NHSDLC Fall 2020: Advanced Research Packet

Resolved: Countries should not impose price controls on pharmaceutical companies.

Academic Committee of the NHSDLC *

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Contents

1 Letter from the Directors

We're excited to be releasing a supplemental research packet in addition to the main research packet. Intended as a supplement with some more advanced articles and cards, this packet contains several more background, Pro, and Con cards that are a little more advanced. Don't let this scare you! Several of the cards are somewhat lengthy but worth the read.

This is not a standalone research packet as it does not contain any of the information or articles from the main research packet. Instead, it is intended to supplement the main research packet. Therefore, it is **highly recommended** that debaters begin by reading the Main Research Packet before reading beginning this supplemental research packet. Remember: this is a supplement. You do not need to read it. But it will greatly advantage you if you read this because many of your competitors will probably read it.

One thing to keep in mind, this introduction is **not** to be cited as an authoritative source in debate rounds. In other rounds, you should not cite "The Research Packet" in debate rounds. You may cite the articles contained in the research packet and use this Introduction as a springboard for ideas, but you should not cite it as a credible source in and of itself. Most of the evidence in this research packet is formatted in the form of "cards". A **card** refers to a section or portion of evidence cut from an article that is used as evidence in a case or "blocks". The is from a time before computers when debaters would hand write their sources on an index card.

Every card begins with a **tagline**, a brief introduction to the article used in the card. Additionally it includes a full citation with at least the title of the study, the author(s) name and qualifications, and the source and year of publication.

We hope that this research packet helps debaters conceptualize the arguments, aid in cutting cards, and writing blocks. We are looking forward to to see you debate at the upcoming tournaments.

Good luck!

2 Pro Evidence

2.1 Innovation

2.1.1 The Chemical Industry Model

Price controls create a chemical industry model — that slashes RD budgets by 80%

Robert J. Easton (Co-chairman of Bionest Partners, a global medical business consultancy serving pharmaceutical, medical device, and diagnostic firms and their investors). *"Price controls would stifle innovation in the pharmaceutical industry."* Stat News. 22 January 2018. https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/

If price controls pressure the U.S. industry into a more conventional process industry model, like that of the chemical industry, pharmaceutical RD budgets would be slashed. To achieve the chemical industry's rate of RD spending, as would be required to achieve profitability competitive with the chemical industry, top pharmaceutical companies would have to reduce their RD 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 bio pharmaceutical 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 RD.

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.

2.1.2 Cost

Developing new products is expensive and risky — only high PLS profits enable RD sufficient to innovate

Robert D. Atkinson (President of the Information Technology and Innovation Foundation). *"Drug price controls will be more pain than gain."* The Hill. 10 November 2018. https://thehill.com/opinion/healthcare/416068-drug-price-controls-will-be-more-pain-than-gain

Developing a new pharmaceutical compound takes an average of 12 to 14 years of

research, development and clinical trials at a cost of about $2.6 billion. That's why the U.S. life-sciences sector invests more than 21 percent of its revenues in RD — over $56 billion in 2014, according to the latest data from the National Science Foundation.

Drug revenues enable that investment. Indeed, the Organization for Economic Co-operation and Development has found there is almost a one-to-one correlation (0.97) between drug sales revenues and RD expenditures and economists have repeatedly found the connection extends to pharmaceutical output, too. The inverse also will be true: If bio-pharma companies' revenues decline because of price controls or other policy measures, their RD also will decline and the pace of drug innovation will falter.

So, the debate about price controls isn't really about whether to lower prices at drug companies' expense. It's about whether society should lower drug prices now in exchange for less and slower drug innovation for our children.

2.1.3 The European Union

Price controls harm RD innovation – this leads to fewer products being introduced, which turns cost arguments. The EU proves

Wayne Winegarden (Senior Fellow in Business and Economics at the Pacific Research Institute and the Director of PRI's Center for Medical Economics and Innovation). *"Price Controls Are Not The Answer To Expensive Drugs."* Forbes. 18 October 2019. https://www.forbes.com/sites/waynewinegarden/2019/10/18/price-controls-are-not-the-answer-to-expensive-drugs/30cc9e97715e

The advocates of price controls now are targeting the pharmaceutical industry with these ill-considered policies. Take H.R. 3, the Lower Drug Costs Now Act. As the name implies, the bill's proponents hope to lower the cost of drugs by empowering the Centers for Medicare Medicaid Services (CMS) to negotiate prices on certain drugs. Manufacturers who refused to negotiate with the government would face a 95% tax on sales revenue (not profits). Such a lopsided structure is not a negotiation, it is the government mandating a price regardless of its economic viability.

The consequences from implementing price controls on the pharmaceutical industry will be no different than the consequences that occurred in the grain or housing markets. But, one does not even have to look toward these markets to see the consequences. Just look to the European Union's drug industry, where pharmaceutical price controls were implemented two decades ago.

Before its price controls, EU firms were the global leaders in bio pharmaceutical innovation. Since the implementation of price controls, research spending in the EU has stagnated, much of it diverting to the U.S. where price controls do not

exist. Over time, these diverging trends have enabled the U.S. to become the global innovation leader.

As a result, the EU has endured many adverse consequences. Access to existing medicines have faltered. While the U.S. has access to nearly 90% of newly launched medicines, patients in Germany only have access to 71%. In France, the access rate is even lower at 48%.

By some estimates, the RD slowdown has led to 46 fewer medicines being introduced into the marketplace. The actual costs to patients (worldwide) from not having access to new (possibly better) treatments is unknowable. The lost savings potential these medicines could have created, by avoiding the need for other more expensive health care treatments (e.g. surgeries), is also unknowable. The EU has also faced economic consequences as the lost RD activity has cost the EU nearly 1,700 high paying research jobs. History clearly illustrates that government mandated prices create more harm than good. Should drug price controls, such as H.R. 3, be implemented, the U.S. will not be exempt from the adverse consequences. Instead, access will be reduced, innovation will suffer, and the economy will be less vibrant.

Price controls harm innovation — EU proves

Doug Badger (Visiting Fellow in Domestic Policy Studies at the Heritage Foundation). *"Why Pelosi's Drug Price Control Scheme Would Be a Poison Pill to Innovation and Access."* Heritage Foundation. 24 September 2019. https://www.heritage.org/health-care-reform/commentary/why- pelosis-drug-price-control-scheme-would-be-poison-pill-innovation

Hindering Innovation Countries with price controls also suffer a decline in pharmaceutical research and development.

