation have boosted the number of drugs for rare diseases.** More than 500 drugs for orphan diseases have been developed since the act passed in the US alone, with other countries adopting similar orphan drug programs (21). **Numerous empirical studies show a strong connection between the enactment of price controls and reductions in pharmaceutical R&D investment – leading to decreases in new drug innovation** (22, 23). Another study estimated that a 10 percent decrease in the growth of real drug prices caused an approximate six percent decrease in the growth of R&D intensity (24). A more recent study concluded that enactment of patents and exclusivity provisions, while having pros and cons as a policy approach (e.g., the establishment of monopoly drug pricing), still play a dominant role in incentivizing biopharmaceutical R&D (25). Overall, there is an established body of academic literature that establishes the relationship between drug pricing and price controls, and pharma R&D investment and drug innovation. But what of the second link in the chain – the relationship between the adverse effects of R&D development and drug innovation, and patient health outcomes? Here too, the literature can guide us. The most direct study is one that estimated the effect of real (inflation-adjusted) price declines from price controls on reductions in R&D investment, and then in turn, on life-years lost (in millions) (26). Model estimates determined that a 10 percent, 30 percent, and 50 percent decrease in real drug prices from price controls, decreased R&D investment by 5.8 percent, 17.5 percent, and 29.2 percent, and led to life years lost (in millions) of 40.1, 113.5, and 178.8, respectively. This connection to reductions in life-years lost depends on the relationship between the diffusion and utilization of new drug innovation, and patient health. Pharmaceutical innovation was estimated to increase life expectancy by 1.27 years during the period 2000–2009 for 30 developing and high-income countries (27). **Similar studies have been conducted by the same author showing country life expectancy rising alongside pharmaceutical innovation.** However, not all empirical studies show a strong relationship between pharmaceutical spending and life expectancy; for example, one study in Canada found no effect between drug spending, and infant mortality and life expectancy at 65 (28). Economic theory may explain how reduced pharmaceutical R&D and lower diffusion of drug innovation could result in lower health outcomes, but the empirical challenges of determining a robust effect amongst all the other factors that can affect life expectancy and/or health outcomes is a daunting task. While **the empirical studies presented here generally show a strong relationship between price controls and patient health outcomes**, more research is likely needed to determine the robustness of the effect and its magnitude.

Pharma industry on the brink, regs bad now

George A. Chressanthi is Principal Scientist at Axtria, USA. This article was co-published with Axtria, a big data and analytics company, November 2016, <https://themedicinemaker.com/issues/1016/the-potential-pitfalls-of-price-controls/> The Potential Pitfalls of Price Controls

Given that drug pricing has been a big topic during the US elections, it is possible that the country will see some form of direct drug price controls in the future. **Instituting drug price controls would be a policy approach consistent** with a populist-oriented

Trump presidency. Whether the Republicans in Congress – who now control both chambers and have traditionally voted against such controls – would go along with it remains to be seen. Pressure will be exerted by the progressive wing of the Democratic party, which has gained in influence during this election cycle from the Bernie Sanders run, and will most certainly push for direct government-imposed drug price controls. Yet, **the US government already has a number of powerful mechanisms to help control**

prices. For example, the federal government establishes Medicaid drug pricing based on significant discounts from the best commercial price being offered. It is important to remember that significant market forces affect pricing, from increased branded drug competition and competition from generic entry post-patent expiration (including early patent challenges), to bioequivalent and therapeutic drug substitutions. Concentrated market power is shown to affect drug pricing and utilization by drug wholesalers, large health payers, and dominant pharmacy benefit managers. What those advocating for drug price controls often fail to recognize is that the pharma industry is undergoing rapid and fundamental changes. The easy disease targets that can be addressed with small-molecule drugs are rapidly vanishing and more incentives, not less, are needed for pharma companies to unlock the solutions to the most challenging unmet medical needs. Complicating the challenge facing drug companies is the fact that both improvements in health outcomes and costs of care will be measuring sticks to determine future rewards from drug innovation. This will be an expensive endeavor, and questions exist as to whether society is willing and able to pay for increases in drug innovation needed to solve these medical challenges – the future is admittedly uncertain. Various groups have traditionally banded together to advocate against direct drug price controls in the US and to date their efforts have been successful (29). However, the dramatic increases in prices necessary to support drug innovation are straining the coalition. Increasingly, new drugs are being priced beyond the means of both payers and patients. Even for drugs that deliver both extraordinary health outcomes and cost-effectiveness – such as new treatments that cure Hepatitis C and so prevent costly complications – patient access is limited because widespread use would quickly bankrupt healthcare reimbursement systems. **At the same time, the current commercial model that companies are using to**

maintain profitability (mainly through price increases) is clearly unsustainable in the long run (30), (31).

As the public demand that new drugs be more widely available, a complete re-evaluation of the system that determines drug pricing is taking place, with drug price controls being increasingly deemed part of the solution. In light of this, pharma companies must radically re-evaluate the commercial models traditionally used to generate and support the prices of specialty medicines. The shift to focus on specialty medicines means the current commercial model – based on a set of increasingly obsolete market dynamics and less-emphasized drug technology going forward – is rapidly decreasing and will need to be changed. Companies need to be demonstrating improvements in everything they do, along the entire product lifecycle, to produce better health outcomes and lower costs of care. The backlash against drug pricing and greater calls for price controls likely reflects that the industry has not yet effectively delivered on this value-based argument. The good news for the industry is that there is still time for internal changes to strengthen this argument. However, if changes are not made, the politicization of drug pricing and public discontent will mean greater government involvement – with negative effects for the industry and patients. **As Milton Friedman, a Nobel Prize-**

winning economist, once said, “If you put the federal government in charge of the Sahara Desert, in 5 years there’d be a shortage of sand.” The empirical evidence presented here suggests that a more heavy-handed approach by the US government to erect price controls will not promote overall social well-being but will decrease drug innovation needed to address significant unmet medical needs, and adversely affect patient health outcomes.

San Diego-based Pharmaceuticals have already found deep ocean fungus that can cure cancer, and their research has lead to massive breakthroughs like penicillin.

Timmerman 09 (Luke Timmerman is an award-winning journalist specializing in life sciences. He has served as national biotechnology editor for Xconomy and national biotechnology reporter for Bloomberg News; “Having Scoured the Ocean for Cancer Drugs, Nereus Aims to Prove Its Concept

Works", February 26, 2009; <http://www.xconomy.com/san-diego/2009/02/26/having-scoured-the-ocean-for-cancer-drugs-nereus-aims-to-prove-its-concept-works/>, RJ)

Off the coast of the Bahamas, in sea grass more than a half-mile deep, San Diego-based **Nereus Pharmaceuticals found a fungus that may be the key ingredient for an innovative new cancer drug. This will be a key year for gathering evidence that will either support or debunk the idea.** I got the download on Nereus last week in a conversation with co-founder and CEO Kobi Sethna and Charles White, the company's chief business officer. Nereus has raised a whopping \$125 million in venture capital in almost a decade of business, from big name investors like Roche Venture Fund, Alta Partners, and San Diego-based Forward Ventures, among others, so I figured it was worth taking a look. **The company is built on the idea that many of the biggest pharmaceutical breakthroughs, like penicillin, come from natural microbes. The bulk of these fungi and bacteria that led to drugs come from land, but, of course, Mother Nature has plenty of more biodiversity in the ocean. After years of sailing expeditions that trawled up potential drug candidates in hot and cold water, shallow and deep, from the Pacific and the Atlantic, Nereus has looked at hundreds of candidates for treating autoimmune disease and cancer—and now has settled on two lead horses against cancer that it thinks have a real shot.** So the sailing expeditions are over, and **now it's time to push through the hard, unpredictable slog of clinical trials to see if these drugs really work in people.**

"In this business, you've got to be focused. It's the name of the game," Sethna says. "We've morphed into an oncology company." So what does Nereus have to show for all that investment? The lead candidate (the one found off the coast of the Bahamas) is called NPI-2358. It's a small-molecule drug synthesized in the lab to be similar in structure to a unique fungus it found in the ocean. This drug is designed to be a "vascular disrupting agent" to tumors. It's made to attack existing blood vessels in tumors, unlike big-name cancer drugs like Genentech's bevacizumab (Avastin) or Pfizer's sunitinib (Sutent) that are meant to block the formation of new blood vessels to tumors, White says. The reason the Nereus drug is still alive in the clinic is that it showed a long-lasting, potent ability to disrupt tumor blood flow, without causing the heart damage that has plagued other vascular-disrupting drugs in the class, White says. The first clinical trials supported further testing, confirming the drug wasn't harming the heart while shrinking tumors at least partially for about three-fourths of patients when given in combination with Sanofi-Aventis' docetaxel (Taxotere). This molecule is in competition with Waltham, MA-based Oxigene's OXi4503, which is in early clinical trials, and about "five or six others" still in animal testing, White says. The advantage he sees with the Nereus drug is that it appears to enhance the effectiveness of chemotherapy, without adding on any new layers of toxic side effects, as often happens with chemo cocktails. The drug is currently being tested against lung cancer, the leading cancer killer in the U.S.

Innovation – Oceans

Land based pharmaceutical development has plateaued – new drugs are needed in the face of emerging disease resistance. Ocean exploration unlocks innovative drugs.

National Research Council 9 The National Academies Advisors to the Nation on Science, Engineering, and Medicine, 2009, <http://dels.nas.edu/resources/static-assets/osb/miscellaneous/Oceans-Human-Health.pdf> jml

In 1945, a young organic chemist named Werner Bergmann set out to explore the waters off the coast of south-ern Florida. Among the marine organisms he scooped from the sand that day was a Caribbean sponge that would later be called *Cryptotethya crypta*. Back in his lab, Bergmann extracted a novel compound from this sponge that aroused his curiosity. **The chemical** Bergmann identified **in this sponge**, spongothymidine, eventually **led to the development of** a whole class of **drugs that treat cancer** and **viral diseases** and are still in use today. For example, Zid- ovudine (AZT) fights the **AIDS** virus, **HIV**, and cytosine arabinoside (Ara-C) is used in the treatment of **leukemias and lymphomas**. Acyclovir speeds the healing of eczema and some herpes viruses. These are just a few examples of how the study of marine organisms contributes to the health of thousands of men, women, and children around the world. **New antibiotics**, in addition to new **drugs for fighting cancer, inflammatory diseases**, and **neurodegenerative diseases** (which often cannot be treated successfully today), **are** greatly **needed**. **With drug resistance nibbling away** at the once-full toolbox of antibiotics, **the limited effectiveness of currently available drugs has dire consequences** for public health. Compounds with **medical potential have been found in** several species of **marine sponges**, such as this bright orange sponge. (Image from Harbor Branch Oceanographic Institution, Fort Pierce, Florida) _ OCEAN SCIENCE SERIES exploring the promises of ocean science OCEANS AND HUMAN HEALTH 3 Historically, **many medicines have come from nature** —mostly from land-based natural organisms. Because **scientists have nearly exhausted** the supply of **terrestrial** plants, animals, and microorganisms that have interesting **medical properties, new sources of drugs are needed**. Occupying more than 70 percent of the Earth's surface, **the ocean is a** virtually unexplored **treasure chest** of new and unidentified species—one of **the last frontiers for sources** of new natural products. These natural products are of special interest because of **the dazzling diversity and uniqueness** of the creatures that make the sea their home. One reason marine organisms **are** so **interesting to scientists** is **because in adapting** to the various ocean environments, **they have evolved** fascinating **repertoires of unique chemicals** to help them survive. For example, anchored to the seafloor, a sponge that protects itself from an animal trying to take over its space by killing the invader has been compared with the human immune system trying to kill foreign cancer cells. That same **sponge**, bathed in seawater containing millions of bacteria, viruses, and fungi, some of which could be pathogens, has developed antibiotics to keep those pathogens under control. Those same **antibiotics could be used to treat infections** in humans. **Sponges**, in fact, **are** among **the most prolific sources of diverse chemical compounds**. An estimated 30 percent of all potential marine-de- rived medications currently in the pipeline—and about 75 per- cent of recently patented marine-de- rived anticancer compounds—come from marine sponges. **Marine-based microorganisms are another** particularly **rich source of new medicines**. More than 120 drugs available today derive from land-based microbes. **Scientists see marine-based microbes as the most promising source of novel medicines** from the sea. In all, more than 20,000 biochemical compounds have been isolated from sea creatures since the 1980s. Because **drug discovery in the marine frontier is a relatively young field**, only a few marine-derived drugs are in use today. Many others are in the pipeline. One ex- ample is Prialt, a drug developed from the venom of a fish-killing cone snail. The cone snails produce neurotoxins to paralyze and kill prey; those neurotoxins are being developed as neuromuscular blocks for individuals with chronic pain, stroke, or epilepsy. Other marine- derived drugs are being tested against herpes, asthma, and breast cancer. The National Research Council report Marine Biotechnology in the Twenty-First Century (2002) concluded that the **exploration of** unique habitats, such as **deep-sea environments**, and the isolation **and** culture of **marine microorganisms offer** two underexplored **opportunities for** discovery of **novel chemicals** with therapeutic potential. **The successes to date**, which are based upon a very limited investigation of both deep-sea organisms and marine microorganisms, **suggest a high potential for continued discovery of new drugs**.

And – Independently, a revitalized and innovative pharmaceutical sector prevents economic collapse

Washington Post, 2014 (Pharmaceutical Research and Manufacturers of America, “One Prescription for U.S. Economic Growth”, May 5, <http://www.washingtonpost.com/sf/brand-connect/wp/enterprise/one-prescription-for-u-s-economic-growth/>)

After withering under six years of financial storm clouds, the U.S. economic forecast appears to be showing new life. But **leaders** in government and business **have work to do if they want to create an environment that** not only **encourages continued growth**, but accelerates it versus global competitors. **One area ripe for harvest: U.S. biopharmaceuticals.** The U.S. currently leads the world in biopharmaceutical invention. And according to a new report by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Battelle Technology Partnership Practice, this pioneering role and investment in **innovation not only creates a favorable environment for** improved patient outcomes and **the development of new medicines, it could also help spur the U.S. economy by adding more than 300,000 jobs** in the next 10 years. The report looks at two possible 10-year trajectories. One examines a future of continued investment and growth, while the other imagines the U.S. falling behind competitor nations, including Brazil, Singapore and China, which are investing in their own biopharmaceutical industries. Germany, Japan and the United Kingdom have been longstanding competitors in this sector as well. The differentiator? Whether or not the U.S. embraces advanced policies. If current trends continue, industry leaders cited in the report predict the next 10 years will bring only modest growth, and biopharmaceutical companies could lose nearly 150,000 jobs, according to the report. **A lack of investment in innovation could have major implications for** both **the overall economy** and the biopharmaceutical industry, **which generates nearly \$790 billion in the U.S. each year, supports more than 3 million jobs** and helps improve the quality of life for millions of Americans. “The message is clear: **the continued success of the biopharmaceutical industry — both in delivering** life-saving and life-enhancing **medicines** to patients **and in contributing to U.S. economic growth — is dependent on** thoughtful, forward-looking **policies that prioritize innovation**,” says John J. Castellani, President and CEO of PhRMA. What are the factors that promote growth? The report outlines a number of recommendations, including the following: Increase understanding around the costs of new product development. Ensure appropriate protection for intellectual property and promote access to innovative medicines to give biopharmaceutical companies the incentive they need to continue to develop cutting-edge therapies. Ensure that startup efforts have the private financial backing they need to develop new medicines. Revise the drug-approval process to help get new medications to market more quickly. Back educational efforts to create a strong workforce. Provide economic innovation incentives to fuel growth. The current regulatory climate without these changes may stifle growth and have a negative effect on innovation. “This report vividly illustrates the inextricable link between a healthy biopharmaceutical R&D system and the health care policy environment,” says Robert J. Hugin, PhRMA Immediate Past Chairman and CEO of Celgene Corporation, in a written release. “Sustainable, market-based access and reimbursement for innovative medicines today is essential to incentivize the long-term, high-risk investment needed for new medical innovations in the future.” **The ability to innovate quickly is becoming the most important determinant of economic growth** and a nation’s ability to compete and prosper in the 21st century global knowledge-based economy. As this new report indicates, **the U.S. must focus squarely on ensuring that its policies help encourage such invention,** not hinder it.

And – An innovative pharmaceutical industry is also critical to sustain long-term growth

Lechleiter, 2012 (John, Ph.D. and Senior Organic Chemist in Research and Development, “Beyond the Fiscal Cliff, Pharmaceutical Innovation is the Key to Long-Term Fiscal Health”, December 11, <http://www.forbes.com/sites/johnlechleiter/2012/12/11/beyond-the-fiscal-cliff-pharmaceutical-innovation-is-the-key-to-long-term-fiscal-health/>)

When you look beyond the current “fiscal cliff” brinksmanship, **the long-term budget deficit will depend in large part on two key trendlines: health care costs and economic growth.** I’d like to explain how **pharmaceutical innovation can be a key positive factor in both areas** – if it isn’t choked off by short-sighted efforts to close the budget gap. The first trendline: health care costs. Back in 2009, then-budget director Peter Orszag wrote, “Over the long run, **the deficit impact of every other fiscal policy variable is swamped by the impact of health-care costs.**” That hasn’t changed. One big

reason: 10,000 Americans will reach retirement age every day for the next 19 years. Medicare is the fastest-growing major entitlement, growing 68 percent since 2002, according to the Heritage Foundation. And these folks, as a whole, can be expected to live longer than those who started receiving benefits when Medicare was enacted in the 1960s. So, while pharmaceuticals account for only 10 percent of health care spending, medicines are inevitably caught up in efforts to tame its growth. In countries around the world – including the U.S. – our biggest customer is the government, operating a health care system faced with relentlessly rising costs of caring for an aging population. Yet those medicines often represent the most cost-effective approach to preventing and treating disease. That’s the true value of pharmaceutical innovation. To cite just one example, Columbia University economist Frank Lichtenberg has estimated that every dollar Medicare spends on new medicines saves six dollars in other health care costs, on things like hospitalizations and physicians’ services. This finding was borne out by a 2011 study of the Medicare Part D prescription drug program, published in the Journal of the American Medical Association. The study found that older Americans who previously lacked comprehensive drug coverage saved about \$1,200 in medical costs the year they signed up for Part D. If we apply that to the 11 million seniors who have gained comprehensive coverage through Part D, total savings exceed \$13 billion. And new medicines ultimately yield a legacy of cost-effective generics, which today account for 80 percent of U.S. prescriptions and are actually less expensive here than in other countries around the world. But **we need continued innovation to address serious medical needs unmet by current medicines** or by any other medical intervention. **For example**, a recent study found that **new treatments that could delay the onset of Alzheimer’s disease for five years would save U.S. government health care programs \$140 billion annually** by 2030. As Washington grapples with the difficult trade-offs of entitlement reform, innovation is the best hope of making those choices less painful – of providing better health care without busting the budget. The second trendline: economic growth. As President Obama has noted, “The single most important thing we can do to reduce our debt and deficits is to grow.” Here’s an area where our industry would appreciate more attention. **Innovative pharmaceuticals are a U.S. economic strength**, a 21st century industry where the U.S. has gained world leadership in the past 30 years. The U.S. share of new medicines during the decade 2001-2010 was 57 percent, compared with 33 percent for France, Germany, Switzerland, and the UK combined – reversing the relative positions in the 1970s. **The biopharmaceuticals sector accounts for about 650,000 jobs nationwide, and contributes around \$917 billion to the economy each year**, according to a 2011 report by Battelle. And if we include clinical testing centers, supply chain managers, and other partners, our industry supports 4 million jobs across the nation. **The value of U.S. biopharmaceutical exports totaled \$232 billion** between 2005 and 2010 and grew 61 percent over six years. **It’s hard to find another U.S. industry that can match that record.** In sum, **innovative pharmaceuticals can contribute to both sides of the long-term fiscal ledger by helping hold down health care costs and driving economic growth.** But that may not happen if pharmaceuticals are seen first and foremost as a ready source of near-term revenues. One particularly troublesome idea, included in the President’s proposals, calls for extending Medicaid price controls on medicines into Medicare Part D. The Congressional Budget Office estimates that such a proposal would cut revenues for research-based pharmaceutical companies by well over \$100 billion over the next 10 years. Keep in mind that it takes well over \$1 billion for companies like ours to bring a new medicine to patients. In a March 2011 report, the CBO cites a key “disadvantage” of extending Medicaid rebates to Part D would be to “reduce the amount of funds that manufacturers invest in research and development of new products.” The potential cost is real, as R&D cutbacks delay or derail the next breakthrough treatment for diabetes or Alzheimer’s. And it would impose costs on the economy, as well. A 2011 analysis by Battelle Memorial Institute estimated that such a \$10 billion to \$20 billion per year reduction in pharmaceutical industry revenue would result in 130,000 to 260,000 lost jobs. Ironically, Medicare Part D happens to be the rare example of a government program that has cost far less than anticipated. According to the CBO, it is coming in 43 percent – or \$435 billion – below initial projections for its first seven years. Part D shows how the power of competition can improve government health care programs – but that’s a subject for another day. **Policymakers face a daunting task in closing the yawning gap between revenues and expenditures** in the coming years, **but targeting medical innovation is a particularly counterproductive approach.** The trends are clear: Starving medical innovation to hit short-term fiscal targets will only make the next round of budget talks that much harder.

US Lagging Behind

United States Lagging Behind in S&T and Pharmaceuticals

Barnard 13, (John Barnard, Professor of Pediatrics and vice chair for Research at The Ohio State University College of Medicine, "United States at risk of losing research leadership", The Columbus Dispatch, 10/20/13, <http://www.dispatch.com/content/stories/science/2013/10/20/1-united-states-at-risk-of-losing-research-leadership.html>)

I recently had the pleasure of hearing Alan Leshner, the CEO of the American Association for the Advancement of Science, speak at a research conference. He is an entertaining speaker with a dynamic style befitting the leader of a highly respected scientific society. One of Leshner's major themes was the increasing globalization of research. **The epicenter of scientific research and innovation used to be in North America and Europe, but it is steadily moving from the West to Asia. This movement can be quantified. For example, research-and-development expenditures in Asia now exceed spending in the United States. And the gap is widening. From 2012 to 2013, U.S. research-and-development spending decreased by 5 percent while expenditures in China increased by 15 percent.** The annual number of **research publications is growing faster in Asia than elsewhere in the world.** Simply put, **U.S. dominance is fading after a decade of federal research funding stagnation.** Growth of **research funding by the U.S. pharmaceutical industry also lags other countries.** With the national debate about the government shutdown, these collective observations got me thinking about the implications if the United States loses its leadership position in research. Is the loss of U.S. eminence, which will certainly happen if trends continue, so terribly bad? Subra Suresh, former director of the National Science Foundation, recently wrote that "good science anywhere is good for science everywhere." From a humanitarian viewpoint, this seems true. Humankind benefits from an expanding global-research enterprise. In support of this optimistic interpretation of trends, Leshner pointed out in his speech that authors of nearly half of the research published in the journal Science are from more than one country. This implies that the world's best research involves collaborative teams comprised of the top scientific minds on the planet. My view is this: Even though the world benefits from globalization of research and development, **there is certain harm in the United States' losing its dominant position as a research-and-development leader. A significant fraction of the U.S. scientific work force includes trainees and career scientists from the international community. Historically, these talented scientists come to the United States to train with the best and the brightest. And they remain in U.S. industry and at our universities because our facilities and resources are currently the most advanced in the world.** But should recent trends continue, **foreign scientists will not have to come to the United States to realize their career dreams, and established American scientists will move abroad.** In fact, most of us know colleagues who have moved abroad or have strongly considered doing so. The result is a vicious cycle of brain drain that will unwind a U.S. innovation economy that has dominated the global scene for more than a century.

Alternatives

Many good alternative to price controls

Paul **Howard** is a senior fellow and director of health policy at the Manhattan Institute, **2015**, New York Times, <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/to-lower-drug-prices-innovate-dont-regulate> To Lower Drug Prices, Innovate, Don't Regulate

Absent price controls, however, private negotiation works. A report from the Government Accountability Office **concluded that the Medicare Part D drug program** (where private insurers negotiate with drug manufacturers) **obtained lower** (pre-rebate) **prices than the defense department or Medicaid**. For generic drugs, where competition is the greatest, Part D's prices were essentially no different than Medicaid's. **Better prices can be enjoyed today without compromising tomorrow's cures. But instead of exercising greater control over the industry, reformers should opt for less — focusing instead on efficiency, innovation and competition. First, modernize the drug development process** to ensure that companies can develop safe and effective medicines for Food and Drug Administration approval faster and at less cost than is currently possible. Getting more drugs to market means more competition between producers. As we've seen from new medicines combating hepatitis C, the emergence of multiple drugs has helped insurers negotiate up to 50 percent price cuts. And because the health benefits of new medicines are so large, advancing one generation of F.D.A. drug approvals (or 25 new drugs) by a just a single year would generate \$4 trillion in benefits to U.S. patients. **Second, Congress should retool entitlement programs to encourage greater competition among providers and insurers based on real health outcomes.** Ground level efficiency in patient care, not top-down price controls, will ensure consumers and taxpayers get the maximum value for their health care dollars without dampening innovation. Price controls sacrifice the health of future generations in exchange for a short-term fix. They remain a poor choice for any policymaker with a holistic view of American health care.