In 1986, European firms led the U.S. in spending on pharmaceutical research and development by 24%. After the imposition of price control regimes, they fell behind. By 2015, they lagged the U.S. by 40%.

If the U.S. emulates the European price-setting example, innovation here almost certainly will suffer. Trading innovation and access to new medicines in exchange for lower prices on existing products may strike some as a good deal. But according to the president's Council of Economic Advisers, it wouldn't be.

The council concluded that while price controls might save money in the short term, they would cost more money in the long run. Government price-setting, it wrote, "makes better health care costlier in the future by curtailing innovation."

2.1.4 Historical Experiences

History proves — price controls, in any industry, harm product quality and lead to shortages.

Wayne Winegarden (Senior Fellow in Business and Economics at the Pacific Research Institute and the Director of PRI's Center for Medical Economics and Innovation). "Price Controls Are Not The Answer To Expensive Drugs." Forbes. 18 October 2019. https://www.forbes.com/sites/waynewinegarden/2019/10/18/price-controls-are-not-the-answer-to-expensive-drugs/30cc9e97715e

Others preach that, instead of a complete government takeover of the health care system, the best way to lower the cost of health care is through increased government regulations. These piecemeal proposals will identify a specific problem that plagues the health care system, and then offer targeted government programs to address each one. Take the cost of medicine. In response to the high cost of branded and originator biologic medicines, there has been a bipartisan push to impose price controls on drugs. Here too, history argues that the big-government approach will disappoint its proponents. In post-revolution France, for instance, the government imposed grain price controls to ease the pain from the grain shortages that were plaguing the country. The price controls not only failed to alleviate the problem, they worsened the shortages and helped create an even greater economic crisis. Rent control policies also exemplify the adverse consequences from government mandated pricing. The purpose of rent control is to expand the availability of affordable housing. The actual consequences, as exemplified by cities like New York and San Francisco, are housing shortages and sharp declines in housing quality. No matter where they have been tried, price controls have always made bad situations worse because it is impossible for policymakers to have the necessary knowledge to dynamically set the efficient price level. Just as all of these past price control experiments ended up making a bad situation worse, applying price controls to the U.S. health care sector will further reduce the quality of care and create inequitable outcomes.

2.1.5 Political Risk

Price controls create political risks for companies seeking to innovate — that alone deters RD

Wall Street Journal Editorial Board. "The Drug Price-Control Threat." Wall Street Journal. 8 January 2019. https://www.wsj.com/articles/the-drug-price-control-threat-11546909348

European countries make trade-offs that are severe but often not transparent. Britain's National Health Service routinely puts conditions on which patients can receive oncology drugs, for instance. Some drugs are denied approval on grounds that they don't produce results worth the cost, a judgment most American patients might prefer to make themselves. The Food and Drug Administration doesn't consider cost, at least not explicitly.

Price controls in Europe mean drug companies must recoup most of their investment in the U.S. market. But the Sanders bill wants drug developers to spend years and

take extraordinary risk to develop drugs, even as government could invalidate their patents on a political whim. This new political risk means less capital for drug development.

2.1.6 Spillover

Private innovations spill over to other companies and the public domain, leading to further innovation.

Robert D. Atkinson (president of the Information Technology and Innovation Foundation). "Drug price controls will be more pain than gain." The Hill. 10 November 2018. https://thehill.com/opinion/healthcare/416068-drug-price-controls-will-be-more-pain-than-gain

Finally, the industry is a prolific contributor to open science through publications in science journals. In fact, the largest number of partnerships between corporations and academic institutions in the 2016 Nature Index was in the life sciences — 13,114 collaborations. One reason for this is intellectual property protection. By obtaining patents for their drugs, companies are more assured their discoveries will be protected, thus lowering the risk of direct copying from information being shared in scholarly journals. The Information Technology and Innovation Foundation examined the top 93 companies that, in 2016, accounted for 76 percent of global life science RD. In 2017, researchers from these companies were authors or coauthors of 12,792 papers, many in leading journals such as the Proceedings of the National Academy of Sciences, Nature, Cancer Cell and Nature Medicine. That was up from 8,322 papers in 2007 — an increase of 54 percent. This works out to 116 articles for every $1 billion of RD invested and 8.8 articles per 1,000 employees. To be sure, this is less than the 95,000 peer-reviewed journal articles published by researchers who had received NIH funding. But given that the vast majority of NIH recipients are academic scholars whose bread and butter are peer-reviewed journal articles, it is not surprising this number is as high as it is. What is perhaps more surprising is that the industry numbers are 13.4 percent of NIH's numbers. Biomedical innovation is critical to addressing human health challenges. And a healthy life-sciences innovation system depends on robust funding of biomedical RD, both public and private. Not only are drug company revenues strongly correlated with the amount of RD they invest in, but much of the RD they fund spills over both to other firms and to the public domain, thereby helping to spur even more life-sciences innovation. Price controls and other steps to reduce revenues, like weakening intellectual property protection, would stifle knowledge generation and sharing, leaving future generations less access to effective new drugs than would otherwise be the case.

2.1.7 US Key

Maintaining a deregulated US market is key

Sally C. Pipes (president, CEO, and Thomas W. Smith Fellow in Health Care Policy at the Pacific Research Institute). "Executive Order On Drug Price Controls Would Backfire." Forbes. 22 July 2020. https://www.pacificresearch.org/executive-order-on-drug-price-controls-would-backfire/

There are better ways to shrink the gap between U.S. and European drug prices—ones that don't involve government price-setting. The anticipated executive order would specifically tie U.S. drug prices to an "International Pricing Index"—an average of the prices paid in a set of reference countries. These nations all have fully- or partly-socialized healthcare systems that cap the price of medicines. Moving forward with this measure would prove disastrous for U.S. innovation. The United States leads the world in research and development, producing nearly two-thirds of all new medicines precisely because our healthcare system rejects price controls and incentivizes innovation. Successfully bringing a new drug from the lab to pharmacy shelves is a process riddled with risks. The average research and development venture demands an investment of more than $2 billion over the course of a decade. Just 12% of experimental treatments that enter clinical trials ultimately secure FDA approval. To remain viable, bio-pharmaceutical companies have to price their creations that make it to the marketplace in a way that reflects these risks. They thus rely heavily on the U.S. market, where patients and doctors value medicines and the improvements they bring. Sales in price-controlled countries yield marginal revenue at best.