Additional alternatives

Alison **Kodjak**, November 30, **2017**, <https://www.npr.org/sections/health-shots/2017/11/30/567308250/report-27-things-the-feds-could-do-to-cut-drug-prices> Report: Here's What The Feds Can Do To Cut Drug Prices

Allow the federal government to negotiate drug prices and refuse to cover some expensive

medications. This idea is not new, and Trump himself has advocated for allowing the government, through Medicare, to negotiate lower prices for the drugs it buys. But doing so would take an act of Congress. Current U.S. law prohibits Medicare officials from interfering in the negotiations between drugmakers and the insurance companies that administer Medicare's prescription drug program. Medicare accounts for about 29 percent of all prescription spending, so bringing that purchasing power under one roof could give it the ability to force drugmakers to slash their list prices. The National Academies report points out that the government negotiates or sets prices in almost every other industry where it is a buyer, including defense equipment, uniforms and even stationery. "The effect of not allowing HHS to negotiate prices is to tilt the balance of bargaining power further in favor of drug manufacturers," the report says. It adds that Medicare and other government health plans also should have the authority to refuse to pay for medications that have cheaper equivalents or that aren't adequately effective. **Speed the approval of generics and biosimilars and ensure patients have access.** Scott Gottlieb, the administrator of the Food and Drug Administration, has been preaching this message since he took office in May. "While FDA doesn't have a direct role in drug pricing, we can take steps to help address this problem by facilitating increased competition in the market for prescription drugs through the approval of lower-cost generic medicines," he said in a June blog post. The National Academies point to so-called "pay for delay," where a branded drugmaker pays a generic company to delay putting its competitor drug on the market. The practice "tends to inflate prices and reduce the quantity of prescriptions for several years after the settlement," the report says. But eliminating pay-for-delay won't be easy because courts have ruled that the agreements between the companies have to be evaluated individually. **Shed light on who pays what for prescription drugs.** This is something that lawmakers and regulators have called for many times. The prescription drug payments system is a tangled web of prices, incentives, discounts and rebates among drug companies, pharmacy benefit managers and insurance companies. When pharmaceutical companies are criticized for raising their list prices, they routinely protest that nobody actually pays those prices. Yet the true money flows remain a mystery. There are bills in both houses of Congress designed to increase drug price transparency, and several states — most recently California — have proposed or passed laws to require more information on what drugmakers and pharmacy benefit managers actually charge for medications. The National Academies panel recommends that HHS require pharmaceutical manufacturers to report each year the list price of medications, along with all the rebates and discounts in the system and, finally, the average price paid for those drugs.

Discourage those endless ads pushing prescription drugs and stop giving patients coupons to try

medication. Pharmaceutical companies spend far more advertising their medication than they do on research into new products, the report notes. That marketing boosts drug costs both by directly increasing costs to drugmakers that they then incorporate into the price of drug and by increasing consumer demand for medication they may not need. "Direct-to-consumer advertising of prescription drugs can adversely influence consumer choices," the report says. The reports says lawmakers should prohibit drug companies from deducting the cost of advertising from their taxes and should also ban coupons that allow people to purchase expensive brand-name drugs for the same out-of-pocket cost as generics. Cut the cost to consumers for their prescription drugs. This recommendation seems at odds with the earlier one calling for the elimination of coupons. But the National Academies report concludes that keeping costs low to consumers can ensure that patients take the medications they need, which could reduce overall health care spending. Insurance companies often require patients to pay bigger copayments for expensive medications as a way to encourage them to use cheaper options. "High cost sharing can also have downsides, since it can lead to reduced adherence or the discontinuation of medications because of high out-of-pocket costs to consumers," the report says. The report recommends that Congress limit how much people should have to spend on prescriptions in government-run health programs like Medicare and Medicaid. **Take away incentives for doctors to administer high-cost drugs.** This recommendation goes to a failed effort by the Department of Health and Human Services to encourage doctors who treat cancer and arthritis to use lower-cost medications if they're appropriate. Medicare pays doctors who administer drugs in their offices, including chemotherapy or arthritis drugs that are delivered intravenously, a percentage of the drug's price. That gives physicians a financial incentive to choose the most expensive medication available. Last year, HHS proposed changes to that system, but doctors launched an intense lobbying effort against it. Bruce Gould, the president of the Community Oncology Alliance, called it an "inappropriate, potentially dangerous and perverse experiment on the cancer care of seniors who are covered by Medicare." The program was killed. Given the outcry, the chances that HHS will try again are slim. But there was dissent, too. The report also includes a dissenting opinion from two of the 16 members of the committee. The dissent defends the need for profits in the pharmaceutical industry to give companies the incentive to chase treatments and cures for difficult diseases like Alzheimer's. "Creating a drug is a problem completely subject to human biology with all its intrinsic complexity, variability, and unpredictability," the dissenting report reads. "If drug invention were simply an engineering problem, then by now we would have a vaccine for AIDS (35 years after the beginning of the outbreak) and a cure for Alzheimer's disease." But even in the dissent, there was some agreements, specifically in the need for greater transparency in how drugs are priced, and how the money flows through the system. The dissenters suggest that pharmacy benefit managers have outsized power and take too much money from the system. Trump has said he wants to make lowering drug prices a priority. This report offers up plenty of suggestions on how to do that.

States acting to limit drug price increases now

Yale Global Health Partnership, **2017**, The Yale Global Health Justice Partnership (GHJP) is a joint initiative between Yale Law School (YLS) and Yale School of Public Health (YSPH) that trains the next generation of scholars and practitioners to tackle the complex interdisciplinary challenges of global health. The GHJP works with international partners at the interface of law and governance, public health, and medicine to theorize, build analytical frameworks, create knowledge, and mobilize research to help drive the social change necessary for improving the health and wellness of people around the world. Learn more at www.yaleghjp.org., *Curbing Unfair Drug Prices: A Primer for the States*, https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf

As often occurs, **state legislatures have stepped in to fill the policy vacuum**. In 2017, **more than 80 pharmaceutical pricing bills were proposed in over 30 states around the country**.³ Recently, path-breaking drug pricing legislation has passed in Maryland, New York, and Nevada. **Several other states have considered bills mandating the study of options to lower drug prices, and some significant legislation could pass within the next year**.⁴ Clearly, drug pricing will remain high on state legislative agendas next year, with many now poised to follow up on these initial forays.

R & D Critical to Gene Therapies

Price controls undermine investment in gene therapies

Tim **Rice** is the project manager for health policy at the Manhattan Institute, May 4, **2018**,
<http://www.weeklystandard.com/tim-rice/want-companies-to-innovate-life-saving-drugs-dont-dissuade-them-with-price-controls> Want Companies to Innovate Life-Saving Drugs? Don't Dissuade Them With Price Controls.

ast month, the Centers for Medicare & Medicaid Services announced that Medicare patients taking Gilead's \$373,000 lymphoma drug Yescarta would only be responsible for a \$79,076 co-pay—just over 20 percent of the sticker price. And believe it or not, some of the biggest critics of high drug prices said that it was totally appropriate. **Yescarta belongs to a new class of medicines called “gene**

therapies,” which work by extracting a patient's own genetic material, and engineering it to fight potentially deadly diseases, like cancer.

Gene therapies are borderline miraculous, but they are also incredibly expensive. Hoping to save some lives

while turning a profit along the way, **pharmaceutical companies are clamoring to develop their own gene**

therapy, devoting tons of R&D to developing their own breakthrough cure. With gene therapies, we've seen the future of medicine. The question now is: Can we afford it? The answer is no, at least according to congressional Democrats, who have made lowering drug costs one of the focal points of their midterm agenda. The same goes for the 35 states currently considering laws that would cap how much companies could charge for drugs, how much they could spend on R&D, and even how much of a profit they could turn. So-called “price controls” come in many forms, but the one thing they all have in common is the underlying belief that the government has the authority to decide the right amount to pay for a life-changing drug. The argument goes something like this: Unlike drug companies, who set high prices to try and make money, a government agency will be motivated by just the public interest and keep prices low. This argument gets one thing right: A government agency wouldn't set prices with an eye to turning a profit. However, it's precisely that profit-seeking incentive that leads pharmaceutical companies to develop groundbreaking new drugs.

Global Pharmaceuticals Will Rise With Price Controls

Mexican pharmaceuticals are key

North American Production Sharing Incorporated 13 [4-11-13, NAPS , "The Medical Device Industry Manufacturing in Mexico has a Clean Bill of Health" , <http://www.napsintl.com/news/index.php/2013/04/11/the-medical-device-industry-manufacturing-in-mexico-has-a-clean-bill-of-health/> , 7-10-13 , JC]

Medical device companies manufacturing in Mexico continue to exhibit steady growth with no sign of a slow down in sight. As costs in the United States and Eastern Europe continue to rise, especially with the implementation of "Obamacare" and its direct impact on medical device companies, more organizations are considering manufacturing in Mexico as a viable solution. No other place in Mexico is this more evident than in Tijuana, where they now claim the largest concentration of medical device companies in all of North America. The ability to provide both timely deliveries and consistently high quality products are a few reasons why medical device manufacturers are choosing Mexico. Also, there is a tremendous base of talented labor with experience in medical device, automotive, electronics, aerospace and other sophisticated industries to support the growth of manufacturing in Mexico. Furthermore, the labor laws in Mexico provide companies much more flexibility in terms of compensation, scheduling and seasonality, which plays an important roll on profitability. Another factor drawing medical device manufacturers to Mexico is the government's enforcement, and employee's respect, for intellectual property. Unlike many other low-cost manufacturing countries, Mexico is known for its low piracy rates, which cost companies billions of dollars a year. One of the challenges facing these companies is understanding the business landscape and culture in Mexico, which is why many of these firms are choosing to outsource their administration and compliance management to shelter companies. A good shelter company will handle 100% of the administration, including Human Resources in Mexico, Payroll in Mexico, Accounting in Mexico, Import/Export in Mexico and Environmental, Health & Safety in Mexico, allowing the manufacturer to focus on production and quality control. "We are receiving a record number of inquiries from medical device manufacturers around the world who want to explore Mexico as a competitive solution," said Scott Stanley, Sr. Vice President of North American Production Sharing, Inc. (NAPS), Tijuana's largest and most sophisticated shelter service provider. "NAPS guides these companies through the process of feasibility by providing all the facts and figures about expanding into Mexico so sound business decisions can be made. Thereafter, we essentially become partners and typically work together for many years." With an increase in demand for medical device products, not only in the United States but also within Mexico's public health sector, Mexico will continue to be the primary choice for medical device manufacturing.

South African pharmaceuticals solve - has US approval

Zachariasen 8 [Angela, writer for South African Info and Nelson Mandela Bay Municipality, "SA's Pharmaceutical Success Story" –South African Info, July 29, 2008, <http://www.southafrica.info/business/success/aspen-290708.htm#.U7HaFvldXUU>, LS]

When Steven Saad established Aspen Pharmacare in a suburban home in 1997 at the age of 33, little did he think his small sales company would one day become South Africa's leading pharmaceuticals producer and play a pivotal role – with support from two United States presidents – in tackling a global pandemic. Aspen, which has its primary plant in Nelson Mandela Bay and a second facility in East London, is one of the top 20 manufacturers of generic medicines globally. December 2007 statistics confirm its local generic market share at 34%, compared to its nearest rival at 14%. Go to Eastern Cape Madiba Action This achievement is thanks to Saad's foresight in securing voluntary licences from multinational pharmaceutical companies for the manufacture of more affordable generic antiretrovirals. Antiretrovirals (ARVs) substantially extend the lives of people living with HIV/Aids and help prevent mother-to-child transmission of HIV. Apart from developing Africa's first generic ARV (Stavudine), launched in 2003, Aspen also manufactures an extensive basket of ARVs all registered with the SA Medicines Control Council. Backing from two US presidents Aspen is the only southern hemisphere manufacturer selected by the US-based Clinton Foundation to produce cheaper HIV/Aids ARV medicines. The 2006 agreement between former US President Bill Clinton and Aspen focuses on reducing costs and scaling up production of ARVs. It has resulted in the cost of generic ARVs in developing countries being reduced by one-third to one-half of the original price. "Treatment, once started, is a lifelong commitment, and over time patients move from low-price first-line drugs to second-line combinations that are at least 10 times more expensive," Clinton is on record as saying. "Keeping the global cost of Aids treatment sustainable will only be possible if we lower the prices of these medicines." Aspen was also chosen as the world's first supplier of generic

ARVs under US President George Bush's \$15-billion Emergency Plan for Aids Relief. Part of the approval process involved a rigorous assessment of Aspen's R200-million oral solid dosage facility in Port Elizabeth, which manufactures generic ARVs and capsules. The facility is considered to be the most modern of its kind in Africa. Believing in the Eastern Cape Saad was recognised for his leadership and entrepreneurial spirit when he won the coveted Ernst & Young 2004 World Entrepreneur of the year award for South Africa. He narrowly lost the World Entrepreneur title in a vote-out. Speaking of his love for the Eastern Cape, Saad said he decided to establish Aspen's primary plant in Port Elizabeth because he believed in the capability and intellectual property of the local manufacturing facility. **"Aspen is committed to the development and upliftment of the South African pharmaceutical manufacturing industry.** At a time when most pharmaceutical manufacturers are divesting locally, Aspen has continued to show commitment with a capital injection of more than R1-billion in the Eastern Cape." Port Elizabeth, East London plants The Port Elizabeth plant is South Africa's leading producer of tablets and capsules, and also manufactures liquid dosage forms such as syrups, suspensions and solutions, as well as creams, ointments and suppositories. Continual enhancements to the plant include additional bottle packing capabilities to service a growing need in the ARV market for delivery of product in this format. In March 2006, Aspen began construction of a R400-million sterile facility in Port Elizabeth, with production capabilities in injectables (including hormonal), freeze-dried vials for multi-drug resistant tuberculosis, and other products. Commercial production was scheduled to commence by the end of 2008. Aspen's East London-based facility has extensive manufacturing capability and capacity in various categories, including penicillin, oral contraceptives, fast-moving consumer goods (FMCGs), complementary medicines, cosmetics, capsules, powders, creams, ointments, lotions, liquids and tinctures. The site continues to grow, with increased volume being driven by buoyant toothpaste and penicillin sales. Production capabilities have been enhanced through ongoing investment, and further increase in output is planned with the re-alignment of products from other facilities that suit East London's flexible short-run production profile.

IPASA will provide South Africa with high level research in pharmaceuticals and medicine

Pharmaceutical Companies News, 14 (New expanded Committee for IPASA, Pharmaceutical Companies News, Biz Community, <http://www.bizcommunity.com/Article/196/326/111461.html>, TS)

The Innovative Pharmaceutical Association South Africa (**IPASA**) **has appointed its 2014 committee**, led by Dr Timothy Kedijang, CEO of Novo Nordisk, as president and Kobus Venter, CEO of Janssen Pharmaceuticals as VP.¶ The other Exco committee members are Dougy Kevan, CEO of Norgine; Frans Labuschagne, CEO of Bayer; Darryl Langford, CEO of Merck and Luciano Marques, CEO of Novartis.¶

The association was formed in April 2013, bringing together all the research-based pharmaceutical companies that had previously belonged to either the Pharmaceutical Industry Association of South Africa (PIASA) or Innovative Medicines SA (IMSA). The new entity was created to support and promote the highest standards of research, development and production in the supply of quality medicines, vaccines and biotechnology, as well as to advance ethical codes of practice for the pharmaceutical industry. ¶ The association now represents 25 leading pharmaceutical companies. Only companies that conduct their own research and development qualify for membership. It provides the industry with a single platform for communicating with government, medical industry stakeholders, communities and consumers and continually engages stakeholders in both the private and public sectors with the objective of providing universal access to quality pharmaceutical products.¶ "The association is committed to fostering an environment that supports excellence in the pharmaceutical industry and provides access to quality medicines for all of South Africa's people," says Dr Kedijang. "It is an important forum for engaging various stakeholders on issues such as research, policy and quality control and in this way, protects both the integrity of the industry and the interests of consumers.¶ "It adheres to both international and local best-practice guidelines and this demonstrates its members' commitment to operating within the framework of the highest professional and ethical standards."¶ As a member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), **the association and its members uphold the research and development of safe, high-quality and effective disease treatments designed to improve patients' health and prolong life. Members also make a substantial contribution to the South African region by investing in local healthcare and by ensuring continued access to new medicines. In addition, pharmaceutical companies stimulate the local economy by providing employment, paying taxes, supporting skills development and facilitating the transfer of technology.¶ "Access to quality medicines is a fundamental requirement for an effective healthcare system and**

association members are committed to researching and developing pharmaceuticals that are tailored to meet each individual's healthcare needs. More than that, they are committed to being good corporate citizens and to being active and engaged members of the greater South African community," concludes Dr Kedijang.

Mexico can become a global Pharmaceutical player – Trade agreements, Indian Influence, Strong Generic Drugs, and effective intellectual property laws

Pharmaceutical-technology.com 13 [March 26th 2013, "Mexico: growing South America's pharmaceutical industry," <http://www.pharmaceutical-technology.com/features/featuremexico-drugs-pharmaceutical-brazil-south-america>, Accessed 7/10/13, CB]

Mexico is **the 12th largest pharmaceutical market in the world** - the second largest in Latin America after Brazil. There are a reported 2.5 billion unit sales of medication annually in Mexico. Between 1999 and 2006, the industry grew more than 200%, and by a further 14% between 2007 and 2009. This steady growth **indicates a promising market, one that currently accounts for 37% of all pharmaceutical sales in Latin America.** Free Trade Agreements (FTAs) **"Between 1999 and 2006, the industry grew more than 200%, and by a further 14% between 2007 and 2009."** Mexico has signed a **total of 12 FTAs with 33 countries,** including Japan, the European Union, the United States (US), Canada and Israel. As a member of the North American Free Trade Agreement (NAFTA), **Mexico has access to the most well-established and emerging pharmaceutical markets in North and Latin America.** First signed on 1 January 1994, the 15-year NAFTA has provided businesses with the freedom to invest without restrictions imposed by tariffs and other tax regulations. **The manufacturing operations in a free trade zone,** referred to in Mexico as the maquiladora programme, **has meant that out of the countries signing the agreement, Mexico has reaped the greatest benefits.** The maquiladora programme resulted in exports from Mexico to the US rising by 135% between 1994 and 1999, and also allowed US companies to establish manufacturing plants in Mexico. Harnessing the economic power of India Outside of NAFTA, Mexico are taking full advantage of the emerging economic power of India, with the Indian pharmaceutical industry becoming a growing presence within Mexico. **The strength of the Indian pharmaceutical industry is in utilising the country's skills in organic synthesis and process engineering, which is facilitating the rapid development of cost-effective technologies without compromising on quality.** In addition to this, India holds the largest number of US Food and Drugs Administration licenses for their manufacturing facilities. It also holds the largest Drug Master Files, which are used to penetrate the generic drugs market. **India has invested millions of pounds in Mexico, with Indian giant pharmaceutical companies** such as Ranbaxy Laboratories and Wockhardt **Limited leading the way in the expansion of generic drugs** in Mexico. Today, India holds the largest portion of generic drug manufacturing in Mexico along with the export of Ayurvedic medicines. The changing Mexican healthcare system **The expanding production and distribution of generic medicines within the public health sector has been greatly influenced by Mexico's changing healthcare system.** The Mexican healthcare system was developed under the presidency of Vicente Fox in 2000 with a simplified system designed to provide millions of families with healthcare. As a result, **generic drugs generate \$2bn (£1.31bn) in annual sales, which has translated into a domino effect whereby increasing numbers of people are accessing medical services,** including purchasing over-the-counter (OTC) and prescription medications. In addition, the Mexican Government has also changed its mindset regarding innovative medicine, with the Business Monitor International (BMI) forecasting a Growth Domestic Product (GDP) growth from 2.7 to three percent in 2013. This is due to the Mexican Government's approval of the production of innovative drugs by giant pharmaceutical companies, as well as increasing patient access to anti-cancer drugs. This projection in GDP was made at the beginning of 2011, when Mexico's Ministry of Health and the Mexican Association of Industrial and Pharmaceutical Research gave a joint press conference to officially introduce 31 types of innovative drugs for cancer, hepatitis C and rare genetic syndromes, among others. In addition, in February 2012, the Mexican Federal Commission for Protection against Health Risks (COFEPRIS) agreed to the introduction of three active drug substances that are present in medicines used in treating cancer, osteoporosis and degenerative disease. Intellectual property **In 1991, the Mexican Government established laws protecting intellectual property rights. This gave pharmaceutical companies an incentive to produce high-quality and affordable medications in Mexico. The protections also gave well-established companies exclusive**

rights to manufacture products in and out of Mexico. To date, **the pharmaceutical industry is the second largest manufacturing sector in the Mexican economy,** second only to the automobile industry. **There are 400**

pharmaceutical companies that dominate the Mexican industry, most of which are multinational companies manufacturing 80% of the nation's pharmaceuticals. Among the big names are Pfizer Corp., Novartis AG, Merck & Co. and Sanofi. Japanese companies such as Taisho Pharmaceutical Holdings Co. Ltd. have also been positioning themselves as major players in the Mexican pharmaceutical industry. Taisho, which popularised the energy drink Lipovitan, acquired four Mexican pharmaceutical companies in 2012. This illustrates just how fast the industry is evolving as new players enter the scene. Challenges ahead Despite the promise of further growth, Mexico's pharmaceutical industry has some challenges ahead. In particular, they are facing a serious threat from the illegal market via theft, unlawful sales practices and counterfeiting. Counterfeiting alone comprises 80% of the illegal pharmaceutical market, with total sales of counterfeit drugs in 2008 costing companies more than \$1.5bn (£989m). Despite leaders of the pharmaceutical industry joining forces with global institutions, such as the World Health Organization (WHO), in a concerted effort to successfully put an end to counterfeiting, "even if you write the law and you bring someone in, how do you ... prevent the trafficking of drugs across borders?" asks Dr. Howard Zucker, WHO assistant director general for Health Technology and Pharmaceuticals. This question remains to be answered. Moving forward **The Mexican**

pharmaceutical industry is fast-growing, with the generic and OTC markets showing particular potential. Indeed, a large part of the generic market remains untapped; some experts project growth of 11 times the current market, or \$2.2bn (£1.45bn). **It is, however, imperative that key players remain pro-active in the prevention of problems resulting from a fragile economic climate** **if** they are to remain at the top.

Pharmaceutical Research Key to Pandemics/BioWar

Pharmaceutical research is crucial to fighting pandemics

Bandow, Cato Institute senior fellow, **5** (Doug, senior fellow at the Cato Institute and a former special assistant to President Reagan, 3/27/05, U-T San Diego website, "A strong pharmaceutical industry is the best defense against pandemics",

http://www.utsandiego.com/uniontrib/20050327/news_lz1e27bandow.html, accessed 7/1/13, JZ)

Diseases like SARS and avian flu, which have proved resistant to drugs commonly used to fight influenza viruses, demonstrate how we all benefit from profitable drugmakers and abundant pharmaceutical research. Although governments have an important role to play in fighting any disease pandemic, **necessary for developing any effective treatment and putting into mass production any vaccine or other medicine is private industry.** Indeed, the initial fight against SARS focused on finding an existing medicine that worked. Laboratories screened some 2,000 federally approved and experimental drugs to see if they were useful in fighting SARS. Gurinder Shahi, a doctor in Singapore, explained: **"Given how little we know about SARS and the reality that it is killing people, it is justified for us to be daring and innovative in coming up with solutions."** **Daring innovation is most likely in a competitive, profit-driven market.** For instance, Pfizer worked with the U.S. National Institute of Allergy and Infectious Diseases to test 350 compounds developed as part of an earlier project to cure the common cold. NIAID also collaborated with the California biotech company Vical Inc. to test a new, experimental vaccine that has protected mice from the disease. Aventis and Merck as well as laboratories around the world began working to develop vaccines. Indeed, **most of today's medicines exist only because there is a bevy of sophisticated pharmaceutical companies devoted to finding drugs to heal the sick. Progress has been particularly dramatic in recent years.** For instance, **two decades ago not one drug was available to fight AIDS. Today 74 have been approved and another 83 are in development.**

Pharmaceutical industry is the only way to stop biological warfare

Shorett, Research Fellow at the Council for Responsible Genetics, **2004**, (Peter, "THE CRACK IN BIOSHIELD'S ARMOR", September-December 2004,

<http://www.councilforresponsiblegenetics.org/ViewPage.aspx?pagelId=152>) Kristof

Congress will face an uphill battle in passing what is sure to be viewed as a giveaway to the pharmaceutical industry. A few of its provisions may significantly delay the introduction of generic drugs to treat illnesses that affect millions of U.S. voters. **Large drug companies, however, may be the only players with the necessary expertise, resources and experience to develop effective vaccines, antibiotics, and other countermeasures against biological weapons.**

Pharmaceuticals is key to the development of DOD non-lethal chemical weapons

The Sunshine Project, International NGO against biological warfare and military abuse , **3** [2-11-3 , "Pentagon perverts Pharma with New Weapons" ,

<http://web.archive.org/web/20130120220549/http://www.sunshine-project.org/publications/pr/pr110203.html>, 7-10-13 , JC]

The conventional view is that pharmaceutical research develops new ways to treat disease and reduce human suffering; but the Pentagon disagrees. **Military weapons developers see the pharmaceutical industry as central to a new generation of anti-personnel weapons.** Although it denied such research as recently as the aftermath of the October theater tragedy in Moscow, **a Pentagon program** has recently released more information that **confirms that it wants to make pharmaceutical weapons.** And on February 5th, US Secretary of Defense Donald Rumsfeld went a big step further. Rumsfeld, himself a former pharmaceutical industry CEO (1), announced that the US is making plans for the use of such incapacitating biochemical weapons in an

invasion of Iraq (see News Release, 7 February 2003). **The Joint Non-Lethal Weapons Directorate** (JNLWD) and the US Army's Soldier Biological Chemical Command (SBCCOM) **are leading the research. Of interest to the military are drugs that target the brain's regulation of many aspects of cognition**, such as sense of pain, consciousness, and emotions like anxiety and fear. **JNLWD is preparing a database of pharmaceutical weapons candidates, many of them off-the-shelf products**, and indexing them by manufacturer. It will choose drugs from this database for further work and, according to Rumsfeld, if President Bush signs a waiver of existing US policy, they can be used in Iraq. Delivery devices already exist or are in advanced development. These include munitions for an unmanned aerial vehicle or loitering missile, and a new 81mm (bio)chemical mortar round. **Many of the Pentagon's so-called "nonlethal" (bio)chemical weapons candidates are pharmaceuticals**. Different names are used for these weapons ("calmatives", "disabling chemicals", "nonlethal chemicals", etc.). Used as weapons, **all** minimally **aim to incapacitate their victims**. They belong to the same broad category of agents as the incapacitating chemical that killed more than 120 hostages in the Moscow theater. That agent was reported to be based on fentanyl, an opiate that is also among the weapons being assessed by JNLWD. In the US, pharmaceutical fentanyl is sold by Johnson & Johnson's subsidiary Janssen Pharmaceutica. Remifentanyl, a closely related drug, is a GlaxoSmithKline product. **US military contractors have identified a host of other agents manufactured by a Who's Who list of the pharmaceutical industry**. In 2001 weapons researchers at the Applied Research Laboratory of Pennsylvania State University assessed the anesthetic drugs isoflurane and sevoflurane, produced by Syngenta and Abbott Laboratories, respectively. The same Penn State team recommended other drugs for "immediate consideration," some of which are in the chart below. The Pentagon is also interested in industry's new ways to apply (bio)chemicals through the skin and mucous membranes, which could bring previously impractical drug weapons closer to reality by overcoming technical hurdles related to delivery of certain agents.