2.1.8 AT: Bias

Bias goes the other way – it's populist Wall Street Journal Editorial Board. "The Drug Price-Control Threat." Wall Street Journal. 8 January 2019. https://www.wsj.com/articles/the-drug-price-control-threat-11546909348

Mrs. Warren wants government to solve drug shortages created in part by government. Some hospital drugs are often in short supply because making these drugs in sterile facilities is expensive and difficult, yet government basically reimburses these drugs at cost. This means only large companies have the economies of scale to make the drugs, and even they sometimes can't make money. If one of these companies stops producing the drug, a third of the supply can dry up. Government could agree to pay more than cost for the drugs. But "higher reimbursement rates for certain generic drugs" is not a winning political line, which explains the bipartisan glibness on high drug prices. Mrs. Warren's new government drug manufacturer would undercut every generic producer on the market, which would reduce the reason to bring any drug to market. This "populism" would result in higher prices. This is only one of the ways in which a left-right condominium might do economic damage in the next Congress. Patients who want affordable medicine and faster cures need to fight back with a populist campaign of their own.

2.1.9 AT: Companies Hide Discoveries

Biopharma research does spill over — data

Robert D. Atkinson (president of the Information Technology and Innovation Foundation). "Drug price controls will be more pain than gain." The Hill. 10 November 2018. https://thehill.com/opinion/healthcare/416068-drug-price-controls-will-be-more-pain-than-gain

One aspect of the U.S. bio-pharma industry that many advocates of price controls overlook is the extent to which the industry contributes to the global "commons" of knowledge development. In their view, drug research only benefits the companies doing the research, so the consequences of any reduction in RD that may come with price controls aren't likely to be all that bad. But the evidence shows otherwise. Even though new discoveries are protected with trade secrets and patents — which provides the incentive for drug companies to assume the risks involved in developing a new drug — a considerable share of bio-pharma industry research spills over, contributing to knowledge discovery and drug development overall, not just in the labs of the firms that conduct the research. In fact, these knowledge spillovers are very much like public knowledge generated by government agencies such as the National Institutes of Health. This knowledge dissemination occurs in three main ways. First, many of the benefits of firm-level RD spill out to the rest of the industry. In fact, economists Nicholas Bloom, Mark Schankerman and John Van Reenen find that spillovers are significantly greater in large bio-pharma firms compared with smaller ones, because the latter "tend to operate in technological 'niches'" where fewer other firms operate. The industry also supports broader knowledge generation at American universities. While it accounts for 16.8 percent of U.S. business RD, it accounts for 61 percent of business RD funding for universities. In 2016 bio-pharma companies provided over $2.5 billion in life sciences research funding to universities in all 50 states, ranging from $366,000 in Maine to $329 million in California.

2.1.10 AT: Foreign Reference Pricing

Foreign reference pricing is a de facto price control — harms innovation, treatments, and cures

Sally C. Pipes (president, CEO, and Thomas W. Smith Fellow in Health Care Policy at the Pacific Research Institute). "Executive Order On Drug Price Controls Would Backfire." Forbes. 22 July 2020. https://www.pacificresearch.org/executive-order-on-drug-price-controls-would-backfire/

Rumor has it that President Trump will soon issue a sweeping executive order to lower prescription drug prices by fiat.

Nothing is set in stone. But the order would reportedly index the government's reimbursements for medicines to the prices that Britain, France, Canada, and other

developed nations pay. Since all those nations use various forms of price caps to suppress the cost of medicines, this "reference pricing" order would function as a *de facto* price control.

President Trump is right to think it's unfair that Americans pay more for drugs than people in other rich nations. But the order wouldn't make American patients' lives any better. Everywhere they've been tried, price controls have reduced bio pharmaceutical research spending, resulting in fewer vaccines, therapeutics, and cures.

2.2 Economy

2.2.1 Jobs

Price controls would cost drug makers over $1 trillion in a decade, in the US alone. That costs 700,000 US jobs

Thomas J. Donohue (chief executive officer of the U.S. Chamber of Commerce). "The Real Cost of Drug Price Controls." U.S. Chamber of Commerce. 21 October 2019. https://www.uschamber.com/series/above-the-fold/the-real-cost-of-drug-price-controls

The U.S. is the medical innovation capital of the world – but a new bill in Congress could change that. In the next few weeks, the U.S. House of Representatives is expected to pass the Lower Drug Costs Now Act, legislation that some claim would rein in the cost of prescription drugs by allowing the government to set prices. In reality, however, this legislation would endanger the livelihoods of hundreds of thousands of Americans and cut off medical research dollars that are essential to finding cures for diseases like cancer and Alzheimer's. According to recent estimates, the House proposal would cost drug makers approximately $1 trillion over the next decade, forcing them to drastically reduce investments in RD. This cost-cutting would lead to fewer workers and ultimately fewer treatment options for families in need. The U.S. bio-pharmaceutical industry directly employs more than 800,000 workers. And the industry supports an additional 3 million jobs in various sectors, ranging from construction (building labs) to business services (sales, marketing, and administrative support). In total, the proposal could result in the loss of over 700,000 jobs. While every state would be impacted, some would see greater job losses than others, including California, Texas, and New Jersey.

2.2.2 Small Businesses

Price fixing causes small business closures.

Karen Kerrigan (president and CEO of the Small Business Entrepreneurship Council). "Prescription drug costs are spiraling, but price controls are the wrong solution." Fortune. 18 April 2020. https://fortune.com/2020/04/18/prescription-drug-prices-costs-policy/

Unfortunately, the Wyden-Grassley blunt force approach would impact more than innovative cures and U.S. drug leadership. In 2017 alone, biopharmaceutical firms directly employed over 811,000 people and supported 3.2 million additional jobs, per a report from PhRMA and TEConomy Partners. The industry could potentially see large job losses as a result of the legislation. That's the last thing these firms need when small businesses are suffering under the economic impacts of COVID-19, with many expected to go under and at rates that will surely shock us once the damage is totaled. A little over half of pharmaceutical firms have fewer than 20 workers,

and about four in five have fewer than 100, according to census data analyzed by the Small Business Entrepreneurship Council. Drug innovation as we know it depends on small, entrepreneurial businesses that bring life-saving drugs to the market. They need certainty, and a policy ecosystem that encourages risk taking and investment. These businesses would flounder if the Wyden-Grassley bill became law. The less money companies have to spend on research, the fewer people they can employ. Nearly half of drug firms say that reductions in research and development spending could lead to layoffs and facility closures, according to a survey of PhRMA members.

2.3 Treatments

2.3.1 Access

Price controls result in less access to treatments. Comparing between nations with and without them proves

Thomas J. Donohue (chief executive officer of the U.S. Chamber of Commerce). "The Real Cost of Drug Price Controls." U.S. Chamber of Commerce. 21 October 2019. https://www.uschamber.com/series/above-the-fold/the-real-cost-of-drug-price-controls

Even more troubling, this plan would likely result in Americans having access to fewer treatments. Of all the new medicines launched across the world between 2011 and 2018, 90% are available in the U.S. But many of these new drugs are not available in countries with government price controls. In fact, only 50% of these drugs are available in France, and only 46% of them are available in Canada. If this legislation were to become law, American workers who like their employer-sponsored health care plans would find they have increasingly diminished access to the latest and most innovative treatments.

2.3.2 COVID-19

Price fixing harms our ability to respond to deadly pathogens — like Covid-19

Karen Kerrigan (president and CEO of the Small Business Entrepreneurship Council). "Prescription drug costs are spiraling, but price controls are the wrong solution." Fortune. 18 April 2020. https://fortune.com/2020/04/18/prescription-drug-prices-costs-policy/

I have good reason for my opposition to the Wyden-Grassley legislation. Unfortunately, there are too many instances where government command-and-control "solutions" have gone horribly wrong, especially with price controls. The Wyden-Grassley proposal offers a massive expansion of government power. The bill would slap *de facto* price controls on drug manufacturers by forcing companies to pay Medicare back for price increases past the rate of inflation. That could drain the industry of a staggering $50 billion over the next decade if it becomes law, according to a Congressional Budget Office score. We've already seen what government price-setting has done to research companies in Europe. Half a century ago, European labs invented the vast majority of medicines, according to a Milken Institute study. That is not the case currently. European governments have imposed ever-stricter price controls over the course of time, which has contributed to the decline of RD in Europe. The U.S., by contrast, has largely maintained its market-based approach. That very approach is why companies in America are leading the way on a COVID-19 treatment. Moderna, a small biotech based in Massachusetts, entered human

trials for its COVID-19 vaccine only 10 weeks after the virus's genetic code was sequenced, according to a Guardian report. Thanks to the U.S.'s robust intellectual property protections for innovative therapies, as well as how highly valued they are in the marketplace, American scientists are able to attract significant private capital for the development of new medicines. As a result, two in three new medicines are developed in the U.S.

2.3.3 Death

Hindering access to care costs thousands of life years

Doug Badger (Visiting Fellow in Domestic Policy Studies at the Heritage Foundation). *"Why Pelosi's Drug Price Control Scheme Would Be a Poison Pill to Innovation and Access."* Heritage Foundation. 24 September 2019. https://www.heritage.org/health-care-reform/commentary/why- pelosis-drug-price-control-scheme-would-be-poison-pill-innovation

Major Impact on Access to Care Proponents of H.R. 3 claim that it would have no adverse effect on innovation or on access to pharmaceuticals. But aggressive government price-setting has damaged innovation and limited access to new treatments in all six of the countries whose price controls the bill would import. If the U.S. adopts price controls, it risks the same results here. Access to new drugs is much greater in the U.S. than in countries with price controls, in part because of having shunned price controls. Of new active substances introduced between 2011 and 2018, 89% are available to Americans, compared with 62% in Germany and 60% in the United Kingdom. One-half or more of these new therapies are unavailable to Australian, Canadian, French, and Japanese patients. This lack of access can have damaging effects. A study by IHS Markit examined outcomes for non-small cell lung cancer, the leading cause of cancer mortality in the U.S. and the world. The report compared how Americans with that disease fared, compared with citizens of other highly developed countries, including Australia, Canada, France, and the U.K. The study concluded that Americans gained 201,700 life years as a result of faster access to new medicines. Half those gains would have been wiped out, the study found, if Americans had the same limited access to those treatments as patients in other countries. Patients will be worse off if Washington emulates the price control regimes of foreign governments.

2.3.4 Diseases

Pharma innovation has been critical in reducing deaths from heart disease, leukemia, AIDS, Hepatitis C, melanoma, and so forth. Continuing innovation is key to solve Alzheimer's, diabetes, anti-biotic resistant bacterial diseases, and more — but price controls hinder that

Robert J. Easton (Co-chairman of Bionest Partners, a global medical business

consultancy serving pharmaceutical, medical device, and diagnostic firms and their investors). "Price controls would stifle innovation in the pharmaceutical industry." Stat News. 22 January 2018. https://www.statnews.com/2018/01/22/price-controls-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. 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. 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 RD and commercial operations in the U.S. to take advantage of its pricing environment.

It disincentivizes innovation against orphan and complex diseases

Robert J. Easton (Co-chairman of Bionest Partners, a global medical business consultancy serving pharmaceutical, medical device, and diagnostic firms and their investors). "Price controls would stifle innovation in the pharmaceutical indus-

try." Stat News. 22 January 2018. https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/

Squeezing pharmaceutical RD spending down to one-fifth of what it is today would also have an enormous impact on the problems that drug developers often choose to address. Orphan diseases would be deprioritized, as the returns under price controls would not warrant the investment. Complex diseases would also be deselected. While Alzheimer's disease and diabetes have huge patient populations, the extremely high cost of conducting the difficult research and the need for huge and complex clinical trials would dissuade all but the largest companies from pursuing those illnesses if the potential pricing upside was to be significantly constrained. Moreover, for difficult diseases like schizophrenia, where today's treatments are mostly inadequate, the flow of more effective new treatments would slow from a trickle to a rivulet, depriving those with these conditions from the possibility of relief. The upshot is simple. Forcing drug prices down would surely shave a few percentage points off what we spend on health care today. By 2032, drug prices could be half of what they are today, as every drug would be a generic. But our ability to treat or cure the many serious diseases that still afflict us will have been crippled and squandered. In my view that is terrible policy.