Vaccine development fails – too many regulations and inconsistent trials

Hoskins, Pennsylvania Hospital, ALS Center, Coordinator **10** [Katelin Hoskins, University of Pennsylvania, M.A. Science in Nursing, July 2010, vaccineethics.org, "Vaccines and Bioterrorism II. Obstacles to Bioterror Vaccine Development", http://www.vaccineethics.org/issue_briefs/bioterror_development.php, accessed, 7-12-13 AMS]

The **clinical testing process presents significant obstacles to the production of bioterror vaccines**.¹⁻³ The Food and Drug Administration (FDA) requires rigorous safety and efficacy standards which all vaccine candidates must meet in order to be licensed. Furthermore, researchers involved in vaccine development must abide by certain ethical guidelines, while Institutional Review Boards (IRBs) monitor the safety of human subjects and ensure that subjects are not placed at undue risk. **The development of bioterror vaccines is complicated by the scarcity of such pathogens in nature**. Typically, a small number of research subjects naturally become infected with a target pathogen throughout the course of a new vaccine's development: these infections are necessary to assess the clinical efficacy of the vaccine being studied. **It is unlikely, however, that subjects in bioterror vaccine clinical trials will naturally encounter those target pathogens**, however. **While researchers can measure whether a new vaccine generates a robust immune response in research subjects, such data are less valuable than evidence showing whether those vaccinated actually are protected from infection. Obviously, legal and ethical regulations prohibit the deliberate exposure of research subjects to dangerous pathogens, resulting in a significant challenge for assessing the efficacy of bioterror vaccines in development. Recognizing the difficulties inherent in the development of bioterror vaccines**, in 2002 the FDA instituted a regulatory exception permitting the licensure of certain vaccines and drugs without data from human efficacy studies. The FDA amended its drug and biological product regulations so that certain pharmacological entities, those for which typical human clinical testing is not possible or those intended to relieve or prevent severe or life-threatening conditions, could be licensed based on "substantial evidence" of efficacy in two animal species. The "Animal Efficacy Rule" contained the caveat that products would be withdrawn from the market if post-licensure evidence indicated intolerable risk or lack of efficacy.⁴ While the Animal Efficacy Rule succeeded in addressing conflicts between the FDA and the Department of Defense (DoD), **the use of animal surrogates is an imperfect method of determining clinical efficacy in humans**.⁵ The **specific immune responses that lead to protection in humans often cannot be determined through animal trials. While the safety of a vaccine can generally be ascertained, efficacy cannot be assessed with confidence until vaccinated humans are exposed to the target pathogen. While attempting to infer human response to a vaccine, researchers may employ models that mimic patterns of human disease and statistical analyses that determine immune correlates between species**.⁶ Though it may

sometimes be possible to approximate a human reaction through animal trials, some diseases--such as smallpox and dengue fever--**only affect human beings, complicating vaccine development even further.** An alternate approach is needed for evaluating safety and efficacy when animal trials are impossible. Though the FDA may resist pressure to relax testing requirements, bioethicist Jonathan Moreno suggests that, in the event of a severe public health crisis, it might be ethical to expose fully informed volunteers to pathogens in order to test a pharmaceutical or vaccine candidate.⁷

Stops Bioterrorism

Billions of dollars invested into the pharmaceutical industry to stop bioterrorism and disease

Gozner, former NYU journalism professor, **12** [Merrill, winner of numerous journalism awards, his freelance writing in recent years has appeared in various publications including the New York Times, Washington Post, Columbia Journalism Review, The Nation, The American Prospect and the Washington Monthly, 3/20/12, “Billions to Stem an Unlikely Bioterror Attack,” <http://www.thefiscaltimes.com/Articles/2012/03/30/Billions-to-Stem-an-Unlikely-Bioterror-Attack.aspx#page1>, accessed: 7/12/13, ML]

But Republicans and Democrats agreeing on industrial policy for the pharmaceutical industry to develop drugs and vaccines to combat bioterror agents? It not only passed by unanimous consent in the Senate earlier this month, **it will likely be approved by the conference committee that will soon consider the \$4.5 billion** Pandemic and All-Hazards Preparedness Act (PAHPA), **the reauthorization of the 2006 law coordinating the nation’s decade-long effort to prepare for a terrorist biological warfare attack.** Despite the reality that the only bioterrorist attack that has ever taken place on U.S. soil (one week after 9/11) was launched by a rogue U.S. scientist who had worked in the Cold War biological weapons program and was one of the world’s few experts in weaponizing anthrax, **the nation has spent an estimated \$66 billion** in the past decade preparing for the next assault. **Tens of billions** of dollars have been poured **into basic science** and applied research **to develop vaccines** and drugs to combat diseases like anthrax, smallpox (a disease that no longer occurs naturally on earth), botulism and plague. **Billions more** has gone **into beefing up the public health system’s ability to respond** to emergency health crises. Hospitals have been paid to expand their capacity to respond to surges of patients stricken by a pandemic or a terrorist attack. **These nationwide grant programs have helped build a broad base of political support for the programs.** And now, **in the reauthorization bill sponsored** by Sen. Richard Burr, R-N.C., Congress **has earmarked \$50 million** for a “strategic investor” venture capital fund to invest in start-up biotechnology companies that are developing drugs and vaccines that combat bioterror pathogens. Structured as a public-private partnership outside the government, **the goal is to bring more private funding into the hunt for new “countermeasure” products. It will be added to the \$450 million a year the government already doles out** in grants to companies through the Biomedical Advanced Research and Development Authority (BARDA) and the \$2.9 billion earmarked over the next five years for procurement of new drugs and vaccines for government stockpiles. As the votes in Congress attest (the House version of the bill also passed on a voice vote), the massive commitment to biodefense spending in the 2000s has won broad support from the nation’s research and scientific establishment. The National Institute for Allergies and Infectious Diseases (NIAID), headed since the 1980s by Anthony Fauci, receives over \$1 billion a year for bioterror-oriented scientific research. The National Cancer Institute, by comparison, receives about \$5 billion to look for cures for the tumors that kill over a half million Americans annually. Officials at NIAID and legislators on Capitol Hill say **the massive investment** in preventing and curing diseases that rarely if ever occur naturally **is providing a huge boost to the moribund U.S. effort to develop new antibiotics to fight the drug resistant bacterial strains that are causing tens of thousands of deaths annually** in U.S. hospitals. **“The goal of this basic research is to lay the groundwork for developing broad-spectrum antibiotics and antivirals—drugs that can prevent or treat diseases caused by multiple types of bacteria or viruses—and multi-platform technologies that potentially could be used to more efficiently develop vaccines against a variety of infectious agents,”** the agency says on its website.

The pharmaceutical industry is a crucial sector in combating bioterrorism, but insufficient funding hampers efficient actions

Poupard 5 (James, BA in natural science from Temple University, an MS in clinical microbiology from Thomas Jefferson Medical College, started his PhD studies in the history of science at Bryn Mawr College and completed his PhD studies at the University of Pennsylvania, supervisor of clinical microbiology at the Hospital of the University of Pennsylvania and microbiology director of Bryn Mawr Hospital and later became associate professor of microbiology, pathology, and medicine at the Medical College of

Pennsylvania, 2005, "Pharmaceutical Industry (Drug Industry, Pharma Companies, Biotech Companies)", published in *Encyclopedia of Bioterrorism Defense*, edited by Richard F. Pilch, M.D., and Raymond A. Zilinskas, Ph.D., pg. 385, accessed 7/1/13, JZ)

PHARMACEUTICAL INDUSTRY DRUG DISCOVERY PROGRAMS As noted, **a vital approach to responding to highly resistant organisms in the future is the continued implementation of drug discovery programs** to enhance the pipeline of novel agents. **At present, however, a number of large pharmaceutical companies are in the midst of reducing or eliminating these programs because of practical concerns**, namely, that the expenses pertaining to maintaining such a program and taking a single drug through development all the way to the market (average cost is about \$800 million) are prohibitive (Gwynne and Heebner, 2003). Further, in large pharmaceutical companies, **antiinfective programs must compete with other therapeutic areas for funding**. When one considers that antiinfective drugs are only required for a short duration (days) whereas drugs from other therapeutic areas are often given to patients for years or even life, it is difficult to justify their development and production from a financial perspective. Thus, pharmaceutical companies honoring the commitment to their shareholders cannot, in the contemporary situation, pursue antiinfectives as a high priority, creating a void that will most likely be filled by small pharmaceutical and biotechnology companies in the immediate future (though it should be noted that many of the drugs being developed by these companies have come from lead compounds generated by the larger pharmaceutical companies). This is an issue that must receive the attention of policy planners when setting future priorities.

ADDITIONAL PHARMACEUTICAL INDUSTRY INITIATIVES **Most pharmaceutical companies with marketed antiinfectives have offered their drugs either free of charge or at cost to the government for use in an emergency situation. Several pharmaceutical companies have offered teams of scientists and laboratory space to conduct research, leading to solutions against potential microbial weapons as well.** Other initiatives include a program coordinated by PhRMA in cooperation with the U.S. government, which involves the delivery by pharmaceutical company representatives of printed summary data on anthrax and smallpox to health care personnel in order to raise their awareness of these diseases and provide an informative source for related questions that these personnel may have. In addition to these programs, **some pharmaceutical companies sponsor scientists from foreign countries to work at the Centers for Disease Control and Prevention (CDC) in Atlanta in order to develop skills for addressing bioterrorism in their respective countries.**

THE FUTURE **The pharmaceutical industry will continue to play a significant role in providing therapeutic drugs against the most likely bioterrorist threat agents. However, there are significant gaps in the current therapies available for highly resistant bacteria and many viruses, and significant time, research, and money must therefore be invested to address these gaps.** This will involve the continuing cooperation of the pharmaceutical and biotech industries with various government agencies, academic researchers, and private foundations. Incentives must be provided to conduct research in identified areas of need (Fox, 2003b), and new paradigms must be developed to evaluate drugs and vaccines that cannot be tested in human clinical trials to determine efficacy. New surrogate markers, such as animal or even in vitro models, will have to be accepted as indicators of efficacy as an incentive to develop some of these needed therapies (Friedlander et al., 1993). The pharmaceutical industry will continue to be an active participant in the dialog necessary to move forward in these areas in the years to come.

Answers to Affirmation

Healthcare is a right

Alright there's a lot wrong with this argument so let's break it down.

FIRST this isn't even a topical argument for them to make. Under the resolution, the USFG is imposing price controls on the pharmaceutical industry not health insurance companies. The pharmaceutical industry is a market that sells a product whereas healthcare companies provide insurance. Their advocacy makes no sense whatsoever.

SECOND even if you somehow think that what they're saying is a topical argument, you can delink it because according to Neurosurgeon, Philip Barlow from the British Medical Journal in 1999 there are 2 reasons why healthcare is not a human right: a) Healthcare is too broad and difficult to define. Make the AFF prove whether the so-called human right to health care is a right to basic provision of clean water and adequate food, OR does everyone in the world have the right to organ transplants, cosmetic surgery, and the most expensive medication? For something to count as a human right the minimum requirement should surely be that the right in question is capable of definition. The other reason is that human rights that are accessible by any individual imply a duty on the part of others. They don't tell you on whom these duties to provide health care to all American citizens would fall on. Is it a duty on individual doctors, or hospital authorities, or the government? It is difficult to see how any provision of benefits can be defined as a human right, especially when meeting such a requirement would impose an intolerable burden on others

THIRD, the status quo solves anyway. According to the Washington Post in 2017, the right to health care is the right of access to health care, not the right to insurance coverage. Health care is a commodity, like food or clothing; people should have the right to purchase it at market cost, which they already do.

FOURTH, you can turn the argument because by categorizing healthcare as a right they take away resources and funding from other societal factors, making their advocacy counter-productive. According to Mark Waymack from Loyola University in 1993, the concept that healthcare is a human right forces indefinite spending. He furthers, that healthcare being perceived as a right becomes less about the interests of certain individuals and more about the interests of the entire society. Spending increases by this perception leads to an unethical trade off with other social responsibilities like schools, housing, and infrastructure.

Philip Barlow

Philip Barlow, "Health Care Is Not a Human Right", *British Medical Journal*, 1999,
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1126951/>, DOA 10/7/2018

A human right is a moral right of paramount importance applicable to every human being. **There are several reasons why health care should not be considered a human right.** Firstly, **health care is difficult to define.** It clearly encompasses

preventive care (for example, immunisation), public health measures, health promotion, and medical and surgical treatment of established illness. **Is the so called human right to health care a right to basic provision of clean water and adequate food, or does everyone in the world have a right to organ transplantation, cosmetic surgery, infertility treatment, and the most expensive medicine? For something to count as a human right the minimum requirement should surely be that the right in question is capable of definition.** Secondly, **all rights possessed by an individual imply a duty on the part of others.** Thus the right to a fair trial imposes a duty on the prosecuting authority to be fair. **On whom does the duty to provide health care to all the world's citizens fall? Is it a duty on individual doctors, or hospital authorities, or governments, or only rich governments? It is difficult to see how any provision of benefits can be termed a human right (as opposed to a legal entitlement) when to meet such a requirement would impose an intolerable burden on others.** Thirdly, the philosophical basis of all human rights has always been shaky. Liberalism and humanism, the dominant philosophies of Western democracies, require human rights. Religion requires a God, but this is not in itself evidence of God's existence. Most people can see some advantage in maintaining the concept of civil and political rights, but it is difficult to find any rational or utilitarian basis for viewing health care in the same way. To propose that health care be considered a human right is not only wrong headed, it is unhelpful. Mature **debate on the rationing and sharing of limited resources can hardly take place when citizens start from the premise that health care is their right, like a fair trial or the right to vote.** I suspect that the proponents of the notion think that to claim health care as a human right adds some kind of weight or authority to the idea that health care, and by extension healthcare professionals, is important. A more humble approach would achieve more in the long run.

The Washington Post

Washington Post. Roger, MD, policy analyst for Washington Policy Center's Center for Health Care, April 30, 2017, "Health Care Is Not a Right", The Washington Times, <http://www.washingtontimes.com/news/2017/apr/30/health-care-is-not-a-right/>, DOA 10/7/2018.

"We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness." These words in the Declaration of Independence define the "rights" of American citizens. They do not include health care. Yet for over 100 years, some Americans have believed that health care is not only a right, but that the government should provide it and taxpayers should pay for it. **If medical treatment is a right, then what exactly does that mean? Does it mean that your neighbors, through the government, are obligated to provide all health care for you? Does it mean that anyone can demand the government to pay for hospitalization, for prescription drugs, and for specialty treatments such as organ transplants? Does it mean that every American has a right to the skill and knowledge of all physicians and providers?** These questions lead to other questions. **How does society pay for health care for all? Who gets to decide who should receive health care and how much? Who gets to decide what the health care budget should be? Who should have the power to make health care decisions for us? Or rather than confront these issues, do proponents of health care as a right mean everyone should have health insurance? The problem with this belief is that simply having health insurance does not guarantee timely access to actual medical care.** Every citizen of Canada has government-paid health insurance, but the long wait times for treatment, most notably for specialty care, would be unacceptable for Americans. **Everyone can agree that health care is a necessity of life. So are food, shelter, and clothing. Yet no one is demanding universal "food care" or universal government housing. The critical issue is that people expect access to food, shelter, and clothing. Americans expect choices and competition when they shop for these necessities of life. The government exists to guarantee free-markets for Americans when they seek access to virtually any product,** but especially access to food, shelter, and clothing. No one would expect society, through government, to pay for these necessities of life for everyone. **If "food care" was controlled, paid for, and regulated by the government, we would have overutilization, fewer choices, and a limited supply. The private system of grocery stores and supermarkets guarantees access, choice, and competitive prices for everyone. The free-market system is efficient, voluntary, and fair.** The critical point is utilizing the best mechanism to allow the greatest number of Americans access to health care. The Canadian single-payer system does not guarantee timely access. The American experience with the Veterans Administration hospital system, a comprehensive government-controlled, single-payer health care program, reveals unacceptable wait times and huge inefficiencies. Fundamentally, these systems ration health care by waiting lists and limited money. The quality of care can be variable. Because of budgetary constraints, the demand for health care is much greater than the supply in virtually every county with a government-controlled health care system. Even Medicare, essentially a single-payer plan, is not financially sustainable. Just like in all other economic activities, the free-market offers the best solution to provide the greatest access to health care and to control costs. **People freely making their own health care decisions and using their own health care dollars would give Americans the best chance to utilize their "right" to access health care,** with safety-net health programs provided for those who can't afford it. At the end of the day, health care is an economic activity like any other, albeit with the most personal of

interactions between patient and provider. Society should work toward putting patients in charge of their health care, reducing the role of government, and focusing on access, not health care as a supposed “right.”

Mark Waymack

Waymack, Mark H. “Ethical Issues in Healthcare Reform.” *Ethical Issues in Healthcare Reform*, 1993, pp. 136–137. Loyola University Chicago, <https://ageconsearch.umn.edu/bitstream/17147/1/ar930131.pdf>

Finally, we also regard health as a social good. It is not in our nation's own best interest to have a populace wracked and consumed by disease. From even the most cynical view, sick people do little to contribute to economic production and income taxes. A healthy workforce can produce more than a sick workforce. From a more generous point of view, few of us would disagree with the statement that suffering is bad and health is good. **But when regarded as a social good, the question is not simply how much health care is in the best interests of the individual** (that was our first moral perspective). **Rather, the question becomes how much health care is in the best interests of society, given our limited resources and the welter of other good and services that are of value.** For example, **how much should we spend on health as opposed to education? As opposed to public housing? As opposed to law enforcement? As opposed to our physical infrastructure-roads, utilities, etc.?...** A health care reform program that satisfies our rhetoric of health care as a moral right of the individual would presumably cover the Lakeberg twins. It would pay for liver and pancreas transplants. But **such a program would devastate the economy and draw much needed funds away from other social goods such as schools, housing, roads, defense and job** opportunities.

Canada

Canadians spend more on average, not less

Skinner, Brett. "Canada's Drug Paradox." *The Fraser Institute*, 2005,
www.fraserinstitute.org/sites/default/files/CanadasDrugPriceParadox.pdf.

I calculated the difference between the international median price and the Canadian median price for generic prescription drugs based on the PMPRB's published data and found that **Canadians pay at least 30% more than they would if the domestic drug industry was as competitive as other international markets**. The study estimated that for consumers of generic drugs who made up 42% of the market in Canada, this amounted to a lost savings of at least \$810 million in 2004, based on the expected value of sales revenues to generic manufacturers. All of these studies have found that **prices for generic prescription drugs are higher on average in Canada than in the United States. And brand name drug prices in Canada cannot solely be attributed to price controls because the average Canadian income is lower. Canadian average incomes are lower than US incomes and, therefore, even without price controls, economic theory predicts that Canadian drug prices should be lower on average than US prices.**

Protecting Individuals

Less regulated markets tend to have larger generic market share and lower priced generics

Nancy **Rose** [Professor of Applied Economics, MIT], "Regulation of the Pharmaceutical-Biotechnology Industry" in Economic Regulation and Its Reform: What Have We Learned? University of Chicago Press, **2014**. Available at: <http://www.nber.org/chapters/c12572.pdf>

Cross-national comparisons of drug prices vary significantly, depending on the time period, sample of drugs used, the price index methodology used—including unit for measuring price (grams, units, daily doses), consumption weights, and exchange rates. Most price comparisons have been biased by use of very small, nonrandom samples including only branded drugs, and have not adhered to standard index number methods (GAO 1992; GAO 1994). The exclusive focus on branded drugs tends to bias comparisons in favor of countries with strict price regulation. Regulation and competition are to some degree substitutes: **less regulated markets tend to have higher brand prices but larger generic market shares and lower priced generics**. Overall, **countries that use direct price controls do not consistently have lower prices than countries that use other indirect means to constrain prices** (Danzon and Chao 2000a, 2000b; Danzon and Furukawa 2003, 2006). However, comparisons are very sensitive to the sample of drugs, weights, exchange rate, and prices used.

U.S Dept. of Commerce calculates price controls among OECD countries reduces 5-8 billion in potential pharmaceutical development investment every year. This loss deprives all individuals of life saving treatments.

Peter J. **Pitts**, 5-19-**2017**, National Review, "The False Promise of Drug-Price Controls", 10-22-2018, <https://www.nationalreview.com/2017/05/drug-price-controls-bad-idea/>

Companies are willing to make such a risky investment because a breakthrough product can generate a huge payoff. But price controls squeeze that payoff. They prevent drug firms from charging prices commensurate with those massive development costs. For some companies, the payoff is no longer worth the risk, and they're forced to scale back on new research. The **U.S. Department of Commerce calculates that price controls among countries in the OECD**, a major economic organization comprising much of Europe, **drives away \$5 billion to \$8 billion in potential pharmaceutical development investment every year. That prevents the creation of three to four new drugs annually. This loss** of development dollars doesn't just hurt citizens in controlled markets; it **deprives all of us of new, life-saving treatments**. This is the terrible toll of drug-price controls. Foreign authorities need to wake up to the harm they're causing.

Cutting prices by 40-50% will decrease R&D projects being taken by 30-60%. On net, a RAND Study on price controls in Europe found pharmaceutical price controls hurt patients.

Paul **Howard**. "To Lower Drug Prices, Innovate, Don't Regulate", The New York Times, Sep 23 **2015**, <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/to-lower-drug-prices-innovate-dont-regulate>

"Price control advocates argue that curtailing profits in the pharmaceutical industry would save the country money without reducing innovation. There is, however, no such Pro Arguments with Con Responses Nov/Dec 2018 Champion Briefs 64 thing as a free lunch. Bureaucratic price manipulation would only hurt the sickest patients. Streamlining drug approvals would get more drugs on market, increasing competition and lowering prices. Research shows that price controls in the United States would powerfully dampen innovation. **Cutting prices by 40 to 50 percent in the U.S. will lead to between 30 to 60 percent fewer R&D projects being undertaken," one study found. A 2008 RAND study exploring the effect of U.S. price controls on those aged 55 to 59 in the United States and Europe similarly found that, on net, pharmaceutical price controls would hurt patients**. The idea that we "overspend" on drugs is also misleading. In 2014, drug spending accounted for just 10 percent of U.S. health care spending, and according to government actuaries, spending will increase by only 0.4 percentage points over the next decade. Hospitals, for comparison, account for more than 30 percent of total health care spending. Countries that use price controls advocated by industry critics actually spend a larger share on drugs and use fewer cost saving generics than the United States does."

Drug costs are a large part of healthcare

Drug prices as a percentage of healthcare expenditures have not increased since 1960

Wayne **Winegarden**, Ph.D. is a Sr. Fellow in Business and Economics at the Pacific Research Institute, Policy Advisor to the Heartland Institute, and the Managing Editor for EconoSTATS, May 17, **2018**, <https://www.forbes.com/sites/econostats/2018/05/17/pharmaceutical-price-controls-will-not-improve-health-care-outcomes-in-illinois/#6194945570d5> Pharmaceutical Price Controls Will Not Improve Health Care Outcomes in Illinois

De facto price controls will not solve the health care affordability problem. **Despite the headlines about high-priced drugs, pharmaceuticals represent a small portion of overall medical costs. According to the Centers for Disease Control and Prevention, about 10 percent of all health spending goes toward prescription drugs nationally; that's roughly the same share as in 1960.** Further, **pharmaceutical expenditures are not growing faster than overall health care expenditures**. According to the latest national health expenditure data, retail prescription drug expenditures rose 1.3 percent in 2016, less than one-half the growth in overall health care expenditures of 4.3 percent. Generic medicines play an invaluable role creating these positive outcomes. The purpose of generic medicines is to enable a competitive market that drives down prices and creates significant budgetary savings. According to **the Association for Accessible Medicines, generic medicines in 2016 (the latest data** available) have enabled \$9.6 billion in savings for Medicare, Medicaid, commercially insured, and uninsured patients in Illinois alone. The competitive environment that generic medicines enable also means that these firms will typically operate with very small profit margins. Due to these thin profit margins, HB 4900's price controls are particularly damaging for these manufacturers. Consequently, HB 4900 could have the perverse impact of driving out manufacturers. This would worsen the competitive environment and (ironically) lead to higher cost pressures.

Spending is too high

First, we're going to non-unique this argument in two ways. Jayne O'Donnell of USA Today finds that there are multiple ways to address high costs. Drug makers offer billions of dollars in grants to help patients in need. Pharma companies also offer free and reduced-price drugs to those in need. Beyond drug companies, is a project called needymeds which offers coupons of up to 80% discounts for helping these drug prices. The second way we can do this is that Times Magazine in 2017 reports that only 9.1% of Americans are uninsured. That leaves 90.9% of America with an easy solution to high drug costs

Second, if you don't buy that you'll buy the turn - Rose from MIT in 2014 finds that empirically, countries that impose price controls only affect brand name drugs and charge higher prices on generic drugs. This is problematic because Senate chair member, Orrin Hatch finds in 2018, that 89% of drugs on the US market are composed of generics. Our opponent's advocacy does not take the majority into consideration and by trying to reduce prices for a small sector of the pharmaceutical industry they increase prices for the majority of the market.

Jayne O'Donnell, 2-2-2016, "High drug prices mean you can't afford your medications? There's help," USA TODAY, <https://www.usatoday.com/story/money/personalfinance/2016/02/02/high-drug-prices-help-afford-medications/79201120/> Drugmakers' patient-assistance programs are the place to start if you need help paying for your prescriptions. Leigh Purvis, director of health services research at AARP's Public Policy Institute, calls them a "necessary evil" in the face of drugmakers' continued price increases. These programs provide co-payment assistance or free or discounted medicines to people who can't afford them. Purvis suggests people try the Centers for Medicare and Medicaid Services' list of recommended programs and NeedyMeds.org, which lists hundreds of programs. "These programs give away billions of dollars each year and help millions of people," says Rich Sagall, the retired physician who founded NeedyMeds. Eligibility varies based on the drug, says Sagall, but it often takes into account someone's income, insurance status and diagnosis and can be as high as 500% of the federal poverty limit, or just over about \$100,000 a year for a family of three. Erin Singleton, chief of mission delivery for the Patient Advocate Foundation, warns that some of the programs don't have retroactive approval, so it's important to research your options before you begin treatments, if possible. Even if you don't think you'll need the help now, Singleton notes that illnesses require many people to cut back hours or stop working, so it's good to be aware of available assistance just in case. Sagall also suggests thinking about your entire family's medication needs, because if there's no assistance program for your expensive drug, there could be one for another family member's drugs, which could free up money for your medicine. NeedyMeds also offers free drug discount cards offering up to 80% off the cash price of prescription drugs, one of many drug-discount programs out there. RefillWise has a savings card that also tracks prescriptions, offers "points" that can be redeemed for cash rewards and reminder emails when it's time to call in your next prescription. Nancy Rose. Professor of Applied Economics, MIT, "Regulation of the Pharmaceutical-Biotechnology Industry" in *Economic Regulation and Its Reform: What Have We Learned?* University of Chicago Press, 2014. Available at: <http://www.nber.org/chapters/c12572.pdf> Cross-national comparisons of drug prices vary significantly, depending on the time period, sample of drugs used, the price index methodology used—including unit for measuring price (grams, units, daily doses), consumption weights, and exchange rates. Most price comparisons have been biased by use of very small, nonrandom samples including only branded drugs, and have not adhered to standard index number methods (GAO 1992; GAO 1994). The exclusive focus on branded drugs tends to bias comparisons in favor of countries with strict price regulation. Regulation and competition are to some degree substitutes: less regulated markets tend to have higher brand prices but larger generic market shares and lower priced generics. Overall, countries that use direct price controls do not consistently have lower prices than countries that use other indirect means to constrain prices (Danzon and Chao 2000a, 2000b; Danzon and Furukawa 2003, 2006). However, comparisons are very sensitive to the sample of drugs, weights, exchange rate, and prices used. Sen. Orrin G. Hatch, a Republican, is the senior senator from Utah and serves as chairman of the Senate Finance Committee and a senior member of the Senate Health, Education, Labor and Pensions Committee, June 25, 2018, <http://www.rollcall.com/news/opinion/opinion-competition-is-key-to-promoting-innovation-and-prescription-drug-affordability> Opinion: To Keep Drug Costs Low, Think Competition, Not Price Controls More than three decades ago, I championed the Hatch-Waxman Act, which established a system for regulating drugs that continues to provide sensible ways to reward new products while encouraging generic competitors. Because of this law, nearly 89 percent of the drug market today is composed of generics, giving more patients access to high-quality medicine. Based on generic approvals in 2017, the Food and Drug Administration estimates a whopping \$16 billion in savings.

Health spending is sustainable and won't drag down growth - GDP after subtracting healthcare is steadily increasing and sustainable

Graham 16 – John Graham, Director of the Health Technology Forum, MBA from London Business School, Senior Fellow at the National Center for Policy Analysis, Chartered Alternative Investment Analyst, “The U.S. Health System Is Not An Economic Burden”, Forbes, 4-20, <https://www.forbes.com/sites/theapothecary/2016/04/20/the-u-s-health-system-is-not-an-economic-burden/#4339025b2832>

Health spending consumes a higher share of output in the United States than in other countries. In 2013, it accounted for 17% of Gross Domestic Product. The next highest country was France, where health spending accounted for 12% of GDP. **Critics of U.S. healthcare claim this shows the system is too expensive and a burden on our economy, demanding even more government intervention. This conclusion is misleading and leads to poor policy recommendations, according to new research** published by the National Center for Policy Analysis (U.S. Health Spending is Not A Burden on the Economy, NCPA Policy Report No. 383, April 2016). Discussing health spending in dollars, rather than proportion of GDP, the report notes Americans spent \$9,086 per capita on healthcare in 2013, versus only \$6,325 in Switzerland, the runner-up. (These dollar figures are adjusted for purchasing power parity, which adjusts the exchange rates of currencies for differences in cost of living). This big difference certainly invites us to question whether we are getting our money's worth. However, **it is not clear that this spending is a burden on Americans, given our very high national income. After subtracting health spending from U.S. GDP, we still had \$44,049 per capita to spend on all other goods and services we value. Only two countries, Norway and Switzerland, beat the United States on this measure. But compared to larger developed countries, Americans have higher income per capita after subtracting healthcare spending.** For example, in the United Kingdom, GDP per capita after health spending was only \$34,863 in 2013. So, even though Americans spent significantly more on healthcare than the British, the average American enjoyed \$9,185 more GDP after health spending than his British peer; and just under \$6,000 more than his Canadian neighbor. Britain socialized its health system shortly after World War II, completing the work by 1948. Canada's healthcare was more gradually socialized by provincial and federal governments during the period 1947 through 1966. Many assert these so-called single-payer systems relieved the burden of private payment from citizens and made the economy more productive. On the contrary: **Since 1960, the U.S. economy has outperformed all comparable developed countries except Norway and Switzerland with respect to economic growth, after subtracting health spending.** From 1960 through 2013, **the share of U.S. GDP allocated to healthcare more than tripled. However, this had no impact on the ability of the U.S. economy to deliver high GDP per capita, outside healthcare.** Adjusted for purchasing power parity, U.S. health spending increased \$8,937, while GDP per capita increased \$50,269, from 1950 through 2013. Thus, **GDP per capita available for other goods and services, after spending on health care, increased** \$41,332, or \$780 per year. Over these 53 years, only Norway and Switzerland increased their non-health GDP per capita more than the United States. Norway, which had become a petro-state due to revenue gushing from the North Sea oilfields, increased this amount by \$57,981, which is \$16,649 more than the United States, or \$314 more in non-health spending per year per person. The report concludes **the theory that health spending influences economic growth for better or worse is too simple. In fact, wages, prices and resources allocated to healthcare are a consequence of economic activity in other parts of the economy** as well as health policy.

There's no economic impact to high health spending

RCA 17 (Random Critical Analysis – Economics Blog, “Health care prices do not play the role most believe,” <https://randomcriticalanalysis.wordpress.com/2017/07/27/health-care-prices-do-not-play-the-role-most-believe/>)

The relative differences between the two US PPPs are quite modest. **A given amount of US dollars within the US only goes a little further if spent throughout the entire economy (GDP) than if spent on health if we compare the differences in how far these expenditures go throughout the OECD.** My eyeball estimate of these figures suggests **health is only about 14% more expensive according to the differences in the volumes they derived there.** By way of reference the real volumes of GDP per capita was about 37% higher and AIC about 47% higher in the US in 2014 (note: if you look carefully at the plot, figure 4, you might also notice there is a pretty strong correlation between relative price levels and how wealthy these countries are).

Spending will slow - ACA expansion has been completed - Drug spending declining - Pent up demand will soon be over

Hempstead 17 – Katherine Hempstead, PhD, MA, Senior Adviser to the Executive Vice President, leads Robert Wood Johnson Foundation's Work on Health Insurance Coverage. "Is the Slowdown Slowing Down?," 4/7/17, <http://www.rwjf.org/en/library/research/2017/04/rate-of-health-care-spending-growth.html>)

Had the American Health Care Act passed into law, it was widely expected that sharp reductions in health care spending growth, due to both coverage losses and reduced-per-enrollee spending, would have occurred. Yet in the absence of the bill becoming law, **there is every reason to anticipate a slowdown in health care spending growth, as the sizable coverage expansion of the last three years has largely been completed. The Altarum Institute's monthly reports have been documenting this trend**, and their most recent analysis suggests that this slowdown is unfolding at a more leisurely pace than anticipated. Health care services spending, seemingly on its way down in the final three quarters of 2015, gave way to somewhat stronger growth in 2016. While overall health spending growth in 2016 was lower, at 5.2 percent, than the 5.8 percent reported for 2015, the 2016 quarterly health care services growth rates send a somewhat mixed message—with the Q4 growth rate of 6.1 percent the highest since Q2 2015. Health care services spending growth did not show a markedly downward trend during 2016, suggesting that perhaps spending growth will not return to pre-expansion levels so quickly. For its part, **prescription drug spending growth declined steadily throughout the year, and was well below overall trend by the third quarter. The continued high growth in health care services spending is particularly concentrated in the outpatient setting.** Since 2014, growth in spending in physicians' offices has exceeded that in hospitals, and this trend persisted through the first two quarters of 2016. For 2015, and all but one quarter of 2016, physician spending grew by more than 6 percent. Consistent with this trend, health care jobs grew in ambulatory settings the fastest. From what we can tell, **this trend largely reflects continued growth in utilization, since health care services prices seem to have increased relatively little since 2014.** This stands to reason—since utilization increases among those who gain coverage—as financial barriers to health care are reduced. Additionally, **among some newly insured populations there may be “pent-up demand,” as long deferred health care needs are addressed.** Aside from coverage expansion, there are other factors that may be affecting trends in ambulatory utilization. New forms of ambulatory care have grown in recent years, both new physical settings—like retail and urgent care clinics—and various types of telemedicine. Health systems are investing heavily in both channels, adding urgent care centers and seeking to add telemedicine capacity. Meanwhile consumers are seeking out telemedicine services, sometimes purchasing packages that augment their insurance plan. These recent changes in the availability of new settings for ambulatory care, along with benefit design changes and new payment models that emphasize primary care, have the potential to influence the utilization patterns of the entire population. A number of studies have suggested that new ambulatory settings are complements rather than substitutes for traditional physician office visits, and may actually increase net utilization. A recent study of MinuteClinic use found that more than half of visits represented new uses of medical services rather than a replacement for a visit. Retail and urgent care were recently estimated to comprise 20 percent of primary care encounters. The Blue Cross Blue Shield Association estimated that retail visits doubled among commercially insured members between 2011 and 2015. To the extent to which they may serve as an accelerant to overall utilization, the proliferation of these new sites of care may be changing patterns of health care services use in ways that go beyond meeting the needs of the newly covered, and may affect the trend in spending on health care services. **Coverage expansion is without question a very important component of recent health care spending growth, and as this expansion slows and pent-up demand is satisfied, it would be expected that overall rates of utilization growth would begin to slow as well. And it does appear that some softening in growth has occurred. Altarum estimates that the growth rate in utilization fell from 5.1 percent in 2015 to 4.4 percent in 2016.** Echoing this trend, **job growth in health care declined considerably in 2017**, from more than 30,000 new jobs per month in 2015 and 2016 to less than 20,000 in the first few months of 2017. There is an unfortunate shortage of timely data on ambulatory care use at the population level, but factors other than coverage expansion may be affecting utilization patterns. Going forward, it will be important to better understand these patterns and see what implications they may have for trends in health care services spending.

Shift to preventive care is coming and solves cost

Gruessner, 17 – Breast Health and Healing Foundation department director [Vera, "Humana, Aetna, Cigna Invest in Value-Based Care Payment Models; National health insurers are continuing to advance value-based care payment models such as accountable care organizations," Health Payer Intelligence, 1-6-17, <https://healthpayerintelligence.com/news/humana-aetna-cigna-invest-in-value-based-care-payment-models>, accessed 9-8-17]

Value-based care payment **models are continuing to make headlines among major health insurance companies around the nation.** Last month, Humana entered into a **value-based care arrangement** with the population health management company Fullwell, according to Zacks Equity Research. **The Humana and Fullwell partnership is aimed at creating a wellness-focused, population health-based, and patient-centric healthcare delivery system.** More than 150 Fullwell healthcare providers under the Colorado Health Neighborhoods Network will be available to Humana's Medicare Advantage members in the Denver area. Humana's value-based care payment model will focus on reimbursing providers for quality of care instead of quantity. **Value-based care payment models** depend on patient health outcomes and **move away from fee-for-service** reimbursement structures, **which focused on the volume** of services **instead of preventive care**. "Under the terms of this value-based agreement, both FullWell and Humana are supposed to frame strategies to improve the quality of healthcare at a low cost for the Humana members in Colorado," according to the report from Zacks Equity Research. "Together, **the companies are striving to find the gaps in care**, manage medication adherence, follow up on patients needing PCP visits, **and identify** high Emergency Room (ER) seekers and **at-risk patients to provide** them proper **treatment before their condition turns severe.**" Through the partnership with Fullwell, **the payer has aimed its sights on better managing healthcare costs while improving the overall health** and wellness of its members. From September through November 2016, Humana shares grew 15.01 percent while the general Health Maintenance Organization industry rose by an average of 14.14 percent during the same time period. **Humana decreased healthcare spending by 20 percent in 2015 due to the advancement of value-based care payment models.** About 63 percent of Humana's 1.8 million Medicare Advantage members are currently treated through value-based care payment models. An additional report from Zacks Equity Research shows that **the national health insurance company Aetna has also been heavily invested in transforming its healthcare delivery strategy by expanding value-based care payment models such as accountable care organizations (ACOs).** Currently, more than 40 percent of Aetna's healthcare spending is in the form of a **value-based care payment model.** The payer's goal is to have **75 percent of their spending in a value-based model by 2020.** As such, the company has been expanding their ACO offerings while also growing in international markets, the report states. **Aetna has also decreased its operating costs** to 18 percent in 2016, which is a drop from the expenses in 2014 and 2015. **Cigna** is another health insurer that **has taken on** the task of **advancing value-based care payment models.**

De-Link, Pharmaceutical companies don't make huge profits. Big pharma stock is lagging behind and Biopharma Internal Rate of Return is decreasing. Pharma profits are lower than those of other large companies.

Lamattina 18 of Forbes John Lamattina, 1-23-2018, "About Those Soaring Pharma Profits," Forbes, <https://www.forbes.com/sites/johnlamattina/2018/01/23/about-those-soaring-pharma-profits/#6fd006733f9d>

Actually, available data* are pretty supportive. The average return on equity for key industries from 2014 – 2016 shows that **biopharma's profits stand** at 16.2%, **significantly lower than Computer Sciences** (31.6%), **Beverages** (27.4%), **Aerospace/Defense** (23.0%), **and Trucking** (19.1%) while modestly higher than Software System/Applications (15.2%) and **Another measure, Internal Rate of Return** (IRR) is even more telling. IRR calculates the sales/cash flows resulting from R&D investments, ties R&D and the returns it generates together, and is a more appropriate metric for biopharma productivity. Deloitte reports that the IRR for biopharma R&D **has been steadily falling from 10.1% in 2010 to 3.2% in 2017.** Even Wall Street hasn't bought into the "pharma soaring profits" view. Since February 1, 2014, while the Dow has risen 63%, the stock prices of a number of major pharma companies have been muted with Pfizer and Bristol-Myers each growing by about 15%, and Merck and AstraZeneca by roughly 6.5%. Even Lilly's growth of 43% still lags the Dow.

Mitigate, only 1/10 drugs actually get the fda approval, this is after all the billions of dollars spent testing

Loria 16 of Business Insider Loria, Kevin. "Why Exciting Ideas for Cures Almost Never Make It to Patients." Business Insider, Business Insider, 3 Mar. 2016, www.businessinsider.com/why-its-so-hard-to-get-drugs-approved-2016-3.

There are different ways of calculating how likely the Food and Drug Administration (FDA) is to approve a new drug, but one thing is for sure: Getting a medication from the early "this looks like it could be interesting" stage into clinical trials is a difficult process — and one that, more often than not, ends in failure. Many drugs, especially in early stages, seem like they could have the potential to revolutionize medicine, offering new ways to fight some of our deadliest, most difficult-to-treat diseases. **Yet only about one in 10 drugs that make it all the way to clinical trials (a long and arduous journey in itself) turns out to be safe and effective enough to get FDA approval.** Some argue that the regulatory process and bureaucratic red tape stifle life-saving innovation and prevent cures from reaching patients that need them. Novel types of drugs and medical tests are particularly difficult to get past regulatory screening. Others say that the FDA is too lenient, and that if anything, legislation under consideration right now could make it even easier to sell dangerous drugs and medical devices. Stalling innovation is arguably worth it, if it keeps patients safe from potentially harmful interventions. But is the issue really one of too much or not enough scrutiny? There are areas where regulatory processes could be tweaked to promote innovation. But the real hurdle might be just that inventing and developing something truly new is both incredibly hard and incredibly expensive. Many ideas peter out because of a lack of resources, not because of a lack of promise or a regulatory stumbling block. And that's a tougher problem to address. When there are no approved cures The main question regulators face is how to balance the need to keep patients safe from dangerous drugs while also — when necessary — taking risks to advance medicine. It's hard to say that sick people should take an experimental drug that could have devastating side effects before we even know if it will work. Yet there's a good argument for trying those experimental, unproven treatments if a disease will most likely (or sometimes even certainly) end in death, even after any approved treatments are used. Some cancer doctors in particular argue that we need to be more aggressive in these cases. "The rate-limiting step in eradicating cancer today is not the science but the regulatory environment we work in," top cancer expert Dr. Vincent T. DeVita Jr. argues in his new book, "The Death of Cancer." He writes that he thinks "we have the tools to eradicate cancer" but that the bureaucracy hasn't caught up with the science. DeVita, a former director of the National Cancer Institute, thinks we could cure an additional 100,000 cancer patients a year if doctors were allowed to experiment with more unorthodox ways of trying to stop the disease.

Turn, if prices decrease potential investors would be further decreased then they are now, as it right now according to tech insider potential investors don't invest unless the drug is very likely to succeed.

Loria 16 Business Insider Kevin Loria, 3-3-2016, "Why exciting ideas for cures almost never make it to patients," Business Insider, <https://www.businessinsider.com/why-its-so-hard-to-get-drugs-approved-2016-3>

Most potential new drugs don't actually turn out to be viable, explains Dr. Michael Kurilla, director of the Office of Biodefense Research Resources and Translational Research at the NIH's National Institute of Allergy and Infectious Diseases. That means pharmaceutical companies are only willing to invest in research that is far enough along that it seems likely to have a payoff. **Even organizations like the NIH that are willing to invest in early stage research want to know how that research will pass regulatory hurdles, and the regulatory barriers for radical proposals are difficult to overcome.** "What we've found working with investigators that have very unique modes and types of inventions is that the biggest obstacle is regulatory," Kurilla says. It's hard to show that a new type of medicine, like the one Rider designed to treat many diseases, is safe. Other examples include potential treatments like specially tailored probiotics, which would provide a patient with "good" health-promoting bacteria to treat a wide variety of conditions. Getting the FDA to even approve a trial of these types of drugs is "incredibly difficult," infectious disease physician Dr. Shira Doron recently told STAT, even more so than normal. It took five years for Doron to get approval to test one such drug, and the FDA still hasn't approved any medical use for probiotics.

Mitigation, from the beginning of research to the clinical test run it can cost 2.6 billion dollars for a new drug. Inventors are not going to be incentivized to create new life-saving drugs if they can't even get their money back.

Loria 16 Business Insider Kevin Loria, 3-3-2016, "Why exciting ideas for cures almost never make it to patients," Business Insider, <https://www.businessinsider.com/why-its-so-hard-to-get-drugs-approved-2016-3>

Not only is it hard to make novel, safe medications, it can cost more than \$2.6 billion to shepherd an invention from a promising early study to the end of the clinical trial process. A lot of those really innovative ideas come from universities and small labs that try something truly different from already existing drugs. Their early results might suggest the possibility of a cure, but getting a drug company to invest billions into unproven and even "out-there" ideas is a very different proposition. Many ideas fail because they should; many potential drugs don't live up to their initial promise. That's why rigorous testing and clinical trials are necessary. But we want a system that encourages new ideas and — when necessary — risk-taking to cure patients who don't have any other option. In some ways, we're getting better at that, at least in making some experimental drugs available to patients with fatal diseases.

Mitigate, Paul Howard of the Manhattan institute explains that we don't overly spend on drugs and we actually spend most of our healthcare funding on hospital visits at 30%, while we only spend 10% on drugs.

Howard of the Manhattan Institute Howard, Paul. "To Lower Drug Prices, Innovate, Don't Regulate." Manhattan Institute, 8 Dec. 2015, www.manhattan-institute.org/html/lower-drug-prices-innovate-don%E2%80%99t-regulate-8229.html.

Research shows that price controls in the United States would powerfully dampen innovation. "Cutting prices by 40 to 50 percent in the U.S. will lead to between 30 to 60 percent fewer R&D projects being undertaken," one study found. A 2008 RAND study exploring the effect of U.S. price controls on those aged 55 to 59 in the United States and Europe similarly found that, on net, pharmaceutical price controls would hurt patients.

The idea that we "overspend" on drugs is also misleading. In 2014, drug spending accounted for just 10 percent of U.S. health care spending, and according to government actuaries, spending will increase by only 0.4 percentage points over the next decade. Hospitals, for comparison, account for more than 30 percent of total health care spending. Countries that use price controls advocated by industry critics actually spend a larger share on drugs and use fewer cost-saving generics than the United States does. Absent price controls, however, private negotiation works. A report from the Government Accountability Office concluded that the Medicare Part D drug program (where private insurers negotiate with drug manufacturers) obtained lower (pre-rebate) prices than the defense department or Medicaid. For generic drugs, where competition is the greatest, Part D's prices were essentially no different than Medicaid's. Better prices can be enjoyed today without compromising tomorrow's cures. But instead of exercising greater control over the industry, reformers should opt for less — focusing instead on efficiency, innovation and competition.

Medicare Part D

Medicare D prices not increasing

Peter **Ferrara**, August 14, **2017**, <http://dailycaller.com/2017/08/14/democrats-would-ruin-medicare-part-d-with-price-controls-on-drugs/> DEMOCRATS WOULD RUIN MEDICARE PART D WITH PRICE CONTROLS ON DRUGS

The target is the very prescription drugs covered by Medicare Part D, which furnishes medications to tens of millions of seniors. **Premiums for the Part D program have remained quite stable, and are projected to dip slightly for 2018.** Medicare Part D premiums rose only from \$31.08 to \$35.63 between 2012 and 2017.