As well as cancer, heart disease, and novel pathogens

Sally C. Pipes (president, CEO, and Thomas W. Smith Fellow in Health Care Policy at the Pacific Research Institute). "Executive Order On Drug Price Controls Would Backfire." Forbes. 22 July 2020. https://www.pacificresearch.org/executive-order-on-drug-price-controls-would-backfire/

If the United States adopts de facto price controls through foreign reference pricing, those that fund biomedical research won't sign on for risky development projects. According to estimates from the Congressional Budget Office, reference pricing and other similar price control measures could reduce revenues at research firms by $1 trillion over the next decade. That precipitous drop in revenue would hamper firms' ability to develop innovative treatments. On average, companies allocate 15% to 20% of their revenue to research and development. Implementing a reference pricing measure would wipe out tens, even hundreds, of billions of dollars in research spending over the next decade.

Potential treatments for cancer, heart disease, Alzheimer's, and other debilitating conditions would never come to fruition. Promising research into safe, effective treatments and vaccines against the coronavirus could stall. We'd be woefully unprepared to respond to future waves and mutations of the virus—not to mention the next novel pathogen.

2.4 Government Control

Price controls create an unprecedented expansion of governmental power

Doug Badger (Visiting Fellow in Domestic Policy Studies at the Heritage Foundation). *"Why Pelosi's Drug Price Control Scheme Would Be a Poison Pill to Innovation and Access."* Heritage Foundation. 24 September 2019.
https://www.heritage.org/health-care-reform/commentary/why- pelosis-drug-price-control-scheme-would-be-poison-pill-innovation

Unprecedented Government Power The bill represents an unprecedented exercise of raw government power. The federal government already imposes price curbs across a range of programs, requiring manufacturers to pay the government rebates in Medicaid and the "340B" program, and discounts in Medicare, as well as to make various price concessions in the Veterans Affairs health system. These provisions all are confined to federal programs, but nonetheless have distorted drug prices throughout the health sector. It's one thing for the government to dictate the prices it pays in programs it finances. It is quite another for the government to impose a price for a product's private sale and to extract money from a company on a long-ago settled transaction

2.5 AT: Drug Costs

2.5.1 AT: Insulin

Insulin market dysfunction is caused by the difference between list and net price. Price controls are the wrong solution

Wall Street Journal Editorial Board. "The Drug Price-Control Threat." Wall Street Journal. 8 January 2019. https://www.wsj.com/articles/the-drug-price-control-threat-11546909348

What started as crank progressive politics is becoming a litmus test for 2020 Democratic presidential aspirants. Senator Elizabeth Warren waded in recently with a bill to let the government manufacture generic drugs, which are the commodity version of a branded product. This is shooting at the wrong target, given that generic drugs represent 90% of prescriptions yet less than 25% of prescription drug costs. Mrs. Warren says the government would step in to correct certain market failures—like shortages or a sudden price spike. For example, her bill directs the government to produce a generic insulin. Insulin is always at the center of the debate about drug prices because it seems outrageous that a drug discovered 100 years ago isn't cheaper. Yet the dysfunction in insulin markets is driven by a disconnect between the medicine's list price, which increases every year, and the net price after rebates and discounts, which has held nearly flat. The difference is paid by patients who aren't insured or who pay co-insurance calculated on list prices.

2.5.2 Crapo Bill Solves

Crapo's bill is better. Capping out-of-pocket suspending maintains incentives for innovation while reducing drug prices.

Karen Kerrigan (president and CEO of the Small Business Entrepreneurship Council). "Prescription drug costs are spiraling, but price controls are the wrong solution." Fortune. 18 April 2020. https://fortune.com/2020/04/18/prescription-drug-prices-costs-policy/

Fortunately, Crapo has proposed a strong alternative. The Lower Costs, More Cures Act would cap out-of-pocket spending for Medicare beneficiaries at $3,100 a year. The bill would also allow patients to pay their drug bills in monthly installments, rather than all at once. This approach would make a big difference to patients facing costly copays or other out-of-pocket liabilities. Most importantly, unlike the Wyden-Grassley bill, Crapo's proposal would not resort to statist price-setting. That's good news for American business. Unsurprisingly, the U.S. Chamber of Commerce has strongly endorsed this bill. High out-of-pocket drug costs are a serious problem. But mimicking Europe's failed policies by resorting to price controls is not the answer.

2.5.3 Markets Solve

Removing market barriers to medicines best achieves dual goals of innovation and affordability.

Wayne Winegarden (Senior Fellow in Business and Economics at the Pacific Research Institute and the Director of PRI's Center for Medical Economics and Innovation). "Price Controls Are Not The Answer To Expensive Drugs." Forbes. 18 October 2019. https://www.forbes.com/sites/waynewinegarden/2019/10/18/price-controls-are-not-the-answer-to-expensive-drugs/30cc9e97715e

In contrast to this government approach, as I have discussed here, there is a better way. Too many market barriers currently exist that are inhibiting a more competitive market for medicines (particularly the high-cost biologic medicines) to develop. The best way to achieve the dual goals of incenting innovation and promoting affordability is to remove these barriers and empower a competitive market to directly lower the costs of medicines.

2.5.4 Other Alternatives

Price transparency and fairer trade agreements solve.

Sally C. Pipes (president, CEO, and Thomas W. Smith Fellow in Health Care Policy at the Pacific Research Institute). "Executive Order On Drug Price Controls Would Backfire." Forbes. 22 July 2020. https://www.pacificresearch.org/executive-order-on-drug-price-controls-would-backfire/

President Trump isn't wrong to worry about the gap between U.S. and foreign drug prices. But there are ways to lower drug prices and prevent other countries from shirking their fair share of the research burden without jeopardizing medical advances. He can start by injecting transparency into the pharmaceutical market in the United States. Right now, insurance companies hire "pharmacy benefit managers" to help design their drug plans. PBMs clandestinely negotiate with manufacturers over whether to include drugs on formularies —the insurers' lists of covered drugs—and at what price. PBMs use this leverage to secure tens of billions of dollars' worth of secret rebates from drug makers. They keep some for themselves and share the rest with the insurers, who ostensibly pass along a portion of those savings to beneficiaries in the form of modestly lower premiums. Fortunately, the administration is considering another executive order that would rein in PBMs. The best approach would require these middlemen to disclose the negotiated rebates and pass savings directly along to patients at the point of sale would substantially reduce many patients' pharmacy bills, without reducing the total revenue going to researchers. The president and his aides could also negotiate fairer trade agreements that prevent foreign freeloading. He can begin by appointing a special bio-pharmaceutical negotiator with the U.S. Trade Representative, who can help

ensure that nations value U.S. medicines appropriately. Right now, in the midst of a pandemic, the world needs medical breakthroughs more than ever. An executive order enforcing foreign price controls at home would only harm the very patients the president seeks to help.