Generics have lowered drug prices

Sen. Orrin G. **Hatch**, a Republican, is the senior senator from Utah and serves as chairman of the Senate Finance Committee and a senior member of the Senate Health, Education, Labor and Pensions Committee, June 25, **2018**, <http://www.rollcall.com/news/opinion/opinion-competition-is-key-to-promoting-innovation-and-prescription-drug-affordability> Opinion: To Keep Drug Costs Low, Think Competition, Not Price Controls

More than three decades ago, I championed the Hatch-Waxman Act, which established a system for regulating drugs that continues to provide sensible ways to reward new products while encouraging generic competitors. Because of this law, nearly 89 percent of the drug market today is composed of generics, giving more patients access to high-quality medicine. Based on generic approvals in 2017, the Food and Drug Administration estimates a whopping \$16 billion in savings.

New cancer drugs on the brink of development

Sen. Orrin G. **Hatch**, a Republican, is the senior senator from Utah and serves as chairman of the Senate Finance Committee and a senior member of the Senate Health, Education, Labor and Pensions Committee, June 25, **2018**, <http://www.rollcall.com/news/opinion/opinion-competition-is-key-to-promoting-innovation-and-prescription-drug-affordability> Opinion: To Keep Drug Costs Low, Think Competition, Not Price Controls

Just in cancer treatment alone, more than 700 drugs are in late stages of development, according to a recent study. Many of the new therapeutics are more effective than other options currently available. With cutting-edge innovation, however, comes increased drug costs. In 2017, the median cost of new cancer drugs exceeded \$150,000 in the United States, more than doubling from just a decade ago. And although the majority of these drugs are used by less than 10,000 patients in any given year, it's a challenge for federal and state programs — and consumers — to absorb the increased costs on the front end.

US pharma critical to global innovation

Jay **Taylor** Jay Taylor is Vice President of International Advocacy at PhRMA. Prior to Joining PhRMA, Jay was a partner at the international law firm, McDermott, Will & Emery, where he specialized in international trade policy, export controls and Foreign Corrupt Practices Act (FCPA) matters. Previously, Jay served as Associate General Counsel at the Office of the United States Trade Representative (USTR), where he managed and litigated numerous international trade disputes, and drafted and negotiated several free trade agreements. Mr. Taylor received his undergraduate degree from Princeton University,

and a law degree from Tulane University, May 9, **2017**, <https://catalyst.phrma.org/government-imposed-price-controls-threaten-innovation-and-access>

Government-imposed price controls threaten innovation and access. It's no coincidence that America leads the world in the discovery and development of new lifesaving medicines. **U.S. biopharmaceutical innovators invest \$60 billion in R&D annually – more than any other country – and support 4.5 million jobs nationwide. The rest of the world depends on the U.S. biopharma industry to keep churning, yet the fruits of U.S. innovation and labor are too often diminished by egregious price controls.** Whether the tactic is obscuring price negotiations, mandating price levels below market value or denying due process of pricing policies, the output is the same: **other countries disproportionately reap our rewards, and global public health is threatened. And price controls don't just threaten U.S. innovation and allow other countries to benefit from our hard work and investments—despite what many of these countries think, these tactics often aren't ultimately that effective.** In fact, **the U.S. Chamber of Commerce finds that price control mechanisms “reduce social welfare by depressing the number of new drugs” brought to market and also “delay or reduce the availability of some innovative medicines.”** Looking abroad, **data from India show price controls have limited impact and do not improve access for the neediest patients. However, price controls have existed in India for decades. Congruent with the study, essential medicines are largely inaccessible to India's low-income patients, even though India's price control regulations have produced a market with some of the lowest prices of medicines in the world. So, if access isn't improved, who benefits from India's price controls? The same study found that the primary beneficiaries of price controls have been India's wealthy elites, while the country's poorest citizens, as well as our biopharmaceutical industry, lose out.** It's not just India either—South Korea has taken similar steps. Despite obligations set forth by the U.S.-Korea Free Trade Agreement (KORUS), South Korea implements heavy price control regulations. The Korean government institutes drastic price reductions on the off-patent and generics market, and then bases prices of new, innovative medicines on the weighted average price within that therapeutic class, which includes those now heavily discounted medicines. This price control scheme has resulted in reimbursement for innovative medicines falling to less than half of the OECD average. **As a result, patients get the short end of the stick with severely reduced access to innovative medicines. Price controls handicap U.S. companies, threaten 4.5 million jobs and, as studies have proven, fail to legitimately improve access to medicines. It's time to protect biopharma innovation and eliminate unfair price controls.**

State Budgets

Budget pressure means states legalize marijuana

Joel **Griffith 16**, "Doing More with Less: State Revenue Limitations and Mandates on County Finances", <http://www.naco.org/resources/doing-more-less-state-revenue-limitations-and-mandates-county-finance>

In many instances, the governmental entity issuing the mandate fails to provide the necessary resources, leaving counties to resort to general revenues raised from property taxes. Further, local communities are not being granted the opportunity to weigh the benefits against the increased tax burdens to implement state and federal mandates. 3. COUNTIES ARE ADJUSTING TO NEW FISCAL CHALLENGES ON THE HORIZON. Several developments are challenging local fiscal conditions across the nation. Marijuana legalization In 25 states and the District of Columbia (33 states following the November 2016 election), marijuana legalization promises to increase the flow of revenue into state coffers. However, costs associated with potential substance abuse problems (such as behavioral health, family services and law enforcement) may prevent counties from receiving a net financial benefit from this new source of revenue. Only five states (Calif., Colo., N.Y., N.C., Wash.) have revenue sharing agreements with counties for excise taxes on marijuana. This revenue sharing follows one of two models. First, the state of Washington shares a small portion of the excise tax with local governments opting to allow sale of marijuana for recreational purposes within their jurisdiction.^[19] Second, Colorado shares a portion of marijuana sales revenue only with the localities that have not approved recreational marijuana use and sale; these funds are intended to address local impacts of marijuana legalization from neighboring jurisdictions. In addition, Colorado granted counties the ability to collect their own excise taxes on retail marijuana sales with no rate limitation. ^[20] At the same time, counties in all these states face the possibility of increasing expenses related to issues such as substance abuse or driving under the influence.

Solves cartels and border violence

Eric **Boehm 17**, "Legalizing Marijuana Would Hurt Mexican Drug Cartels More Than Trump's Border Wall", <http://reason.com/blog/2017/02/03/legalizing-marijuana-could-hurt-mexican>

Instead of increasingly militant and expensive measures designed to stop the flow of drugs, Bienenstock told Reason in an email interview this week, Trump should be backing the legalization of marijuana, which has already begun to cut into the drug cartels' profits while creating American jobs. "It's important to understand that the Drug War created the cartels, not the other way around," says Bienenstock. "We've been wasting trillions of dollars for nearly 50 years on wholly ineffective, and even counterproductive, efforts to stop the flow of drugs into the United States, and those efforts have only made the cartels bigger, stronger, and more dangerous." Even by the wasteful standards of the War on Drugs, Trump's wall looks like a boondoggle. Reason's Shikha Dalmia did the math on The Wall this week, and the numbers are sobering. "Just a single-layer fence—not a wall—on the 1,300 miles of the open Southern border will cost upwards of \$6 billion—assuming, as per a CBO study, pedestrian fencing costs of \$6.5 million per mile and vehicle fencing costs of \$1.7 million per mile," she wrote. "A single Border Patrol agent costs about \$171,400 annually. So tripling that force would add up to a whopping \$7 billion or so more a year, according to the CBO. Annual maintenance costs would be hundreds of millions of dollars. In short, the total hit if cost projections don't balloon—a big if, assuming that Trump won't use illegal Mexican workers and will use only American steel—would be somewhere close to \$15 billion upfront." Trump says Mexico is going to pay for the wall, but slapping higher taxes on imports will force American consumers to bear most of the cost. And for what? If Trump actually builds the wall, the cartels will only build more and better tunnels, as the New York Times reported in September, citing Border Patrol agents who have worked to find and destroy drug tunnels for years. Trump says the wall will include technology to detect tunnels, but that technology doesn't exist yet and would only add to the project's price tag. Securing the full length of the 1,900-mile southern border is virtually impossible. "No amount of enforcement, even military-level, can remove the financial incentive of the black market," says Bienenstock, the author of *How To Smoke Pot (Properly): A Highbrow Guide to Getting High*. "In fact, every increase in enforcement only makes the black market more lucrative, and the fight to control this illicit trade more deadly and destructive." The less expensive, more effective way to reduce the flow of drugs over the border is loosen drug laws here in America. In fact, liberalized marijuana laws in some states are already having an effect. The Washington Post reported in March that "marijuana seizures along the southwest border tumbled to their lowest level in at least a decade." "Agents snagged roughly 1.5

million pounds of marijuana at the border, down from a peak of nearly 4 million pounds in 2009," the Post reported. "The DEA has even found evidence that the flow of illegal marijuana is starting to reverse, with some cases of U.S. marijuana being smuggled into Mexico." In December 2014, NPR News spoke to a marijuana grower in Mexico who described a similar economic phenomenon created by the legalization of marijuana in some parts of the United States. "Two or three years ago, a kilogram of marijuana was worth \$60 to \$90," the grower told NPR. "Now they're paying us \$30 to \$40 a kilo. It's a big difference. **If the U.S. continues to legalize pot, they'll run us into the ground.**" Trump knows this, even if he doesn't say so anymore. In April 1990, during a luncheon hosted by the Miami Herald, Trump described U.S. drug policy as "a joke" and said there was only one sure way to win the War on Drugs. **"You have to legalize drugs to win that war,"** Trump said. **"You have to take the profit away from these drug czars."** Trump should listen to his own advice and look to legalize marijuana at the federal level, instead of spending political capital and lots of cash on a border wall that will deserve its place in the War on Drugs hall of shame.

Border instability causes refugee flood – ensures terrorism

Brown 09 (Michael Brown, Undersecretary of Emergency Preparedness and Response in the Department of Homeland Security, "Border Control: Collapse of Mexico Is A Homeland Security & National Security Issue," 1/14/2009, <http://michaelbrowntoday.com/journal/2009/1/15/border-control-collapse-of-mexico-is-a-homeland-security-nat.html>)

By failing to secure the borders and control immigration, we have opened ourselves up to a frightening scenario. The United States could face a flood of refugees from Mexico if it were to collapse, overwhelming state and local governments along the U.S.-Mexico border. During a time of economic duress, the costs would be overwhelming and would simply add to the already burgeoning costs at the federal level. Immigration and border control never was nor should it ever be about racism. Immigration and border control are national security and homeland security issues. **Sleeper cells from numerous terrorist groups could, and probably already have, infiltrated the United States, just laying in wait to attack at an appropriately vulnerable time.**

Nuke terror – it escalates

Kroenig, Associate Professor and IR @ Georgetown, **14** (R. Davis Gibbons and Matthew Kroenig, a Nonresident Senior Fellow at the Brent Scowcroft Center on International Security at The Atlantic Council. "The Next Nuclear War," http://www.matthewkroenig.com/Kroenig_The%20Next%20Nuclear%20War.pdf)

Since the terrorist attacks on September 11, 2001, scholars, analysts, and politicians have focused on the nexus of nuclear weapons and terrorism. In his closing statement at the 2012 Nuclear Security Summit, President Obama concluded, "We've agreed that nuclear terrorism is one of the most urgent and serious threats to global security."⁸⁸ Though there has been some debate on how seriously this threat should be taken,⁸⁹ **evidence indicates that terrorist organizations have both expressed a desire for nuclear weapons and made attempts to buy or seize nuclear material. Declassified documents from the United States suggest Osama bin Laden directed his associates to purchase uranium.**⁹⁰ In addition, Chechnya-based separatist groups, Lashkar-e-Taiba in South Asia, and Aum Shinrikyo in Japan **have also expressed the desire for nuclear weapons** in the past.⁹¹ Most analysts consider it unlikely that a state would knowingly provide a terrorist group with a bomb, **but it is conceivable that a group could steal one. This fear is especially acute in the case of Pakistan, where an unstable government with a growing nuclear arsenal exists** in an area with many terrorist organizations. The government of Pakistan has taken steps in recent years to allay these fears, yet reason for concern remains.⁹² A second means by which **a terrorist group could attain a nuclear capability is by obtaining fissile material and constructing its own crude nuclear bomb.** The main challenge for terrorist organizations seeking this capability is finding sufficient fissile material. **Approximately 8 kilograms of plutonium or 25 kilograms of highly enriched uranium (HEU) is necessary for a bomb.** Since 9/11, the United States, Russia, the IAEA, and other partners have taken on a number of efforts to decrease the risks of terrorists accessing nuclear material. UN Security Council Resolution 1540, the 2005 Amendment to the Convention on the Physical Protection of Nuclear Material, and the 2005 International Convention for the Suppression of Acts of Nuclear Terrorism all seek to increase global cooperation to prevent nuclear terrorism. Overall, **the global stocks of HEU and plutonium are decreasing, but the sheer volume of global fissile material makes this an on-going challenge and the U.S. budget for these activities has recently been cut. Unlike**

nuclear-armed states, it would be relatively difficult to deter terrorists from taking action.⁹³ In other words, **if efforts to keep nuclear weapons out of terrorist hands ever fail, we may witness a nuclear 9/11.**

Revenue shortages mean governments increase property taxes

Daphne A. **Kenyon 7**, PhD, fellow @ Lincoln Institute, "The Property Tax-School Funding Dilemma," LILP, <http://www.lincolninst.edu/publications/policy-focus-reports/property-tax-school-funding-dilemma>

Property taxation and school funding are closely linked in the United States, with nearly half of all property tax revenue used for public elementary and secondary education. There is an active policy debate across the country regarding the degree to which public schools should be funded with property tax dollars. Some policy makers and analysts call for reduced reliance on property tax revenue and increased reliance on state funding; others claim that **the property tax is a critical ingredient in effective local government.** School funding is no less controversial, and nearly every state has dealt with school funding litigation and court mandates at least once over the last several decades. States experiencing taxpayer revolts among homeowners are tempted to reduce reliance on the property tax to fund schools. But a more targeted approach can provide property tax relief and also improve state funding for public education, according to this new report by Daphne A. Kenyon, a visiting fellow at the Lincoln Institute. **Those who have tried to reduce property taxes and improve school performance at the same time have not met with much success,** according to Kenyon.

Solves multiple existential threats

EPSC 16, European Political Strategy Centre | In-house think tank of @EU_Commission, led by @AnnMettler., 11-17-2016, "The Future of Universities and Evidence-Based Research," Medium, <https://medium.com/shaping-the-future/the-future-of-universities-and-evidence-based-research-190f3a6fa688>

Past glories will not sustain us forever. Universities need to change in order to serve the needs of tomorrow's economy and society. This is not in debate. There is a need for more skills — and more research — in science and technology, for example. **Universities will continue to have a central role in the drive for technological innovation. We face a future in which machine capacity** — and machine intelligence, albeit with certain constraints — **will far outstrip human capacity. Technology holds immense promise** — but this promise is **accompanied by threats, and even existential threats.** It follows **that the need to improve our knowledge of the human and social sciences does not diminish — it increases.** Change should not mean throwing the baby out with the bathwater. **Cutting-edge education** and research on the human dimension will **remains fundamental.** It may be that the long-standing division between natural sciences on one side, and social sciences on the other, has become outdated. There is certainly room for a conversation not just about becoming interdisciplinary or cross-disciplinary, but about rethinking inherited concepts of disciplines and their boundaries. Most of all, **universities must play their part in developing the values and norms that are needed to guide and direct our path into a future that will look very different from the present, and that will offer a completely different set of opportunities and risks.**

Legalization solves disease

LS, 13 ("Can Marijuana Combat The 'Catastrophic' Rise Of Drug Resistant Bacteria?", 9-18, <http://www.leafscience.com/2013/09/18/can-marijuana-combat-catastrophic-rise-drug-resistant-bacteria/>)

On Monday, the Centers for Disease Control and Prevention (CDC) released an alarming report that warned of "potentially catastrophic consequences" from the spread of antibiotic-resistant bacteria. For the first time, the U.S. public health agency detailed the damage done by the widespread use of antibiotics. According to the 114-page report, each year more than two million Americans are infected with bacteria resistant to modern day treatments and at least 23,000 die as a result. **The problem is — while antibiotics are effective against weaker strains of bacteria — they create an environment for genetic mutant "superbugs" to survive and flourish.** Unfortunately, that means the single biggest factor in the rise of drug resistant bacteria is

the use of antibiotics themselves. CDC Director Tom Frieden sent a clear warning to the public on the overprescribing and overuse of antibiotics during Monday's news conference. **"Antibiotic resistance is rising for many different pathogens that are threats to health. If we don't act now, our medicine cabinet will be empty and we won't have the antibiotics we need to save lives."** But what are the alternatives? As it turns out, **researchers** like Professor Simon Gibbons, who heads the Department of Pharmaceutical and Biological Chemistry at the University College London School of Pharmacy, have **been investigating the natural antibiotic effects of a variety of plants. And one of the most promising of these plants happens to be cannabis.** In 2008, Prof. Gibbons and Prof. Giovanni Appendino of Italy's Piemonte Orientale University published a study that demonstrated the ability of various chemicals extracted from marijuana (called cannabinoids) to fight methicillin-resistant staph bacteria – one of the most serious and life-threatening sources of bacterial infections in the U.S. **When the scientists tested chemicals from marijuana on six different strains of methicillin-resistant Staphylococcus aureus (MRSA) – including strains that are known to be resistant to traditional MRSA treatments – they found that they were just as effective at killing the bacteria as commonly prescribed antibiotics. In fact, cannabinoids were even as effective as vancomycin – a powerful drug that is only used when other antibiotics fail.** Prof. Gibbons explained the remarkable findings of his 2008 study in an interview with MIT's Technology Review. **"The cannabinoids even showed exceptional activity against the MRSA strain that makes extra amounts of the proteins that give the bugs resistance against many antibiotics... Everything points towards these compounds having been evolved by the plants as antimicrobial defenses that specifically target bacterial cells."** Prof. Appendino added that the most promising cannabinoids in their study – cannabidiol (CBD) and cannabigerol (CBG) – also happen to be non-psychoactive. **"What this means is, we could use fiber hemp plants that have no use as recreational drugs to cheaply and easily produce potent antibiotics."**

Transnational organized crime risks **drug-resistant viruses**

CFR 13 ("The Global Regime for Transnational Crime," June 25, <http://www.cfr.org/transnational-crime/global-regime-transnational-crime/p28656#p2>)

Over the past two decades, **as the world economy has globalized, so has its illicit counterpart. The global impact of transnational crime has risen to unprecedented levels.** Criminal groups have appropriated new technologies, adapted horizontal network structures that are difficult to trace and stop, and diversified their activities. The result has been an unparalleled scale of international crime. As many as **fifty-two activities fall under** the umbrella of **transnational crime, from arms smuggling to human trafficking to environmental crime. These crimes undermine states' abilities to provide citizens with basic services, fuel violent conflicts, and subject people to intolerable suffering. The cost of transnational organized crime is** estimated to be roughly **3.6 percent [PDF] of the global economy.** Money laundering alone costs at least 2 percent of global gross domestic product every year according to UN reports. Drug traffickers have destabilized entire areas of the Western Hemisphere, leading to the deaths of at least fifty thousand people in Mexico alone in the past six years. **Counterfeit medicines** further sicken ill patients and **contribute to the emergence of drug-resistant strains of viruses. Environmental crime—including illegal logging, waste dumping, and harvesting of endangered species—both destroy fragile ecosystems** and endanger innocent civilians. Between twelve and twenty-seven million people toil in forced labor—more than at the peak of the African slave trade. For many reasons, **global transnational crime presents** nations with **a unique and particularly challenging task.** To begin with, by definition, transnational crime crosses borders. But the law enforcement institutions that have developed over centuries were constructed to maintain order primarily within national boundaries. In addition, transnational crime affects nations in diverse ways. **In many states, political institutions have strong links to transnational crime,** and citizens in numerous communities across the world rely on international criminal groups to provide basic services or livelihoods. Finally, **the international community requires solid data to gauge the challenge and effectiveness of responses,** but data on transnational organized crime is notoriously difficult to gather and is often politicized.

Solvency

Price controls fail because most drugs are generic

Dr. **Winegarden** is a Partner in the economic consulting firm Arduin, Laffer & Moore Econometrics (ALME) where he advises corporations, policy & trade associations, and government agencies on the business and economic implications, October 12, **2017**,
<https://www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduce-innovation-and-health-outcomes/#1f0b86f863a6> Price Controls Will Reduce Innovation and Health Outcomes

To start, the price controls would be irrelevant for most patients. Nearly 90 percent of all drugs dispensed in the U.S. in 2016 were generic medicines, according to IMS Health. Therefore, any price control scheme would not apply to the majority of patients who are using inexpensive generics, not more expensive patented products.

Generic drugs cheaper in the US

Dr. **Winegarden** is a Partner in the economic consulting firm Arduin, Laffer & Moore Econometrics (ALME) where he advises corporations, policy & trade associations, and government agencies on the business and economic implications, October 12, **2017**,
<https://www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduce-innovation-and-health-outcomes/#1f0b86f863a6> Price Controls Will Reduce Innovation and Health Outcomes

It is also important to note that generic medicines are significantly cheaper in the U.S. compared to the other major industrialized countries. In fact, total pharmaceutical spending as a percentage of total health care spending is lower in the U.S. (12.2 percent) than the average for the 30 nations that comprise the Organization for Economic Cooperation and Development, or OECD, (16.9 percent). This is due to, in part, the prevalence of generic medicines that are more affordable here than in other OECD nations.