3 Con Evidence

3.1 AT: Innovation

3.1.1 Bias

Their innovation args are just pharma lobbying – don't trust them

Merrill Goozner (Editor of Modern Healthcare from December 2012 to April 2017). "Editorial: Drug price controls? A good idea, but don't bet on it." Modern Healthcare. 1 November 2018. https://www.modernhealthcare.com/article/20181101/NEWS/181109993/editorial-drug-price-controls-a-good-idea-dont-bet-on-it

Pity the poor pharmaceutical industry. Now even the Trump administration backs price controls to contain the unconscionably high cost of specialty drugs. They never used the words "price controls" in announcing their plan in late October. But what else should one call a proposal that would peg Medicare's Part B drug payments to the prices negotiated by foreign buyers of the same products? It would defy political logic for the Trump administration to give the CMS the authority to negotiate drug prices, which is a Democratic proposal. Instead, HHS Secretary Alex Azar embraced letting foreign healthcare bureaucrats do the negotiating, even as he and the president deride them as free riders. I am skeptical that anything even remotely resembling HHS' latest plan to lower spending on Part B drugs will get enacted. As Azar noted at a Brookings Institution forum, the proposal was contained in an advanced notice of proposed rulemaking. That's inside-the-beltway speak for giving Big Pharma lobbyists much of the next year to defang if not totally derail this pre-election embrace of price controls. Don't look for the next Congress to enact this either. Most Democrats, like their Republican colleagues, take tons of pharmaceutical industry cash. Once the heat of the campaign dissipates, a majority in both parties will remain susceptible to their main argument that high prices are necessary to promote innovation.

Data claiming high cost of pharma developing is industry funded and misleading.

Michael Wornow (PhD student in Computer Science, Stanford University). "Just What the Doctor Ordered: The Case for Drug Price Controls." Harvard Political Review. 2 December 2018.https://harvardpolitics.com/united-states/just-what-the-doctor-ordered-the-case-for-drug-price-controls/

Skeptics of price controls, however, often counter that artificial price caps will be "harmful to Americans' future health" by reducing the ability of pharmaceutical companies to invest in high-risk, high-reward drug development research. The high prices of drugs are therefore viewed as a "necessary evil" to ensure the continued development of novel therapies. A closer look at the numbers, however, tells a much

different story — one often distorted by pharmaceutical companies with conflicting financial interests. For example, one of the most cited academic studies regarding high drug development costs, a 2014 study from Tufts University, claims that the average drug takes over $2.6 billion and 10 years to develop. According to Professor of Health Policy Dr. Catherine DeAngelis, however, the study was deeply flawed: not only did pharmaceutical companies provide the funding and data, but the study also double counted the opportunity cost — the theoretical cost incurred by not having invested that capital in other ventures — of developing a novel drug. The New York Times also pointed out that the study focused entirely on the in-house development of "new molecular entities" (NMEs), the most expensive type of drug to develop. Generalizing this misrepresented the typical drug development pipeline, as NMEs are a small minority of the drugs approved annually by the FDA, and public research funding through institutes like the NIH defrays a large portion of most drugs' early development costs.

Drug companies aren't unique and their data is distorted. This ev comprehensively answers every aff arg

Ezekiel J. Emanuel (oncologist, a bioethicist, and a vice provost of the University of Pennsylvania). "Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up." The Atlantic. 23 March 2019. https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/

Drug companies tend to say they are unique in needing to spend a higher proportion of their capital on research than almost any other industry. But of all the companies in the world, the one that invests the most in research and development is not a drug company. It's Amazon. The online retailer spends about $20 billion a year on RD, despite being renowned for both low prices and low profits. Among the 25 worldwide companies that spend the most on research and development—all more than $5 billion a year—seven are pharmaceutical manufacturers, but eight are automobile or automobile-parts companies with profit margins under 10 percent. Amazon's operating margin is under 5 percent. Meanwhile, the top 25 pharmaceutical companies reported a "healthy average operating margin of 22 percent" at the end of 2017, according to an analysis by GlobalData. If you watch television, you know part of the answer to where this extra money is going: sales and advertising. Of the 10 largest pharmaceutical companies, only one spends more on research than on marketing its products. But it's hard to figure out what it actually costs drug companies to conduct the research required to get FDA approval and bring a single drug to market. The pharmaceutical industry and its advocates tend to peg the cost of creating and bringing to market just one new drug at $2.6 billion. This figure comes from a cost report published in October 2016 by the Tufts Center for the Study of Drug Development. There are several reasons to suspect that number is unreliable. According to the Tufts Center's website, more than a quarter of its budget comes from "unrestricted grants" from pharmaceutical companies

and their partners. And no one can verify Tufts' analyses and claims: The authors say the data come from research spending on 106 drugs produced by 10 of the top 50 multinational pharmaceutical companies, but the underlying data are deemed proprietary and confidential. Tufts also uses a cost-accounting methodology that appears to significantly inflate its estimate. About 45 percent of Tufts' $2.6 billion figure is attributed to the amount companies would pay to lenders and shareholders for the capital they invest in research. Tufts uses an interest rate of 10.5 percent a year, but investment bankers tend to use just 6 percent in their economic models. That one change would reduce the Tufts estimate by about a quarter of its total figure. That's not to mention other factors the Tufts team leaves out that reduce the cost of drug development, such as tax credits the federal government offers for research and development. When asked about these issues, the report's chief author, Joseph DiMasi, noted that one other study with public data, published in 2009, comes to similar results. He argues that even if we exclude the cost of capital, $1.4 billion per FDA-approved drug is a high price—and the cost has been growing at about 8.5 percent annually. But in November 2017, a study published in JAMA Internal Medicine examined the costs of developing 10 cancer drugs approved by the FDA from 2006 to 2015 and provided a strong contrast to the Tufts study from a year before. Its authors, from Memorial Sloan Kettering and the Oregon Health and Science University, used annual financial disclosures from the Securities and Exchange Commission for companies that had only one cancer drug approved but had on average three or four other drugs in development. They found that companies took an average of 7.3 years to win FDA approval, at a median cost of $648 million. Only two drugs had research costs over $1 billion. Adding in the cost of capital at 7 percent increased the median research and development cost to $757 million—less than a third of the Tufts estimate. Pharmaceutical companies often claim that the research costs of unsuccessful drugs also have to be taken into account. After all, 90 percent of all drugs that enter human testing fail. But most of these failures occur early and at relatively low costs. About 40 percent of drugs fail in preliminary Phase I studies, which assess a drug's safety in humans and typically cost just $25 million a drug. Of the drugs that clear this first phase of testing, about 70 percent fail during Phase II studies, which assess whether a drug does what it is supposed to do. The research costs of these studies are still relatively low compared with overall RD costs—on average, under $60 million a study. The 2017 JAMA Internal Medicine study incorporated all research costs on drugs not yet on the market into its final calculations. The pharmaceutical companies it examined had an average drug success rate of 23 percent, which the Tufts researchers argue is too high to accurately represent the amount of money that failed drugs would usually add to a company's research costs. But cancer drugs, specifically, do have a success rate of 20 to 25 percent—so the selection of only successful companies does not seem to be the difference. Joaquin Duato, the vice chairman of Johnson Johnson's executive committee, argues that critics fail to deal with the realities of drug RD. He told