Price controls limit new drugs and fail

Peter **Pitts**, May 19, **2017**, <https://www.nationalreview.com/2017/05/drug-price-controls-bad-idea/>
The False Promise of Drug-Price Controls

Fixing the prices of prescription drugs creates shortages and stifles research into new drugs. Are the laws of economics negotiable? Some foreign leaders seem to think so. They're installing price controls in the hope of bringing down prescription-drug costs. They're convinced they can simply decree that drug companies charge less without any consequences on public health. They're wrong. Drug-price controls might conceivably result in small, short-term savings, but ultimately they hurt patients by restricting access to medicines and preventing the creation of new, breakthrough treatments. Consider the Indian healthcare system and its long history of failed price-control policies. Its National Pharmaceutical Price Authority sets hard price caps on a wide variety of Western-sourced drugs and then steadily ratchets the caps down. Since early 2016, the authority has slashed the price of some popular diabetes drugs by 42 percent and some cancer drugs by a whopping 86 percent. Earlier this year, it cut by up to 50 percent the prices for another 33 "essential" medicines, including treatments for the common cold, arthritis, and the skin condition psoriasis. South Korea's price caps work in a similar way. The country's sole public insurance program sets a maximum price for all drugs sold to its beneficiaries and then aggressively negotiates down from there. This process is notoriously opaque, with drug companies usually provided little justification for pricing decisions. And it's drawn out, typically taking between 12 to 18 months for a submitted drug to finally get priced. During that time, sick patients can't access new breakthroughs. And South Korea's price dictates haven't stuck to only brand names. Generics are also under tight control. Initially they can't be sold for over 60 percent of the price of their brand-name counterpart, and that ceiling falls to roughly 53 percent after a year. Foreign countries also control drug costs in more subtle ways. For example, there's the practice of "reference pricing," in which officials group drugs into classes according to their therapeutic effects and then set a single

price for all drugs in a given class. Under this system, a breakthrough, brand-name blood-pressure drug could be priced the same as a decade-old generic in the same class. Sometimes officials group drugs into classes according to their therapeutic effects and set a single price for all drugs in a given class. Under this system, a breakthrough, brand-name blood-pressure drug could be priced the same as a decade-old generic. Reference pricing is particularly popular in Europe. Germany, Spain, and Italy have adopted the practice and now dictate drug prices that can be up to 24 percent below prevailing market rates. Less-developed countries have resorted to abusing the “compulsory licenses” provision established by international law, which allows governments to break patent protections on foreign drugs and produce generic versions locally. These licenses are supposed to be used only in the event of a genuine public-health emergency; a poor country suffering, say, an Ebola outbreak may not have the time or resources to import foreign medicines. But countries have started strong-arming compulsory licenses in non-emergency situations simply to secure deep discounts on popular drugs. Most recently, the lower chamber of the Chilean congress passed a bill demanding licenses for drugs used in treating hepatitis and cancer — serious diseases, for sure, but neither represents a health emergency in Chile. One might ask: **What’s the harm? If foreign countries can regulate down drug prices and make medicines more affordable, why shouldn’t they? There’s no free lunch.** That’s the lesson of the long, ignoble history of price controls. The laws of economics cannot be changed through regulatory or legislative fiat. **If government officials make something artificially cheap, they’ll eventually have less of it. Demand will outstrip supply. That goes for milk, oil, and medicines. Pharmaceutical prices reflect massive development expenses. Creating just one new drug is an extremely expensive, time-consuming process, usually costing several billion dollars and taking at least a decade. And the failure rate is sky-high: Drug scientists test thousands of promising compounds for every one that’s turned into a marketable product.** Companies are willing to make such a risky investment because a breakthrough product can generate a huge payoff. But price controls squeeze that payoff. They prevent drug firms from charging prices commensurate with those massive development costs. For some companies, the payoff is no longer worth the risk, and they’re forced to scale back on new research. **The U.S. Department of Commerce calculates that price controls** among countries in the OECD, a major economic organization comprising much of Europe, **drives away \$5 billion to \$8 billion in potential pharmaceutical development investment every year.** That prevents the creation of three to four new drugs annually. This loss of development dollars doesn’t just hurt citizens in controlled markets; it deprives all of us of new, life-saving treatments. **This is the terrible toll of drug-price controls. Foreign authorities need to wake up to the harm they’re causing.**

Pharma R & D high

Ben Adams, April 26, 2017, <https://www.fiercebiotech.com/special-report/top-10-pharma-r-d-budgets-2016> The top 10 pharma R&D budgets in 2016

Last year, biopharma won its share of new drug approvals, though not as many as we're used to in the U.S., as research spending came to fruition. But drugmakers also suffered a number of R&D setbacks, cut research staff, rejigged their operations and refocused their pipelines. Drug R&D also found itself in the spotlight as one of the biggest political issues to arise last year—drug pricing—became inextricably linked to the cost of biomedical research and development. U.S. industry groups PhRMA and BIO, as well as Europe’s EFPIA and the U.K.’s ABPI, have all said, and will continue to say, that **the inherent reason drug prices are what they are is because of the huge R&D investment** most (though not all) **companies funnel into their scientists and labs. It’s a risky business: The majority of drugs that begin phase 1 won’t be approved, and** over the years, **failures in phase 3 have cost individual companies hundreds of millions of dollars each time.** Sometimes failures stem from problems with the studies themselves, sometimes a company simply refuses to give up on a dead asset, but often, a failure in the lab is simply part and parcel of the trial-and-error approach inherent to pharmaceutical and biotech research. Based on figures from their 2016 annual reports, **the top 10 pharma R&D budgets** (all using their GAAP figures) **combined totted up to \$70.5 billion,** with full-year revenue coming in at \$404.8 billion. On average last year, **the top 10 Big Pharmas spent** just **over 17% of their top line on research,** with GlaxoSmithKline spending the second least in percentage terms at 12.9%, and the least in absolute numbers at £3.62 billion (\$4.49 billion). AstraZeneca and Bristol-Myers Squibb shelled out the most on R&D in percentage terms, both spending just over 25% of their revenue. Both of those companies have, however, sales at the lower end of the Big Pharma list: AZ brought in \$23 billion last year, while BMS took in just \$19.4 billion. Their respective R&D budgets of \$5.89 billion and \$4.94 billion, while topping the ranking percentage-wise, came in near the bottom in absolute numbers. There is a bit more to the BMS story as well: In 2015, the company spent \$5.9 billion on research, but last year, that dropped by \$1 billion, or 16%. In percentage terms in 2015, BMS put 42% of its revenue toward R&D. This was by far the largest drop in an R&D budget for the top 10 last year. Most of the others upped their spend slightly, a few significantly, although AZ also spent less in 2016, with a decline of 1.7% off its total 2015 budget. Eli Lilly was a close third to AZ and BMS, with 24.7% of its total \$21.2 billion in sales last year going into R&D. That spending represented a 9% increase on its 2015 figures. The lowest in percentage terms was Johnson & Johnson, which laid out just 12.6%

of its sales on research in 2016 (this was around 10% for its \$7 billion pharmaceuticals research). J&J's spending was comparatively large at \$9 billion (though that figure included research on medical devices and other areas outside pharmaceuticals), but so was its revenue at \$71.9 billion, more than any of its top 10 peers. Swiss oncology major Roche was tops in total terms, spending a massive CHF11.53 billion (\$11.42 billion) last year, nearly 23% of its CHF50.57 billion in revenue. It also recorded a 20% jump in R&D spending compared with 2015, the biggest increase among the top 10, with most of this increase going into its pharmaceuticals divisions, the rest into diagnostics. Generally, research budgets moved up with sales in percentage terms, although some may feel that an average 17% of its total revenue going into R&D seems a little small. And the \$70 billion R&D figure for the top 10 together is, in fact, the same as it was back in 2012 and 2011, so total spend has remained stagnant for some time.

Pharma revenues critical for R&D

Gleason, 2017, Gleason Patrick Gleason is vice president of state affairs at Americans for Tax Reform, and a senior fellow at the Beacon Center of Tennessee, <https://www.forbes.com/sites/patrickgleason/2017/02/21/states-consider-imposing-drug-price-controls/#4fedc887639b> States Consider Imposing Drug Price Controls

The problem for drug price control proponents like Gov. Cuomo and Bernie Sanders **is that**, despite their claims, pharmaceutical manufacturers do not reap excessive profits. In fact, profits for the pharmaceutical manufacturing industry, among the most research-intensive sectors, are middle of the road. Additionally, drug makers reinvest tens of billions in profits every year on research and development. Research and development of one medicine takes an average of more than a decade and \$2.6 billion. The prolonged timeline and high research costs associated with the drug development process make the pharmaceutical industry a riskier investment than other sectors. As such, a higher rate of return is required to ensure a level of capital that will allow drug makers to continue innovative research and the development of life changing and saving new pharmaceuticals. As those fighting state legislative efforts to impose drug price controls have pointed out, drug price controls will stifle innovation by limiting the ability of drug makers and investors to recover the excessive costs associated with their work and reinvest profits. This could lead to reduced access to life-saving and improving medications in the future. Robert Graboyes, a health care scholar and senior research fellow at the Mercatus Center, explains the pitfalls with the drug price control bill currently pending in Oregon, which applies to similar proposals being debated in other state capitals. "Lawmakers commanding businesses to sell products at lower costs usually does not have a happy ending," Graboyes said, adding "in the future, people may not get well because it was not economically feasible for the manufacturer to research and market the drug that could have helped." Dr. Joel Zinberg, a practicing surgeon at Mount Sinai Hospital and a visiting fellow at the American Enterprise Institute, explains how Europe's experience with drug price controls demonstrates how they reduce the incentive for investment and innovation: Without temporary high prices in the U.S. market before generic competition, there will be less R&D, fewer new breakthrough drugs, fewer competitor drugs developed, and ultimately no lower priced generics to follow. European countries' price controls imposed in the 1980s prove the point. In the mid-80s, European drug R&D was 24% higher than in the U.S. After price controls, European pharmaceutical R&D grew at half the U.S. rate and today substantially trails American R&D." The good news is last year proved voters are smart enough to see through the falsehoods and hyperbole put forth by those pushing prescription drug price controls. Though Hillary Clinton beat Donald Trump by 30 points in the bastion of progressivism that is California last November, voters there rejected the aforementioned ballot measure to impose drug price controls, Proposition 61, by a 53.2% to 46.8% margin. Speaker Paul Ryan and Senate Majority Leader Mitch McConnell are in the process of getting their caucuses on the same page with an Obamacare repeal and replacement plan that will increase access to care by reducing costs through a more consumer-oriented system in which states have greater flexibility to innovate. While that's happening, lawmakers toiling away in the 50 laboratories of democracy should reject misguided proposals to impose state-level drug price controls. While Democrats have total control of the legislature in most of the states considering drug price control legislation this year, many of those states fortunately have Republican governors who could serve as a backstop, should this innovation and investment-stifling legislation be approved by state lawmakers.

Restricting prices means fewer new drugs

Scott Atlas, March 21, 2018, <https://www.cnn.com/2018/03/21/opinions/the-overlooked-ingredient-to-lower-drug-prices-atlas/index.html> CNN Soaring drug prices? Here's how to control them

In addressing legitimate public concern about drug prices, our politicians must avoid the temptation to impose top-heavy regulations. **Price caps may seem intuitively attractive, yet price caps always restrict supply of the product, and drugs are no different. One study showed that price regulation strongly delayed drug launches of 642 new drugs in 76 countries. Another showed that price controls significantly diminish early-stage research and development.**

Lowering the price discourages drug development

Michelle **Mello**, June **2018**, Professor of Law, Stanford Law School, and Professor of Health Research and Policy, Department of Health Research and Policy, Stanford University School of Medicine; Ph.D., University of North Carolina at Chapel Hill; J.D., Yale Law School; M.Phil., University of Oxford; A.B., Stanford University., Minnesota Law Review, ARTICLE: What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?, http://www.minnesotalawreview.org/wp-content/uploads/2018/07/Mello_MLR.pdf p. 2280

There is a risk that taking steps to lower what we pay for pharmaceuticals will diminish manufacturers' incentives to invest in research and development (R&D). In other words, it may reduce the amount of innovation - and thus the availability of innovative, safe, effective drugs in the future

Percentage reduction

Paul **Howard** is a senior fellow and director of health policy at the Manhattan Institute, **2015**, New York Times, <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/to-lower-drug-prices-innovate-dont-regulate> To Lower Drug Prices, Innovate, Don't Regulate

Price control advocates argue that curtailing profits in the pharmaceutical industry would save the country money without reducing innovation. There is, however, no such thing as a free lunch. **Bureaucratic price manipulation would only hurt the sickest patients. Streamlining drug approvals would get more drugs on market, increasing competition and lowering prices. Research shows that price controls in the United States would powerfully dampen innovation. "Cutting prices by 40 to 50 percent in the U.S. will lead to between 30 to 60 percent fewer R&D projects being undertaken,"** one study found. A 2008 RAND study exploring the effect of U.S. price controls on those aged 55 to 59 in the United States and Europe similarly found that, on net, pharmaceutical price controls would hurt patients.

It's just a reality – less investment if less profit

Sara **Kliff**, May 10, **2018**, Vox, <https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained> The true story of America's sky-high prescription drug prices

What's harder to see is that **if we did lower drug prices, we would be making a trade-off. Lowering drug profits would make pharmaceuticals a less desirable industry for investors. And less investment in drugs would mean less research toward new and innovative cures.** There's this analogy that Craig Garthwaite, a professor at Kellogg School of Management who studies drug prices, gave me that helped make this clear. Think about a venture capitalist who is deciding whether to invest \$10 million in a social media app or a cure for pancreatic cancer.

Even advocates agree that controls will lower investment and suggest other investment incentives that the Pro can't topically provide

Bernstein, 2015, Jared Bernstein, a senior fellow at the Center on Budget and Policy Priorities, was the chief economist and economic adviser to Vice President Joe Biden and executive director of the

White House Task Force on the Middle Class from 2009 to 2011.,
<https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-are-vital-in-a-market-thats-not-free> Drug Controls are Vital in a Market that's not free,

Price controls for drugs, which are common in other advanced economies, increase affordability. But **even when the mechanism is "cost-plus" pricing — the government allows drug companies some degree of markup — their profits will still decline from current levels.** The producers argue that this will stifle their incentive to innovate. But the evidence is increasingly clear that we cannot count on the private sector to make necessary medicines affordable. In fact, given the incentive structure, neither can we count on private drug companies to develop the drugs we most need versus the ones that will be most profitable. In health economics, maximizing social benefits is often at odds with private benefits. **The simplest solution is to** take excessive profit out of the equation and **ramp up what is already a robust public medical research infrastructure. This could take the form of an expanded National Institutes of Health**, where researchers are employed by the government, or private research could be subsidized. Either way, the key outcome is that the patents themselves would be public goods in the public domain, meaning no more price gouging. But wouldn't this arrangement fail to inspire the most innovative researchers? To keep such competition alive, economist **Joe Stiglitz recommends a prize fund**, where those who developed the most beneficial medicines would get a windfall reward. The winners could get rich, but they could not restrict the benefits of their findings to extract more profits from sick people.

Cost of bringing a drug to market is enormous

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Companies certainly assert that there is cause for alarm. 32 **They** point to the astronomical **cost of new drug development - an estimated \$ 2.6 billion for each drug that reaches the market**, when the costs associated with those that did not make it are rolled in. 33 **Only five to ten percent of new drugs entering clinical trials obtain FDA approval**, 34 **so innovator companies and firms that furnish the capital to support their R&D must recoup their**

³² See, e.g., NASEM Report, supra note 13, at 169 (presenting a dissenting view from the Committee's consensus recommendations that is animated by concerns about discouraging innovation); Michael Rosenblatt & Henri Termeeer, Reframing the Conversation on **Drug Pricing**, NEJM Catalyst (Nov. 20, 2017), <https://catalyst.nejm.org/reframing-conversation-drug-pricing> ("For companies to justify risking billions on finding a breakthrough **drug**, they need to be able to anticipate a corresponding return on their investment.").

³³ Joseph A. DiMasi et al., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. Health Econ. 20, 27 (2016) (estimating the cost of developing a new **drug** to be in the \$ 2.3 billion to \$ 2.8 billion range). The \$ 2.6 billion figure is controversial. See, e.g., Jay Hancock, Do Pharma's Claims on **Drug Prices** Pass the Smell Test? We Found 5 Stinkers, Kaiser Health News (Oct. 2, 2017), <https://khn.org/news/do-pharmas-claims-on-drug-prices-pass-the-smell-test-we-found-5-stinkers> ("Outside authorities criticize the research, saying it comes from untestable data, ignores enormous tax subsidies that reduce costs and inflates results with imaginary expenses, such as profits that could have been earned if **drug** companies invested research dollars elsewhere."). Competing estimates are lower, ranging from \$ 161 million to \$ 1.95 billion, but the DiMasi et al. study has been influential in policy debates. For a summary, see NASEM Report, supra note 13, at 87-88.

³⁴ NASEM Report, supra note 13, at 42 (citing Gail A. Van Norman, **Drugs**, Devices, and the FDA: Part 1: An Overview of Approval Processes for **Drugs**, 1 JACC: Basic to Translational Sci. 170 (2016)).

investment from the tip of the iceberg. Investors may wait a decade or more to see a return on their investment, given the time required for clinical trials and market approval. ³⁵ **Companies argue that they must promise supernormal returns in order to attract interest in such a high-risk investment** - especially because a great deal of biopharmaceutical innovation today emerges from small companies that rely heavily on private venture capital. ³⁶ **Decrease the rewards for a big hit, they warn, and R&D will suffer.**

Eliminating foreign price controls would lead to new drugs

Charles **Boustany** is a retired physician and former congressman from Louisiana, August 9, **2018**, <http://fortune.com/2018/08/09/trump-drugs-prices-pharmaceutical-research/> Americans Fund Most of the World's Drug Research. Here's How Trump Can End That

In **Canada**, for instance, the Patented Medicine Prices Review Board caps drug prices at the median price paid in a handful of other industrialized countries. In the **U.K.**, the National Institute for Health and Care Excellence—a regulatory body better known as NICE—refuses to cover many advanced drugs at all. **Japan** lowers drug prices every two years by administrative fiat and may cut prices even more often. This **makes its market unpredictable and unstable for drug companies. These price controls prevent adequate funding for research and development. A recent economic analysis from Precision Health Economics shows that eliminating price controls could lead to the creation of eight to 13 new drugs annually by 2030, thereby extending the life expectancy of 15-year-olds by up to 1.6 years.**

³⁵ See DiMasi et al., *supra* note 33, at 24 (finding that the average time from the start of clinical testing of a new molecule to FDA approval is approximately eight years).

³⁶ NASEM Report, *supra* note 13, at 40 ("The returns on investment for successful **drug** products may appear to be abnormally high, since the average expected return, from the manufacturer's point of view, must also compensate for many failures... . More risk leads to a higher average reward for success, thereby encouraging investments that might not otherwise occur.").

Lives Impacts

Drug innovation saves lives

Scott Atlas, March 21, 2018, <https://www.cnn.com/2018/03/21/opinions/the-overlooked-ingredient-to-lower-drug-prices-atlas/index.html> CNN Soaring drug prices? Here's how to control them

Drugs are the most significant reason behind the past half-century gains against both chronic and life-ending disease. Policies aimed at reducing drug costs must not restrict their supply, jeopardize their quality or inhibit essential drug innovation necessary for tomorrow's cures. American patients in particular have benefited more than others from drugs. For decades, **the United States has been the most frequent country, by far, where new drugs are first available. Life-saving cancer drugs, as one critical example, are at least four times more likely to be made first available here compared with any country,** including Germany, Japan, Switzerland, France, Canada, Italy or the UK, as reported in the Annals of Oncology in 2007. Similarly, two-thirds of the novel drugs OK'd in 2015 were approved in the United States before any other country. Most recently in a 2017 study, of 45 new cancer drugs approved by the Food and Drug Administration from 2009-2014, all of which were covered by Medicare in the United States, only 26 were approved and covered in the UK, only 19 in France, only 13 in Canada and only 11 in Australia. **This early and broad drug access is key to delivering America's better treatment results than nationalized systems elsewhere, where drug prices are strictly regulated by government, for virtually all serious diseases reliant on drugs, including cancer, heart disease, stroke and the most important chronic disorders, including high blood pressure and diabetes.**

Global Impacts

US drug research investments funds half of the world's drug R & D

Charles **Boustany** is a retired physician and former congressman from Louisiana, August 9, **2018**, <http://fortune.com/2018/08/09/trump-drugs-prices-pharmaceutical-research/> Americans Fund Most of the World's Drug Research. Here's How Trump Can End That

The U.S. is a pharmaceutical powerhouse. **Our drug companies invest about one-fifth of their revenues into research and development, more than any other industry does.** Developing a new drug is an expensive endeavor. **On average, it costs \$2.87 billion and takes more than a decade of hard work. The burden of paying for this research and development falls disproportionately on Americans. According to a 2018 report by the Council of Economic Advisers, an agency within the executive branch, the U.S. market funds nearly half of the world's medical research and development.**

Stock Market

Regulating prices will undermine the markets. Deciding not to regulate boosts prices

St. Louis Post Dispatch Editorial Board, May 27, 2018,

https://www.stltoday.com/opinion/editorial/editorial-trump-caves-to-drug-industry-on-price-controls/article_2301f010-d69f-5bbc-b768-650bc3eec2ef.html

With the usual ballyhoo, **the White House said** on May 11 that President Donald **Trump would announce his** long-delayed **plans to reduce the costs of prescription drugs. When Trump began speaking** at 2:08 p.m., **stock prices** on Standard & Poor's pharmaceutical sector **dropped. By the time he finished speaking, the sector was soaring.** Big Pharma was very happy with Trump's speech. It contained nothing that will threaten its enormous profits nor anything that will slow down relentless price increases. As president-elect, Trump accused drug companies of "getting away with murder." As president, Trump has become an accessory to that murder. It was yet another broken populist campaign promise, joining "great health care," putting coal miners back to work, a trillion-dollar infrastructure plan and more. Trump has kept his promise to crack down on immigrants and move the U.S. Embassy to Jerusalem, but his economic populism has proved to be a mirage. Of course that doesn't mean he won't try to fool people into thinking otherwise: "Everyone involved in the broken system — the drugmakers, insurance companies, distributors, pharmacy benefit managers and many others — contribute to the problem," Trump said. "Government has also been part of the problem because previous leaders turned a blind eye to this incredible abuse." All of that is true, but the one key to dealing with the problem is to recognize that everything stems from the upfront price that drugmakers charge and that there's no way to rein them in. Medicare accounts for more than a third of the \$360 billion spent on prescription drugs each year. But when Congress passed the Part D drug benefit in 2003, Big Pharma lobbyists wanted Medicare treated like any other customer. Congress caved. The Department of Veterans Affairs was allowed to negotiate prices, but not Medicare. As a result, the VA spends 80 percent less for the same drugs. Trump knows that. "We're the largest buyer of drugs in the world, and yet we don't bid properly," he said shortly before his inauguration. Since then he's been captured by the same lobbyists that he previously scorned. Nor will he allow U.S. citizens to buy drugs from Canada, where they are often 75 percent cheaper. Trump said he'd negotiate with other countries to make them pay more to take some of the burden off the U.S., thereby getting the solution 180 degrees wrong. Trump chose to blame the "middlemen," including pharmacy benefits managers like Express Scripts of St. Louis. How worried are investors that Trump will take serious action? Express Scripts stock has been on a steady, even steep rise since Trump's announcement.

Companies Have Plenty of Money

If companies are squeezed they won't necessarily direct money to research

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³⁹ Yet, **showing that companies have money to spare does not prove that they would redirect it to R&D if their profit margin were squeezed.**

³⁹ See NASEM Report, *supra* note 13, at 89; William Lazonick et al., US Pharma's Financialized Business Model 20 (Inst. for New Econ. Thinking, Working Paper No. 60, 2017).

Developing World Turn

Lowering prices in the US means companies can't afford them to provide them at low prices in the developing world

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Another perplexing moral problem is that tradeoffs may exist between improving the affordability of prescription drugs for Americans and maintaining their affordability to patients in other countries. ⁵³ Branded drug prices in the United States are generally higher than in other countries because most foreign governments have adopted stronger mechanisms than the United States for controlling prices - for example, more consolidated price negotiations or direct price controls. ⁵⁴ Because we pay so much, pharmaceutical companies may be more willing or able to grant price concessions elsewhere, including outright donation of critical medications to low-income countries. Actions we take to restrict price, therefore, could have unintended, but real, effects on drug affordability in less wealthy countries....However, because the market for prescription drugs is global but is propped up by high prices in the United States, tamping down drug prices has a zero-sum-game quality that is unique. Squeezing one part of the drug-price balloon may cause it to bulge out in other areas

⁵³ NASEM Report, supra note 13, at 34-35.

⁵⁴ For a summary of several countries' approaches, see id. at 82-86.

Ethics

No coherent ethical principal that can be utilized to require access – Americans want access to the best care even if it's expensive, no way to determine a fair price, patients need the best drugs, companies must compete for capital, absolute patient interests, companies have a right to strong return because the investment is high

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In a 2016 poll, seventy-seven percent of Americans said that cost of branded prescription drugs was unreasonable.⁴⁰ Yet Americans have steadfastly resisted attempts to ratchet down healthcare costs that could threaten their access to care.⁴¹ We want it all, at reasonable cost. **[*2283]** That is probably not possible. Until we confront this problem and agree on the goal we wish to pursue, we will not reach it. In other areas of healthcare, such as physician services, we also hear distress calls from providers when there is talk of reducing reimbursement. However, it is hard to think of another area of health policy where we risk reducing innovation if we clamp down on reimbursement. Thus uncertainty about the core tradeoff involved in reducing costs is an especially important, unresolved problem for prescription drugs. B. Finding a Coherent Ethical Framework There is no shortage of righteous indignation in discussions of drug prices, but what is lacking is any anchoring of arguments in a coherent ethical framework. Addressing what is wrong in the current system requires that we have some conception of what right and wrong means for a pharmaceutical company. However, **it is surprisingly difficult to fix upon an appropriate ethical principle or set of principles for evaluating drug companies' practices relating to pricing and access. Certainly, no consensus has emerged on this issue.** It is tempting to focus on such scandals in lieu of answering hard moral questions that undergird our intuitions about them. What makes companies' conduct wrongful? **What is a fair price? Instances of egregious conduct do not constitute the modal case of high drug costs.** More commonly, what we tend to feel in response to high drug costs is not, "This is an outrage!" but something closer to, "I don't like this; I wish it were cheaper." We may find ourselves struggling to articulate exactly why drug companies must take steps to make their products more affordable. One line of argumentation proceeds from the fact that **patients who depend on life-preserving drugs are highly vulnerable.**⁴⁵ **Because they have no meaningful choice but to buy the drug at whatever price the seller wishes to charge, the usual presumptions about market exchanges - such as voluntariness, choice, and bargaining power - are disrupted.** This arguably creates an ethical obligation on the part of the seller not to extract excessive benefits from those who cannot refuse its offer.⁴⁶ A reply

⁴⁰ Ashley Kirzinger et al., Kaiser Health Tracking Poll: September 2016 (Sept. 29, 2016), <https://www.kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016>.

⁴¹ See Henry Aaron et al., Can We Say No? The Challenge of Rationing Health Care 1-10 (2005) (outlining the history of medicine in the United States and concluding that there is a propensity for emphasizing access to care rather than cost); Michelle Mello, Book Review, 44 J. Econ. Lit. 1049, 1053 (2006) (reviewing id. and noting that "Americans are steadfastly unwilling to make sacrifices when it comes to the quality and availability of their health care, even when those sacrifices are based on reasoned deliberation about what makes sense for us as a population").

⁴⁵ The remainder of this Section and the next Section draw heavily on a passage of the NASEM report that I drafted in collaboration with Brendan Saloner, Ph.D. I acknowledge his contributions with gratitude. See NASEM Report, supra note 13, at 31-35. I also thank Rebecca Wolitz for identifying useful literature relating to this discussion.

⁴⁶ Mikhail Valdman, A Theory of Wrongful Exploitation, 9 Philosophers' Imprint 1 (2009).

to this argument is that this morally distressing situation may generate an obligation on the part of society to ensure that the patient receives the drug, but not on the part of the drug's producer. ⁴⁷ **Because of pharmaceutical companies' special status as both a for-profit manufacturer of goods and a provider of medical care, it is not clear where to reach for ethical standards to govern their conduct.** As for-profit corporations, **drug companies compete for capital in the open marketplace and must deliver returns to investors.....Yet alternative frameworks, such as classical liberal principles of medical ethics, are also ill fitting. Those principles - respect for autonomy, beneficence, nonmaleficence, and justice** ⁵⁰ **- require absolute fidelity to patients' interests. They are of limited utility in solving population-level problems, balancing competing obligations, and making hard decisions about resource allocation in the face of scarcity. In short, we lack an ethical lodestar to illuminate what ethical obligations to patients, if any, spring from pharmaceutical companies' distinctive role in the market.** Pharmaceutical company leaders may believe that one particular conception of the principle of fairness should drive conclusions about their ethical obligations relating to drug pricing. This conception turns on the notion of just rewards for effort expended and risk incurred. **Because innovator companies take on substantial risk and invest considerable time, money, and effort in the development of new products, fairness arguably requires that they be able to reap the returns.** ⁵² **Discussions about restricting price are deeply offensive to this conceptualization of justice.**

⁴⁷ Richard T. DeGeorge, Intellectual Property and Pharmaceutical Drugs: An Ethical Analysis, 15 Bus. Ethics Q. 549 (2005); Maitland, supra note 31.