me that last year, Johnson Johnson had $41 billion in prescription-drug sales, of which $8.4 billion went to RD and $4.5 billion went to sales and marketing. Other costs included manufacturing, finance, IT, taxes, and more. This funds research on 100 candidate drugs, which result in one or two FDA approvals a year. "For drug companies, the return on capital is in the mid-teens, which is nowhere near tech-company returns," Duato said. Nevertheless, some former pharmaceutical-company executives say that research costs do not determine drug prices—and they explain how. In his book A Call to Action, Hank McKinnell, a past CEO of Pfizer, wrote under the heading "The Fallacy of Recapturing RD Costs": How do we decide what to charge? It's basically the same as pricing a car ... A number of factors go into the mix. These factors consider cost of business, competition, patent status, anticipated volume, and, most important, our estimate of the income generated by sales of the product. It is the anticipated income stream, rather than repayment of sunk costs, that is the primary determinant of price. Raymond Gilmartin, a former Merck CEO, once said to The Wall Street Journal: "The price of medicines is not determined by their research costs. Instead, it is determined by their value in preventing and treating disease."

3.1.2 RD Costs Insignificant

RD is a fraction of sales – less than marketing. And companies refuse to reveal RD costs

Genevieve M. Halpenny (PhD in Chemistry, Attorney at Newman Lickstein). "High Drug Prices Hurt Everyone." ACS Medicinal Chemistry Letters. 3 May 2016. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4904249/

Pharmaceutical companies argue that price regulation abroad forces pharmaceutical companies to charge more for patented medications in the United States to fund research and development of new and improved medicines. However, RD expenditures hover around 20% of sales, less than pharmaceutical companies typically allocate toward marketing. And cuts in pharmaceutical RD spending are regularly reported. Pharmaceutical companies refuse to substantiate their arguments by providing information about the cost of developing new medicines. These circumstances undermine the credibility of such arguments. At the same time, enough profit is required to incentives investment in pharmaceutical innovation.

3.1.3 Offense

High drug prices distort research priorities — financial gains are emphasized over health gains. This turns their innovation arguments

Ezekiel J. Emanuel (oncologist, a bioethicist, and a vice provost of the University of Pennsylvania). "Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't

Add Up." The Atlantic. 23 March 2019. https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/

Second, the high drug prices distort research priorities, emphasizing financial gains and not health gains. Cancer drugs are routinely priced at about $120,000 to $150,000 a year, and more than 600 cancer drugs are now being tested on humans. This can lead to great societal benefits: The United States is expected to face 1.76 million new cancer cases and more than 600,000 cancer deaths in 2019 alone. But many of the drugs that companies are pursuing have low promise, where the health gains are small—weeks of added life, not big cures. While even this short extra time can be valuable to individual families, too much investment in oncology means not enough in drugs for other illnesses whose treatments cannot be so highly priced. Consider antibiotics. The Centers for Disease Control and Prevention ranks antibiotic-resistant infections as one of the nation's top health threats. An estimated 2 million Americans become infected with such bacteria each year, and 23,000 die. A superbug that is resistant to all known antibiotics is an imminent threat. Yet because antibiotics are generally cheap, for most pharmaceutical and biotechnology companies they are not a primary focus. The Pew Charitable Trusts reports that only about 42 new antibiotics with the potential to treat serious bacterial infections were in clinical development for the U.S. market in December 2018. Six hundred drugs for cancer and only 42 for serious infections seems like profit maximization, not a case of sensible research priorities that reflects "value in preventing and treating disease." The simple explanation for excessive drug prices is monopoly pricing. Through patent protection and FDA marketing exclusivity, the U.S. government grants pharmaceutical companies a monopoly on brand-name drugs. But monopolies are a recipe for excessive prices. A company will raise prices until its profits start to drop. To address the problem of high prices and reduced access to drugs, Johnson Johnson advocates eliminating rebates to pharmacy benefit managers and insurers, which would increase price transparency and lower patient co-pays. But it would not necessarily lower total drug prices. The proposal avoids the standard economic response to monopoly pricing: price regulation. Every other developed country regulates drug prices, often through price negotiations pegged to cost-effectiveness analysis or some other measure of clinical benefit. Will RD go down if the United States follows this model? Not necessarily. Remember, the high drug prices fund RD but also marketing, manufacturing, administrative expenses, and profits at the companies. Lower revenue from lower drug prices could reduce marketing, administration, and excessive profits before RD costs have to be reduced. Where cuts are made is up to drug companies. Their claims of lower RD costs appear designed to generate fear, but as some former executives themselves have acknowledged, there is no necessary link between a decline in drug prices and a decline in RD. Drug companies could make other choices that maximally improve the health of all Americans.

3.1.4 Private RD Inefficient

Private RD is inefficient. Much more goes to profits, marketing, and overhead than RD.

Merrill Goozner (Editor of Modern Healthcare from December 2012 to April 2017). "Editorial: Drug price controls? A good idea, but don't bet on it." Modern Healthcare. 1 November 2018. https://www.modernhealthcare.com/article/20181101/NEWS/181109993/editorial-drug-price-controls-a-good-idea-dont-bet-on-it

That's the big lie, of course. The drug industry spends just one-fifth of its revenue on research and development and a significant portion of that is devoted to coming up with drugs that are no improvement to drugs already on the market. It spends twice as much on marketing and overhead and takes home more in profits than it spends on RD. The reality is that innovation doesn't come from pouring more money into the coffers of the pharmaceutical industry. If that were true, we would have had a cure for cancer two generations ago.