⁵⁰ For a general overview of these bedrock principles of medical ethics, see Tom L. Beauchamp & James F. Childress, Principles of Biomedical Ethics 101- 301 (7th ed. 2013).

⁵² DeGeorge, supra note 47, at 549-50.

HIV

HIV threat is overblown – poor transmission, immunity, preventability

Amesh **Adalja**, infectious pathogens physician, June 17, **2016**, "Why Hasn't Disease Wiped out the Human Race?," The Atlantic, <https://www.theatlantic.com/health/archive/2016/06/infectious-diseases-extinction/487514/> (accessed 10/5/18)

Any apocalyptic pathogen would need to possess a very special combination of two attributes. First, it would have to be so unfamiliar that no existing therapy or vaccine could be applied to it. Second, it would need to have a high and surreptitious transmissibility before symptoms occur. The first is essential because any microbe from a known class of pathogens would, by definition, have family members that could serve as models for containment and countermeasures. The second would allow the hypothetical disease to spread without being detected by even the most astute clinicians. The three infectious diseases most likely to be considered extinction-level threats in the world today—influenza, HIV, and Ebola—don't meet these two requirements. Influenza, for instance, despite its well-established ability to kill on a large scale, its contagiousness, and its unrivaled ability to shift and drift away from our vaccines, is still what I would call a "known unknown." While there are many mysteries about how new flu strains emerge, from at least the time of Hippocrates, humans have been attuned to its risk. And in the modern era, a full-fledged industry of influenza preparedness exists, with effective vaccine strategies and antiviral therapies. HIV, which has killed 39 million people over several decades, is similarly limited due to several factors. Most importantly, HIV's dependency on blood and body fluid for transmission (similar to Ebola) requires intimate human-to-human contact, which limits contagion. Highly potent antiviral therapy allows most people to live normally with the disease, and a substantial group of the population has genetic mutations that render them impervious to infection in the first place. Lastly, simple prevention strategies such as needle exchange for injection drug users and barrier contraceptives—when available—can curtail transmission risk.

Failure to acknowledge the antiblack nature of HIV prevention blocks treatment

Robert E. **Fullilove**, community research group for Columbia University, August 3, **2001**, "HIV prevention in the African-American community: Why isn't anybody talking about the elephant in the room?" AIDS Science, <http://aidsscience.org/Articles/aidsscience007.asp> (accessed 10/5/18)

So what is the point? It is simple: Nowhere in our national HIV-prevention agenda for the African-American community do we ever confront "the elephant in the room." This proverbial elephant refers to a significant, critical element of a problem or conflict confronting a particular group that is so huge it cannot possibly be ignored but is, in fact, never acknowledged by group members. Because it is never acknowledged, no effective solution is ever developed. Nowhere do we seriously acknowledge how much the facts of the epidemic pass through a filter in black America that leaves each pamphlet reader, each listener of a public service announcement, each viewer of a televised special on HIV/AIDS to wonder how much of this is real and how much of this is just another element in a genocidal plot to rid the world of "undesirables." As one participant in a Harlem community meeting on HIV/AIDS observed to me, "White folks think AIDS is about a virus; black folks think AIDS is about genocide." The name of the elephant, in other words, is genocide. In "AIDS in Blackface" (7), Dalton wrote at length about the barrier that fears of genocide create for HIV-prevention programs. He wrote, "I have no particular investment in the term genocide; I simply want to jumpstart the conversation that usually dies out whenever the word is deployed" (p. 223). That was written in 1989. Has the conversation died out? Significantly, the prediction that Dalton made for the future--that "AIDS is rapidly changing from mostly white to predominantly black and brown" (p. 223)--is the reality of the year 2001. What may have appeared as paranoia in 1989 now has the suspicious air of a prophesy come true; or worse, a prophesy that came true precisely because it was ignored.

Elephant-in-the-room jokes are funny because of the absurdity of not talking about something that is too big to ignore. If there is to be an effective partnership between the public health community and the African-American community to prevent HIV infection, we must be able to have an open, undoubtedly painful, discussion about AIDS and genocide. Dalton's belief that "we African-Americans have been reluctant to 'own' the AIDS epidemic, to acknowledge the devastating toll it is taking on our communities, and to take responsibility for altering its course" requires that we begin to have that conversation. It has been 12 years since he wrote those words, but never have they held greater import for our nation's future.

HIV is not a crisis now – low transmission rates

DUJS, Dartmouth Undergraduate Journal of Science, May 22, **2009**, "Human Extinction: The Uncertainty of Our Fate," <http://dujs.dartmouth.edu/2009/05/human-extinction-the-uncertainty-of-our-fate/#.WQNtDsa1tPZ> (accessed 10/5/18)

In the past, humans have indeed fallen victim to viruses. Perhaps the best-known case was the bubonic plague that killed up to one third of the European population in the mid-14th century (7). While vaccines have been developed for the plague and some other infectious diseases, new viral strains are constantly emerging — a process that maintains the possibility of a pandemic-facilitated human extinction. Some surveyed students mentioned AIDS as a potential pandemic-causing virus. It is true that scientists have been unable thus far to find a sustainable cure for AIDS, mainly due to HIV's rapid and constant evolution. Specifically, two factors account for the virus's abnormally high mutation rate: 1. HIV's use of reverse transcriptase, which does not have a proof-reading mechanism, and 2. the lack of an error-correction mechanism in HIV DNA polymerase (8). Luckily, though, there are certain characteristics of HIV that make it a poor candidate for a large-scale global infection: HIV can lie dormant in the human body for years without manifesting itself, and AIDS itself does not kill directly, but rather through the weakening of the immune system.

Diseases pose a very limited threat to humanity

Amesh **Adalja**, infectious pathogens physician, June 17, **2016**, "Why Hasn't Disease Wiped out the Human Race?," The Atlantic, <https://www.theatlantic.com/health/archive/2016/06/infectious-diseases-extinction/487514/> (accessed 10/5/18)

But when people ask me if I'm worried about infectious diseases, they're often not asking about the threat to human lives; they're asking about the threat to human life. With each outbreak of a headline-grabbing emerging infectious disease comes a fear of extinction itself. The fear envisions a large proportion of humans succumbing to infection, leaving no survivors or so few that the species can't be sustained. I'm not afraid of this apocalyptic scenario, but I do understand the impulse. Worry about the end is a quintessentially human trait. Thankfully, so is our resilience. For most of mankind's history, infectious diseases were the existential threat to humanity—and for good reason. They were quite successful at killing people: The 6th century's Plague of Justinian knocked out an estimated 17 percent of the world's population; the 14th century Black Death decimated a third of Europe; the 1918 influenza pandemic killed 5 percent of the world; malaria is estimated to have killed half of all humans who have ever lived. And yet, of course, humanity continued to flourish. Our species' recent explosion in lifespan is almost exclusively the result of the control of infectious diseases through sanitation, vaccination, and antimicrobial therapies. Only in the modern era, in which many infectious diseases have been tamed in the industrial world, do people have the luxury of death from cancer, heart disease, or stroke in the 8th decade of life. Childhoods are free from watching siblings and friends die from outbreaks of typhoid, scarlet fever, smallpox, measles, and the like.

Government agencies are already increasing access to HIV preventative medication – price controls are unnecessary

Shefali **Luthra** and Anna **Gorman**, journalists, June 30, **2018**, “Rising Cost Of PrEP To Prevent HIV Infection Pushes It Out Of Reach For Many,” National Public Radio, <https://www.npr.org/sections/health-shots/2018/06/30/624045995/rising-cost-of-prep-a-pill-that-prevents-hiv-pushes-it-out-of-reach-for-many> (accessed 10/5/18)

Beyond these state-based programs, some public health departments and HIV service organizations are hiring PrEP navigators to help patients traverse the maze of copays and deductibles, and to improve recruitment and retention of new PrEP users. Washington, D.C.'s health department has doubled down on prevention, and Truvada is key in that effort, says Michael Kharfen, the department's senior deputy director for HIV/AIDS, Hepatitis, STD and TB Administration. **Insurance usually covers PrEP, and patient assistance programs should fill any financial gaps, he says. But when that isn't feasible, the department steps in, distributing free Truvada starter packs to at-risk patients.**

Homophobia blocks access to HIV treatment, price controls aren't enough

Paula A. **Treichler**, assistant professor, October **1987**, “AIDS, Homophobia, and Biomedical Discourse: An Epidemic of Signification,” Cultural Studies vol 1 no 3, p. 50-51 (accessed 10/5/18)

It was widely believed in the gay community that the connection of AIDS to homosexuality delayed and problematized virtually every aspect of the country's response to the crisis. That the response was delayed and problematic is the conclusion of various investigators.⁴⁹ Attempting to assess the degree to which prejudice, fear, or ignorance of homosexuality may have affected public policy and research efforts, Panem concluded that homosexuality per se would not have deterred scientists from selecting interesting and rewarding research projects. But “the argument of ignorance appears to have more credibility.”⁵⁰ She quotes James Curran's 1984 judgment that policy, funding, delayed because only people in New York and crisis or comprehension of the gay male community. relate to sex,” he said, “and there is not much.” **This was an understatement: according to Curran, many eminent scientists during this period rejected the possibility that cause they had no idea how a man could transmit man.**⁵¹ Other instances of ignorance are reported by Patton and Black. Physician and scientist Joseph Sonnabend attributes ivory towers that many AIDS investigators (particularly those who do straight laboratory research as opposed to clinical work) inhabit and argues AIDS needs to be studied in its cultural totality. Gay male sexual practices need not be dismissed out of hand because they seem “unnatural” to the straight (in both senses) scientist: “the rectum is a sexual organ and it deserves the respect that a penis gets and a vagina gets. Anal intercourse is a central sexual activity and it should be supported, it should be celebrated.” **A National Academy of Sciences panel studying the AIDS crisis in 1986 cited an urgent need for accurate and current information about sex and sexual practices in the US, noting no comprehensive research had been carried out since Kinsey's study in the 1940s; they recommended, as well, social science research on a range of behaviors relevant to the transmission and control of AIDS.**⁵⁴

Price controls won't increase HIV medication access - stigma keeps gay men from disclosing to their doctors

Selena **Simmons-Duffin**, journalist, April 10, **2018**, “PrEP Campaign Aims To Block HIV Infection And Save Lives In D.C.,” National Public Radio, <https://www.npr.org/sections/health-shots/2018/04/10/599606352/prep-campaign-aims-to-block-hiv-infection-and-saves-lives-in-d-c> (accessed 10/5/18)

Millett adds that there are other reasons why people — especially people of color — haven't requested PrEP as much as he and other public health officials would like. Some African Americans distrust the medical community because of historical mistreatment, he says. And there's still a stigma attached to HIV, especially in some minority communities. "In order to be prescribed PrEP you need to be 'out' to your provider," Millett says. "And we see that for African-American men, as well as for Latino gay men, they're less likely to tell their providers that they are gay or bisexual."

Price controls aren't enough to end HIV – poverty, abuse, addiction, mental illness push people out of treatment

Barbara Feder **Ostrov**, health journalist, December 23, **2015**, "It's Not Hard to Treat HIV—if You're Rich," Kaiser Health News, <http://www.thedailybeast.com/articles/2015/12/24/it-s-not-hard-to-treat-hiv-if-you-re-rich.html> (accessed 10/5/18)

Dr. Edward Machtinger, professor and director of the Women's HIV Program at the University of California, San Francisco, said his clinic has been able to achieve viral suppression in up to 80 percent of its patients. But the focus on biomedical treatment of their HIV, he noted, obscures the deep challenges many of his patients face: poverty, domestic abuse, addiction, and mental illness. "Complex trauma is what led many of my patients to get HIV in first place and gets them to remain depressed, stay addicted, and have trouble adhering to their meds," Machtinger said. "Medicine and HIV primary care has not considered these health issues to be in their domain and their responsibility. I've heard many clinicians brag about having patients on crack be undetectable in their viral load, as if HIV was going to kill them in the first place. It's not. Crack is going to kill them." Addressing HIV patients' social and economic challenges—often referred to as "social determinants of health"—is complicated and not reimbursable, Machtinger said. "What we really need to do is find a way for patients to be safer, more empowered, and healthy."

Pharmaceutical manufacturers give assistance to patients struggling with financial barriers

Shefali **Luthra and Anna Gorman**, journalists, June 30, **2018**, "Rising Cost Of PrEP To Prevent HIV Infection Pushes It Out Of Reach For Many," National Public Radio, <https://www.npr.org/sections/health-shots/2018/06/30/624045995/rising-cost-of-prep-a-pill-that-prevents-hiv-pushes-it-out-of-reach-for-many> (accessed 10/5/18)

Gilead spokesman Ryan McKeel says the company has made extra efforts to help patients overcome financial barriers. He cites assistance programs for uninsured and underinsured people. "We have designed our assistance programs with the intent that people can benefit from their full value, and we cannot control the actions or decisions of health insurers," McKeel said via email. The federal Centers for Disease Control and Prevention estimates that more than 1 million people are at high risk of contracting HIV, but Gilead says only about 167,000 people currently are receiving PrEP.

Price controls fail – industries find loopholes

Elizabeth L. **Wright**, director of health and social policy, October, **2016**, "Pharmaceutical Price Controls: A Prescription for Disaster," Coalition Against Government Waste, <https://www.cagw.org/reporting/pharmaceutical-price-controls> (accessed 10/4/18)

Perhaps the most striking impact of Nixon's decision was the evasive action that followed in numerous industries. For example, with price controls in place on conventional cuts of beef, grocers invented new cuts of beef, such as the "watermelon roast," which did not fall under price controls.

Lumber producers took advantage of a loophole for imported lumber, which was exempt from price controls. They simply exported lumber to Canada and then imported it back into the United States. Another loophole was created for “customized” work. Enterprising contractors drilled holes in plywood, then filled the holes back up again to create a customized product.[18] **While some evasive maneuvers were clever and successful, others were almost tragic. Cattle were withheld from the market, driving up the cost of beef; baby chickens were drowned; and, food shelves were sparsely stocked.**[19]

HIV treatment ineffective – the virus is becoming drug-resistant

Kent **Sepkowitz**, news analyst, February 22, **2016**, “Are We Creating Drug-Resistant HIV?” The Daily Beast, <http://www.thedailybeast.com/articles/2016/02/22/are-we-creating-drug-resistant-hiv.html> (accessed 10/5/18)

It is the nature of the drug-microbe tango: Antimicrobials fail because the enemy they are battling—a virus or some bacteria—has the relentless might of natural selection on its side. This means that sooner though hopefully later, because of the rapid winnowing by the drug of a population of a zillion viruses or bacteria, a genetic mutation will emerge that renders the very same drug near worthless. A recent prominently featured report is a case in point. **Last month in Lancet Infectious Diseases, researchers described features of HIV isolates collected from almost 2,000 patients scattered across 36 countries. Importantly, each of the patients in the study had already failed the standard treatment cocktail. To explain the lack of drug effectiveness, the scientists probed each HIV isolate to see whether genetic resistance mutations in the RNA of HIV itself could explain the situation. And indeed mutations were the problem.** Among the 2,000 patients, rates of resistance to an extremely useful and commonly prescribed drug in both treatment and prevention—tenofovir—ranged from about 20 percent of European isolates to more than 50 percent in many areas in Africa. **In other words, people were using tenofovir across the world and, as a result, mutations resistant to tenofovir were emerging in a direct cause-and-effect fashion. The report and others like it are pretty scary. Right now, we have two-dozen active drugs against HIV but they fall into only a half-dozen different drug classes; typically, drug resistance to one member of a drug class extends to the other members. So despite the apparent riches of the moment, when patients can be offered a single pill once a day with minimal side effects, we remain perilously close to real trouble.**

Don’t say there’s a cure for HIV until there is one – false hope leads patients to quit drug treatment

Stuart **Rennie**, researcher for the Center for Bioethics, **2015** “The ethics of talking about ‘HIV cure’,” BMC Medical Ethics, <https://bmcmethics.biomedcentral.com/articles/10.1186/s12910-015-0013-0> (accessed 10/5/18)

With this powerful curative hope in the background, how might cure language ‘do wrong’? The most obvious way is falsehoods through unsubstantiated claims of HIV cure. Many such claims have been made worldwide over the last decades, and this violates ethical norms of veracity and non-maleficence. A study in Tanzania suggests that when traditional healers claim they can cure HIV, there are negative effects on ART adherence among their HIV-positive clients [23]. But misunderstandings are likely to develop in subtler and less intentional ways. Traditional media, Internet news outlets and online social networks use language sometimes suggest a (safe, effective, scalable, affordable) cure may have been discovered or is just over the horizon. **These claims could arguably do psychological harm to persons living with HIV by unduly raising and dashing hopes, and the generation of false beliefs might have other negative effects on behavior.** Is this ‘harms due to false belief

via cure language' scenario plausible? Some considerations in support of this scenario include: the media's vested economic interest in (to a greater or lesser extent) 'sensationalizing' HIV cure research; that even if what is accurately reported is a potential functional cure only applicable to a small minority of HIV-positive persons, the grip of the absolute conception of cure on the public imagination may lead some to misunderstand current HIV research advances. To what extent is this a problem? This is another area for future social science research.

General Health Care Costs Answers

Substantially lowering drug prices only reduces medical spending by 2%

Darius **Lakdawalla** is the Quintiles professor of pharmaceutical development and regulatory innovation in the School of Pharmacy at the University of Southern California, **2015**, New York Times, <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-end-up-costing-patients-their-health> Drug Price Controls End Up Costing Patients Their Health

On the other side of the ledger, **drug price controls would not save that much money. According to federal government data, prescription drug spending makes up roughly one-tenth of America's total bill for health care. Lopping 20 percent off drug prices by negotiating prices would thus shave all of 2 percent off our total health care bill. What's more, we will enjoy only a one-time cost reduction, because drug spending has been growing no faster than overall health care spending over the past 10 years.**

Drugs are a small percentage of costs

Paul **Howard** is a senior fellow and director of health policy at the Manhattan Institute, **2015**, New York Times, <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/to-lower-drug-prices-innovate-dont-regulate> To Lower Drug Prices, Innovate, Don't Regulate

The idea that we "overspend" on drugs is also misleading. In 2014, **drug spending accounted for just 10 percent of U.S. health care spending, and** according to government actuaries, **spending will increase by only 0.4 percentage points over the next decade.** Hospitals, for comparison, account for more than 30 percent of total health care spending.

Countries that use **price controls advocated by industry critics actually spend a larger share on drugs** and use fewer

Price Controls Correct Market Failures

The upfront cost of making new pharmaceuticals is exceedingly high, and drug companies need to be able to recoup that capital.

John **Lamattina**. “About Those Soaring Pharma Profits”, Forbes, 23 Jan **2018**,
<https://www.forbes.com/sites/johnlamattina/2018/01/23/about-those-soaringpharma-profits/#299331d53f9d>

“It’s a critique often heard as pundits attack the costs of new drugs: the high price of drugs is fueling unseemly Big Pharma profits. Typical is the headline, “Drug prices rise as pharma profit soars”. **There is no doubt that the high cost of new drugs is an important issue, although arguments can be made that the prices charged for life-saving medicines such as the cures for hepatitis C, childhood leukemia, and ALL can be more than justified. However, pharma profits are not greatly increasing as a result.** This issue was hit hard by Pfizer CEO Ian Read at the recent Forbes Healthcare Summit. Is this industry obscenely profitable? There is no evidence of that. If you look at our return on investment, our return on capital, if you look at our P/E, if you look at anything inside this industry – looking at the Bloomberg indices – we are in the middle. So **I don’t see an industry that you can say is profiteering. I see an industry that is taking its resources and investing into a high risk business called ‘innovation’ and making modest returns on the capital at risk.** So, I think the societal issue is how do you afford access to medicines that create great value, but require capital and risk to produce - the medicines that may represent 12 – 14% of the total costs and have automatic price adjustments in the form of loss of exclusivity? That’s a pretty good speech, but in an era of fake news, how accurate are Read’s comments? Actually, available data* are pretty supportive. **The average return on equity for key industries from 2014 – 2016 shows that biopharma’s profits stand at 16.2%, significantly lower than Computer Sciences (31.6%), Beverages (27.4%), Aerospace/Defense (23.0%), and Trucking (19.1%) while modestly higher than Software System/Applications (15.2%) and Healthcare Support Services (14.4%).**”

American companies charge high prices for pharmaceuticals because they perform the bulk of the R&D involved.

Jim **Greenwood**. “Impose Price Controls on Drug?”, The New York Times,
<https://www.nytimes.com/2015/09/19/opinion/impose-price-controls-ondrugs.html>

“While Dr. Ezekiel J. Emanuel makes a few good points about the perils of expensive drugs and their efficacy, he misses the big picture. **The American drug industry is by far the most successful and innovative in the world in addition to being the most expensive because we are the only country that pays the true research and development costs, not only for Americans, but for the rest of the world as well.** Using the Australian or the Swiss system here would result in Swiss or Australian limits on who gets what. The easy route to talking about drug prices is to bash company profits. **Limiting profits may sound attractive but it will also be ineffective. The more honest discussion is about what we as a society are willing to pay to improve or extend life. And the answer is that we are willing to pay a lot, which is why reform is always talked about but never accomplished.**”

Price controls would make pharmaceuticals more expensive in the long-run by shifting costs and reducing the efficiency of innovation.

Elizabeth **Wright**. “Pharmaceutical Price Controls: A Prescription for Disaster”, Citizens Against Government Waste, October **2016**,
<https://www.cagw.org/sites/default/files/pdf/Pharmaceutical%20Price%20Controls%20-%20A%20Prescription%20for%20Disaster.pdf>

“Price control measures such as Medicaid rebates, the 340B program, and the VA pricing structures **have distorted the pharmaceutical market and caused price shifting.** In a November 4, 2010, letter to then-House Budget Committee Ranking Member Paul Ryan (R-Wisc.), the CBO confirmed that Obamacare’s increased Medicaid discounts and mandated new Medicare Part D **discounts** in the cover gap (more commonly referred to as the “donut hole” between the end of initial coverage and the start of catastrophic coverage), **would likely cause manufacturers to raise prices to offset the costs of new discounts.[50] Markets respond to pricing pressure as if it were an inflated balloon: push down on one side and the other expands. It should come as no surprise that some drug costs are being shifted to the private sector because of government price controls.”**

Price Controls Reduce Government Spending

Setting price controls would reduce the incentive for pharmaceutical companies to innovate, resulting in fewer and less effective new drugs.

John **Lamattina**. “About Those Soaring Pharma Profits”, Forbes, 23 Jan **2018**, <https://www.forbes.com/sites/johnlamattina/2018/01/23/about-those-soaringpharma-profits/#299331d53f9d>

“If price controls pressure the U.S. industry into a more conventional process industry model, like that of the chemical industry, pharmaceutical R&D budgets would be slashed. To achieve the chemical industry’s rate of R&D spending, as would be required to achieve profitability competitive with the chemical industry, top pharmaceutical companies would have to reduce their R&D budgets by 80 percent — almost \$50 billion in total. This reduction in spending would take a few years to realize, but would be completely evident by 2023 or earlier. An important corollary is that, if profitability and value creation opportunities for new drugs declined, the appetite of the venture community for risky, long-term biopharmaceutical investments would shrink exponentially. Price controls on drugs would have the surprising effect of accelerating the flow of investment into high technology, where timelines to market are shorter, less regulated, and less risky. The venture capital community is flush with cash and anxious to invest where high returns can be achieved — ideally within a much shorter time than is typically possible in the realm of drug R&D. **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.”**

Making drugs artificially cheaper than they should be creates a moral hazard, where people consume more prescription drugs, ultimately increasing public expenditures.

Sergio **Prada**, BioMed Central, ““Higher pharmaceutical public expenditure after direct price control: improved access or induced demand? The Colombian case”, 2 March **2018**, <https://resourceallocation.biomedcentral.com/articles/10.1186/s12962-018-0092-0>

“Background High pharmaceutical expenditure is one of the main concerns for policymakers worldwide. In Colombia, a middle-income country, outpatient prescription represents over 10% of total health expenditure in the mandatory benefits package (POS), and close to 90% in the complementary government fund (No POS). In order to control expenditure, since 2011, the Ministry of Health introduced price caps on inpatient drugs reimbursements by active ingredient. By 2013, more than 400 different products, covering 80% of public pharmaceutical expenditure were controlled. This paper investigates the effects of the Colombian policy efforts to control expenditure by controlling prices. Methods Using SISMED data, the official database for prices and quantities sold in the domestic market, we estimate a Laspeyres price index for 90 relevant markets in the period 2011–2015, and, then, we estimate real pharmaceutical expenditure. Results **Results show that, after direct price controls were enacted, price inflation decreased almost – 43%, but real pharmaceutical expenditure almost doubled due mainly to an increase in units sold. Such disproportionate increase in units sold maybe attributable to better access to drugs due to lower prices, and/or to an increase in marketing efforts by the pharmaceutical industry to maintain profits.”**

Because of the high upfront cost of developing new medicines, we should incentivize research and development on drugs to reduce prices, rather than discouraging it.

John **Graham**. “Crisis In Pharma R&D: It Costs \$2.6 Billion To Develop A New Medicine; 2.5 Times More Than In 2003”, Forbes, Nov 26 **2014**, <https://www.forbes.com/sites/theapothecary/2014/11/26/crisis->

in-pharma-rdit-costs-2-6-billion-to-develop-a-new-medicine-2-5-times-more-than-in2003/#5a33cebe321c

“Given these facts, it may be understandable that the health-insurance industry is campaigning against the high prices of specialty drugs. For its part, the brand-name pharmaceutical industry emphasizes that health insurers (especially in Obamacare exchanges) often put these specialty drugs on the most expensive tier of their formularies. This requires patients to pay high out of pocket costs. While this is an accurate description of the situation, a government policy simply forcing insurers to cover a higher share of the price of a specialty drug does not reduce the price. It just moves it from patients’ direct payment to premium. **Reducing prices of specialty drugs requires improving the productivity of R&D.** On that front, the news is sobering. Last December, Deloitte and Thomson Reuters TRI +0% examined newly introduced drugs from the twelve pharmaceutical companies with the largest research and development (R&D) budgets. **It cost \$1.3 billion to bring a newly discovered compound to market. However, the average forecast for peak sales of an asset declined by 43%, dropping from \$816 million in 2010 to \$466 million in 2013.**”

Price controls distort the pharmaceutical market, ultimately resulting in higher medical costs elsewhere and no real reduction in spending.

Elizabeth **Wright**. “Pharmaceutical Price Controls: A Prescription for Disaster”, Citizens Against Government Waste, October **2016**,
[https://www.cagw.org/sites/default/files/pdf/Pharmaceutical%20Price%20Contr ols%20-%20A%20Prescription%20for%20Disaster.pdf](https://www.cagw.org/sites/default/files/pdf/Pharmaceutical%20Price%20Controls%20-%20A%20Prescription%20for%20Disaster.pdf)

“**Price control measures** such as Medicaid rebates, the 340B program, and the VA pricing structures **have distorted the pharmaceutical market and caused price shifting.** In a November 4, 2010, letter to then-House Budget Committee Ranking Member Paul Ryan (R-Wisc.), the CBO confirmed that Obamacare’s increased Medicaid discounts and mandated new Medicare Part D **discounts** in the cover gap (more commonly referred to as the “donut hole” between the end of initial coverage and the start of catastrophic coverage), **would likely cause manufacturers to raise prices to offset the costs of new discounts.[50] Markets respond to pricing pressure as if it were an inflated balloon: push down on one side and the other expands. It should come as no surprise that some drug costs are being shifted to the private sector because of government price controls.**”

Price Controls Protect the Uninsured

Price controls reduce the incentive for companies to innovate, ultimately resulting in a longer-term problem where there are fewer drugs in the long-term.

Robert **Easton**. "Price controls would stifle innovation in the pharmaceutical industry", STAT News, 22 Jan **2018**, <https://www.statnews.com/2018/01/22/pricecontrols-pharmaceutical-industry/>

"If price controls pressure the U.S. industry into a more conventional process industry model, like that of the chemical industry, pharmaceutical R&D budgets would be slashed. To achieve the chemical industry's rate of R&D spending, as would be required to achieve profitability competitive with the chemical industry, top **pharmaceutical companies would have to reduce their R&D budgets by 80 percent — almost \$50 billion in total. This reduction in spending would take a few years to realize, but would be completely evident by 2023 or earlier.** An important corollary is that, if profitability and value creation opportunities for new drugs declined, the appetite of the venture community for risky, long-term biopharmaceutical investments would shrink exponentially. Price controls on drugs would have the surprising effect of accelerating the flow of investment into high technology, where timelines to market are shorter, less regulated, and less risky. The venture capital community is flush with cash and anxious to invest where high returns can be achieved — ideally within a much shorter time than is typically possible in the realm of drug R&D. **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."**

Introducing new pharmaceutical products is key to ensuring that the uninsured can afford pharmaceuticals.

Cong, Ze. "Value of Pharmaceutical Innovation." (**2009**). Rand Corporation.

https://www.rand.org/content/dam/rand/pubs/rgs_dissertations/2009/RAND_R_GSD242.pdf

"By employing econometrics models with data from various data sources, **we do find statistically significant access effects of new drugs, in terms of increasing number of drugs prescribed.** Those effects are heterogeneous among different new drug subgroups. More specifically, we find that more creative drugs (e.g., NCEs) tend to have larger, more significant access effects, whereas less creative drugs (e.g., generic drugs, nonNCEs) contribute smaller or even negative access effects. **Non-NCE brand-name drugs significantly increase the number of uninsured prescriptions,** whereas no significant effect is found for insured prescriptions. **These findings confirm the hypothesis that new drugs can impact population health not only with change in clinical effectiveness on existing treatments, but also with change in the quantity of prescriptions written and/or people treated"**

Studies have demonstrated that, by dashing innovation, price controls ultimately increase the price of drugs.

Paul **Howard**. "To Lower Drug Prices, Innovate, Don't Regulate", The New York Times, Sep 23 **2015**, <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-governmentimpose-drug-price-controls/to-lower-drug-prices-innovate-dont-regulate>

"Price control advocates argue that curtailing profits in the pharmaceutical industry would save the country money without reducing innovation. There is, however, no such thing as a free lunch. Bureaucratic price manipulation would only hurt the sickest patients.

Streamlining drug approvals would get more drugs on market, increasing competition and lowering prices. Research shows that price controls in the United States would powerfully dampen innovation. "Cutting prices by 40 to 50 percent in the U.S. will lead to between 30 to 60 percent fewer R&D projects being undertaken," one study found. **A 2008 RAND study exploring the effect of U.S. price controls on those aged 55 to 59 in the United States and Europe similarly found that, on net, pharmaceutical price controls would hurt patients.** The idea that we "overspend" on drugs is also

misleading. In 2014, **drug spending accounted for just 10 percent of U.S. health care spending, and according to government actuaries, spending will increase by only 0.4 percentage points over the next decade.**

Hospitals, for comparison, account for more than 30 percent of total health care spending. Countries that use price controls advocated by industry critics actually spend a larger share on drugs and use fewer costsaving generics than the United States does.”

Price Controls Help Stop Patent Monopolies

Patents are necessary for pharmaceutical companies, both in terms of spurring innovation and getting new products onto the market.

Global CCS Institute. “How patents encourage innovation in technological development and deployment”, June **2013**, <https://hub.globalccsinstitute.com/publications/intellectual-property-rightsrole-patents-renewable-energy-technology-innovation/1-how-patentsencourage-innovation-technological-development-and-deployment>

“Advocates of patenting argue that patents act as a strong incentive for innovation, while others are concerned that they restrain innovation. To some extent the role and impact of patents depend on the specific technology involved. While some patents may temporarily limit the use of specific technologies to the patent's owner and licensees in some jurisdictions, such innovations often spur the development of competing technologies. For technologies requiring considerable financial and technical resources, and a long period to develop marketable products that are then relatively inexpensive to reproduce, patent protection is critical. For pharmaceuticals, for example, patents are important both in terms of spurring innovation of new medicines and ensuring access to new medical technologies. **National and regional patent offices**, such as the United States Patent and Trademark Office (USPTO), the Japan Patent Office (JPO), EPO, the Korean Intellectual Property Office (KIPO) and the State Intellectual Property Office of the People's Republic of China (SIPO) **play a critical role in ensuring that patents are granted only to inventions that are genuine contributions** to the state of the art and comply with procedural, as well as substantive requirements prescribed under the applicable patent law of the country or region in question..”

Pharmaceutical companies, despite supposed monopolies, are not capturing exceedingly high profits.

John **Lamattina**. “About Those Soaring Pharma Profits”, Forbes, 23 Jan **2018**, <https://www.forbes.com/sites/johnlamattina/2018/01/23/about-those-soaringpharma-profits/#299331d53f9d>

“It’s a critique often heard as pundits attack the costs of new drugs: the high price of drugs is fueling unseemly Big Pharma profits. Typical is the headline, “Drug prices rise as pharma profit soars”. **There is no doubt that the high cost of new drugs is an important issue, although arguments can be made that the prices charged for life-saving medicines** such as the cures for hepatitis C, childhood leukemia, and ALL **can be more than justified. However, pharma profits are not greatly increasing as a result.** This issue was hit hard by Pfizer CEO Ian Read at the recent Forbes Healthcare Summit. Is this industry obscenely profitable? There is no evidence of that. If you look at our return on investment, our return on capital, if you look at our P/E, if you look at anything inside this industry – looking at the Bloomberg indices – we are in the middle. So **I don’t see an industry that you can say is profiteering. I see an industry that is taking its resources and investing into a high risk business called ‘innovation’ and making modest returns on the capital at risk. So, I think the societal issue is how do you afford access to medicines that create great value, but require capital and risk to produce - the medicines that may represent 12 – 14% of the total costs and have automatic price adjustments in the form of loss of exclusivity?** That’s a pretty good speech, but in an era of fake news, how accurate are Read’s comments? Actually, available data* are pretty supportive. **The average return on equity for key industries from 2014 – 2016 shows that biopharma’s profits stand at 16.2%, significantly lower than Computer Sciences (31.6%), Beverages (27.4%), Aerospace/Defense (23.0%), and Trucking (19.1%) while modestly higher than Software System/Applications (15.2%) and Healthcare Support Services (14.4%).**”

Thorough patent systems encourage the introduction of products to the market sooner, whereas price controls discourage the introduction of new products.

Lanjouw, Jean O. Patents, price controls and access to new drugs: how policy affects global market entry. No. w11321. Cambridge (MA): National Bureau of Economic Research, **2005**.

<http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.610.965&rep=rep1&type=pdf>

"The first two columns of Table 7 present the main results for estimates when additional variables are included in the random effects specification. The first adds a country's R&D share and its level of tariff protection (which together lead to a sizable drop in the number of observations due to missing data). **We again find that having a long process patent regime significantly**

encourages rapid drug launch. A new finding is that countries with a high technical capacity as measured by R&D expenditure are far less likely to see new pharmaceuticals in the market quickly. Starting from no R&D and then increasing R&D to the mean level of one-half of one percent of GDP drops the probability of rapid launch by an estimated 13.6 percentage points. **This negative effect of local capacity, however, is significantly offset if a country offers the strongest level of patent protection**.

Although the effect of a higher R&D share remains negative even when interacted with strong patent protection, its marginal effect is diminished by a third (joint marginal effect = -0.19, p-value = 0.01, versus -0.28). As in the simpler specification, **extensive price control has a significant negative effect on the probability of rapid launch**. Moderate regulation of prices is also found to have a negative effect now that the specification allows for its interaction with GDP per capita.

Limiting Political Power

Even in the event of reducing drug prices, that would not necessarily reduce pharmaceutical profits, as consumers would purchase more pharmaceutical products, offsetting decreases in revenue.

Sergio **Prada**, BioMed Central, “Higher pharmaceutical public expenditure after direct price control: improved access or induced demand? The Colombian case”, 2 March **2018**, <https://resourceallocation.biomedcentral.com/articles/10.1186/s12962-018-0092-0>

“The Colombian experience clearly shows that price controls do not necessarily decrease overall real pharmaceutical expenditures. Pharmaceutical expenditure is determined by variation in prices and quantities.² A drug price regulation that does not consider a set of measures to strictly monitor (and eventually investigate and further control) quantities sold, is likely to fail in its objective of halting expenditure. This is a crucial finding in the context of middle income countries like Colombia that still face challenges to guarantee financially sustainable universal healthcare coverage. **While ERP may lower pharmaceutical prices, it may also spur an increase in the demand of regulated products, defying the cost control objective that motivated price regulation in the first place.”**

Pharmaceutical companies are losing political power currently despite the amount of lobbying they perform because their methods of lobbying are ineffective.

John **Jones**. The Hill. “Big Pharma's lobbyists are losing despite their 'pass the buck' campaigns”, March 5 **2018**, <https://thehill.com/opinion/healthcare/376699-bigpharmas-lobbyist-are-losing-despite-their-pass-the-buck-campaigns>

“This isn’t surprising and certainly not unpredictable, but ignores the basic challenge facing drug companies: **no amount of money can change the fact that Republicans and Democrats know the problem is high drug prices and that drugmakers alone set those prices.** So despite all this overwhelming lobbying and financial firepower, the question remains: **Why are drugmakers losing? In the recent budget bill, drugmakers were singled out by both parties to pay billions more in discounts to help seniors in the Medicare prescription drug benefit “donut hole.”** This comes as states across the country are taking a harder look at drugmaker pricing schemes and passing legislation in California and Nevada that faced significant pushback from drug companies (and their surrogates). Like the emperor who wore no clothes, **drugmakers have confused politician’s fear of speaking out against them with support for their pricing practices.** It appears that most politicians will tolerate, but not believe in the drug lobby’s messages or goals. Drug manufacturers have a number of options to alter public perception of their pricing strategies. They can assert that their products are a great value at any price but there is definitely a level where that argument fails. They can also compete on price and refrain from automatic pricing increases that obviously impact healthcare affordability. **Instead, they peddle distracting narratives and government mandates that undermine federal programs and result in huge industry profit windfalls.”**

Tradeoff Between Hospitals and Drugs

Non-Unique - 83% of hospitals charge patients more than double the cost of medicine, the nationwide average markup for drugs is 83%. Hospitals are for profit and won't charge patients less even if the price of drugs decrease.

The Moran Company 18 The Moran Company, 2018, "Hospital Charges and Reimbursement for Medicines: Analysis of Cost-to Charge Ratios" The Pharmaceutical Research and Manufacturers of America <http://www.themorancompany.com/wp-content/uploads/2018/09/Hospital-Charges-Reimbursement-for-Medicines-August-2018.pdf>

We found that, on average, hospitals charge 479% of their cost for drugs nationwide.⁷ This matches closely with the findings from our prior analysis. **Most hospitals (83%) charge patients and insurers more than double their acquisition cost for medicine, marking-up the medicines 200% or more.** The majority of hospitals (53%) markup medicines between 200-400%, on average. A small share of hospitals - one in six (17%) - charge seven times the price of the medicine. On a medicine with an ASP of \$150, a 700% mark-up would result in a charge of \$1050. **One out of every twelve hospitals (8%) has average charge markups greater than 1000% - meaning they are charging at least 10 times their acquisition cost for medicines,** on average. These data are presented in Chart one and Table one.

People spend less at hospitals because they have fewer reasons to go

Lichtenberg, Frank R. "The Benefits of Pharmaceutical Innovation: Health, Longevity, and Savings." Montreal Economic Institute, Montreal Economic Institute, June **2016**, www.iedm.org/files/cahier0216_en.pdf.

Although the costs of new pharmaceuticals are often the subject of critical media coverage, they are rarely juxtaposed with the benefits that these new drugs bring. Between 1995 and 2012, life expectancy at birth in Canada increased by more than three years and curative care hospital discharges per 100,000 population (a measure of hospital utilization) decreased by 25%. While these improvements naturally have multiple sources, a substantial and growing number of studies have demonstrated that pharmaceutical innovation is responsible for a large part of such long-term improvements in health and longevity. **Furthermore, although new drugs can appear expensive when considered in isolation, pharmaceutical innovation leads to cost savings elsewhere in the system through the reduced use of health services like hospitals and nursing homes.** Studies have also shown that pricing drugs appropriately is important in sustaining a robust rate of pharmaceutical innovation.

We wouldn't have drugs as effective in a pro world because there is less innovation.

Santerre, Rexford E. and John A. Vernon. "Assessing Consumer Gains From A Drug Price Control Policy In The United States," Southern Economic Journal, **2006**, v73(1,Jul), 233-245.

However, over this same time period, Giaccotto, Santerre, and Vernon (2005) estimated that this same **price control regime would have caused firms to reduce pharmaceutical R&D expenditures (in \$2000) by between \$264.5 and \$293.1 billion, because of lower profit expectations and possibly reduced levels of internal funds** (which are the primary source of R&D finance) ¹⁰. **This reduced investment in R&D would have led to approximately 38 percent fewer new drugs being brought to market in the global economy.** If this 38 percent figure is applied to the total number of new chemical entities approved for marketing during this period in the U.S., we can use our simulation results to calculate the average social opportunity cost per new drug.

Healthcare in the United States is expensive in general.

Blumberg, Yoni. "Here's the Real Reason Health Care Costs so Much More in the US." CNBC, CNBC, 3 Sept. **2018**, www.cnbc.com/2018/03/22/the-real-reasonmedical-care-costs-so-much-more-in-the-us.html.

The U.S. is famous for over-spending on health care. The nation spent 17.8 percent of its GDP on health care in 2016. Meanwhile, the average spending of 11 high-income countries assessed in a new report published in the Journal of the American Medical Association — Canada, Germany, Australia, the U.K., Japan, Sweden, France, the Netherlands, Switzerland, Denmark and the U.S. — was only 11.5 percent. Per capita, the U.S. spent \$9,403. That's nearly double what the others spent. This finding offers a new explanation as to why America's spending is so excessive. According to the researchers at the Harvard Chan School, what sets the U.S. apart may be inflated prices across the board. **In the U.S., they point out, drugs are more expensive. Doctors get paid more. Hospital services and diagnostic tests cost more. And a lot more money goes to planning, regulating and managing medical services at the administrative level.**

There are more factors than just drug costs that contribute to high healthcare prices.

Blumberg, Yoni. "Here's the Real Reason Health Care Costs so Much More in the US." CNBC, CNBC, 3 Sept. **2018**, www.cnbc.com/2018/03/22/the-real-reasonmedical-care-costs-so-much-more-in-the-us.html.

The real difference between the American health care system and systems abroad is pricing. Specialists, nurses and primary care doctors all earn significantly more in the U.S. compared to other countries. General physicians in America made an average of \$218,173 in 2016, the report notes, which was **double the average of generalists in the other countries**, where pay ranged from \$86,607 in Sweden to \$154,126 in Germany. **Administrative costs, meanwhile, accounted for 8 percent of total national health expenditures in the U.S. For the other countries, they ranged from 1 percent to 3 percent.** Health care professionals in America also reported a higher level of "administrative burden." A survey showed that a significant portion of doctors call the time they lose to issues surrounding insurance claims and reporting clinical data a major problem

Competition

Since generic medicine manufacturers operate with very small profit margins due to the competitive market, Illinois's price control's bill would drive out manufacturers, worsening competition and leading to higher costs.

Wayne **Winegarden**, 10-22-**2018**,, Forbes, "Pharmaceutical Price Controls Will Not Improve Health Care Outcomes in Illinois",<https://www.forbes.com/sites/econostats/2018/05/17/pharmaceutical-price-controls-will-not-improve-health-care-outcomes-in-illinois/#55f5d28470d5>

The purpose of generic medicines is to enable a competitive market that drives down prices and creates significant budgetary savings. According to the Association for Accessible Medicines, generic medicines in 2016 (the latest data available) have enabled \$9.6 billion in savings for Medicare, Medicaid, commercially insured, and uninsured patients in Illinois alone.

The competitive environment that generic medicines enable also means that these firms will typically operate with very small profit margins. Due to these thin profit margins, HB 4900's price controls are particularly damaging for these manufacturers. Consequently, HB 4900 [a Illinois state bill imposing pharmaceutical price controls] could have the perverse impact of driving out manufacturers. This would worsen the competitive environment and (ironically) lead to higher cost pressures

Accessibility

First, you can delink this argument because Wayne Winegarden of Forbes in 2017 finds 90 percent of drugs dispensed in the U.S. are inexpensive generics, these generics make drugs cheaper in the US than other industrialized countries. This proves that decreased drug access is not due to prices.

Second, if you don't buy that delink you'll buy two: Times in 2016 finds that only 9.1% of Americans are uninsured. That means that 90.9% of Americans can address the issue of high drug prices. Allow insurance companies to achieve their intended purpose by allowing them to help deal with medical costs.

Finally, none of that matters because you can turn the argument. Edward Tate in 2002 explains that empirically, price controls lead to shortages. While insurance helps deal with high drug costs, there is no easy fix when there is not enough necessary meds to go around. Ironically, while the pro tries to increase access, they ultimately lead to less people getting the drugs they need.

Winegarden, Wayne. "Price Controls Will Reduce Innovation and Health Outcomes", Forbes, 12 Oct 2017, <https://www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduce-innovation-and-health-outcomes/#64083a1863a6>

"To start, the price controls would be irrelevant for most patients. Nearly 90 percent of all drugs dispensed in the U.S. in 2016 were generic medicines, according to IMS Health. Therefore, any price control scheme would not apply to the majority of patients who are using inexpensive generics, not more expensive patented products. It is also important to note that generic medicines are significantly cheaper in the U.S. compared to the other major industrialized countries. In fact, total pharmaceutical spending as a percentage of total health care spending is lower in the U.S. (12.2 percent) than the average for the 30 nations that comprise the Organization for Economic Cooperation and Development, or OECD, (16.9 percent). This is due to, in part, the prevalence of generic medicines that are more affordable here than in other OECD nations."

Rovner, Julie. "U.S. Health Insurance Coverage at Record High in 2015 | Money." Time, Time, 13 Sept. 2016, time.com/money/4490196/health-insurance-coverage-census-2015/. Julie Rovner is a Chief Washington Correspondent. She has 16 years of experience as a health policy correspondent for NPR.

The federal health overhaul may still be experiencing implementation problems. But new federal data show it is achieving its main goal — to increase the number of Americans with health insurance coverage. According to the annual report on health insurance coverage from the Census Bureau, the uninsured rate dropped to 9.1%, down from 10.4% in 2014. The number of Americans without insurance also dropped, to 29 million from 33 million the year before. The Census numbers are considered the gold standard for tracking who has insurance and who does not, because its survey samples are so large. It does change methodology from time to time, however (most recently in 2013), so years-long comparisons are not necessarily accurate.

Tate, Edward. "Government Price Controls On Prescription Drugs May be More Than Patients Bargain For", HealthCare Institute of New Jersey, 7 Oct 2002, <http://hinj.org/government-price-controls-on-prescription-drugs-may-be-more-than-patients-bargain-for/>

Another even more important consideration is that price controls stifle innovation and can lead to supply shortages in both the quality and quantity of medications. Consider the recent flu vaccine shortage. The largest purchaser of the vaccine is the federal Vaccines for Children Program. The program buys up nearly 70 percent of all childhood vaccines at government-set prices and then distributes them to states according to a federally-set formula. The end result is that vaccines have been distributed to states where there is no epidemic often leaving a shortage where it is needed. Because the government controls the price, the vaccine makers are discouraged from producing more than what the government orders. Vaccine prices have remained stagnant since 1994. Thanks to these price controls, there now are only four developers of childhood vaccines. That's down from 20 companies just a few years ago."

Black Market

First, you can delink this argument because thinking logically, people will not resort to the black market. Not only do most Americans have insurance, but I certainly would not take illegal drugs, and moreover I have no idea how to access the black market. I don't think I'm alone in saying that

Second, you can non-unique this argument in two ways. Christopher Coyne of the Institute of Economic Affairs in 2015 finds that shortages caused by price controls push people to the black market as well. This means that my opponent have no solvency for their impacts. If you don't buy that, Forbes in 2017 explains that 90% of drugs are affordable generics from smaller companies. These drugs are affordable

Coyne, Christopher, and Rachel Coyne. "Price Controls and the Damage They Cause." IEA, Institute of Economic Affairs, 2015, <iea.org.uk/wp-content/uploads/2016/07/Coyne-Interactive.pdf>

"The emergence of crime and black markets are another indirect negative effect of price controls. Unable to adjust prices legally, producers and buyers may move into the extralegal market to engage in exchange. Others, desperate to obtain goods for which there is a shortage, may engage in theft to obtain goods. To provide one illustration of black market activities, consider the case of farmers in the UK in World War II. Facing wartime meat rationing, many farmers under-reported animal births to the Ministry of Food and then sold the additional meat in the black market."

Winegarden, Wayne. "Price Controls Will Reduce Innovation and Health Outcomes." Forbes, Forbes Magazine, 12 Oct. 2017, www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduce-innovation-and-health-outcomes/#32f4201363a6.

"To start, the price controls would be irrelevant for most patients. Nearly 90 percent of all drugs dispensed in the U.S. in 2016 were generic medicines, according to IMS Health. Therefore, any price control scheme would not apply to the majority of patients who are using inexpensive generics, not more expensive patented products. It is also important to note that generic medicines are significantly cheaper in the U.S. compared to the other major industrialized countries. In fact, total pharmaceutical spending as a percentage of total health care spending is lower in the U.S. (12.2 percent) than the average for the 30 nations that comprise the Organization for Economic Cooperation and Development, or OECD, (16.9 percent). This is due to, in part, the prevalence of generic medicines that are more affordable here than in other OECD nations."