3.1.5 Public R&D Solves

Public RD solves – it's where most biopharma innovations come from, and at less cost

Merrill Goozner (Editor of Modern Healthcare from December 2012 to April 2017). "Editorial: Drug price controls? A good idea, but don't bet on it." Modern Healthcare. 1 November 2018. https://www.modernhealthcare.com/article/20181101/NEWS/181109993/editorial-drug-price-controls-a-good-idea-dont-bet-on-it

Rather, innovation comes from the advance of medical science, which is slow, arduous and totally dependent on government- and philanthropy-funded basic research. Most medical breakthroughs occur in NIH-funded labs. Those technologies are then transferred free of charge to biotech startups, which in turn sell them late in the development process to Big Pharma companies. In some cases, the inventors make the leap to biotech early enough in the process that the NIH-funded institution doesn't even get royalties.

And what does it cost to develop the new therapies? A recent study in JAMA Internal Medicine estimated that biotech startups spend a quarter of what the pharmaceutical industry claims it costs to bring a new therapy to market.

3.2 Prescription Non-Adherence

3.2.1 Internal Link

High prescription drug costs lead to medication noncompliance.

Lisa Ellis (freelance journalist who specializes in writing about health topics for a

variety of consumer websites and publications, including Harvard T.H. Chan School of Public Health's Preparing for What's Next in U.S. Health Reform, which offers key lessons involving health reform from the nation's leading policy experts). "The Need to Treat the Ailing U.S. Pharmaceutical Pricing System." Harvard T.H. Chan School of Public Health. 14 March 2019. https://www.hsph.harvard.edu/ecpe/united-states-pharmaceutical-pricing/

What This Means for Patients Patients often are stuck between a drug they need and high prices they can't afford, Kesselheim stresses. A good example is how insulin prices have jumped over ten years. "Pharmaceutical companies spend more on lobbying in the U.S. than any other industry. This is a major challenge," Kesselheim says, when trying to implement change. The Problem of Medication Noncompliance The bottom line is that high drug prices contribute to the problem of medication non-adherence among American patients. "One out of every four patients reports not filling a prescription today for themselves or a family member due to cost," Kesselheim stresses, worsening poor outcomes, such as increased mortality rates for some drugs. The problem has caught the attention of legislators in all 50 states, some of whom are trying to take action. "When we talk about lowering drug prices, we are trying to ensure that drugs are priced reasonably given payers' budgets, and consistent with the value they provide," Kesselheim says.

3.2.2 Impact

30% of prescriptions in the US are never filled. This causes hundreds of billions in avoidable healthcare costs and 125,000 deaths, while drug companies accrue the highest profit margins of any sector.

Michael Wornow (PhD student in Computer Science, Stanford University). "Just What the Doctor Ordered: The Case for Drug Price Controls." Harvard Political Review. 2 December 2018.https://harvardpolitics.com/united-states/just-what-the-doctor-ordered-the-case-for-drug-price-controls/

Despite accounting for over 40 percent of global spending on prescription drugs, American patients may still be falling short of their recommended dosages. According to a study published in the Annals of Internal Medicine, roughly 30 percent of all pharmaceutical prescriptions in the United States are "never filled," which has directly led to almost $300 billion in avoidable healthcare costs annually and roughly 125,000 deaths from patients failing to adhere to their prescriptions. This would be the sixth leading cause of death in America. Accordingly, the World Health Organization has written that increasing adherence to prescriptions would have a "far greater impact on the health of the population than any improvement in specific medical treatments." Unlike many biological diseases, however, this tragic phenomenon has a readily identifiable cause and, potentially, set of cures. When patients who failed to fill out their prescriptions were asked to provide a reason for doing

so in a 2017 NPR Health Poll, 67 percent of respondents cited high cost, a number which rose to a staggering 94 percent for patients with incomes less than $25,000. Drugs sold in the United States are on average two to six times more expensive than they are in other countries, and are a key contributor to the rising healthcare costs that have caused approximately 62 percent of all personal bankruptcies in the United States. This alarming trend is occurring in spite of record-breaking profits for multinational pharmaceutical companies. The average pharmaceutical company has a profit margin of 21 percent, which according to 2015 Forbes estimates is the highest of any sector. While these companies should be lauded for developing breakthrough therapies and cures never before thought possible, the blatant price gouging that they sometimes practice should not be tolerated by American regulators. To promote public health and ensure that patients are able to fulfill their prescriptions at a reasonable price, American policymakers thus have a moral obligation to replicate the success that other countries have already had in instituting price controls on drugs.

3.2.3 Controls Solve

Price controls solve prescription non-adherence.

Michael Wornow (PhD student in Computer Science, Stanford University). "Just What the Doctor Ordered: The Case for Drug Price Controls." Harvard Political Review. 2 December 2018.https://harvardpolitics.com/united-states/just-what-the-doctor-ordered-the-case-for-drug-price-controls/

First, price controls would help to address the problem of prescription non-adherence and thereby save lives by reducing the cost of drugs. A two year study of 25,000 breast cancer surgery patients found that women who received a Medicare D subsidy (which substantially reduced their out-of-pocket costs for prescribed medication) had 30 percent higher odds of fully adhering to their prescriptions than women who did not receive a financial subsidy. This led the authors to conclude that legislation aimed at increasing prescription adherence should "focus on lowering out-of-pocket cost... [g]iven the high costs of ... medications." A 2014 quantitative analysis of price caps on name-brand drugs echoed these results, finding that capping the price of drugs 20 percent lower than the monopolistic price point at which they would otherwise be sold would lead to a 23 percent increase in the number of patients that could take that drug. The caps would cost only 1 percent of overall pharmaceutical revenues.

3.3 Healthcare Costs

3.3.1 National Expenditure

Rapidly rising prescription drug prices contribute to high health care expenditure in the United States.

Lisa Ellis (freelance journalist who specializes in writing about health topics for a variety of consumer websites and publications, including Harvard T.H. Chan School of Public Health's Preparing for What's Next in U.S. Health Reform, which offers key lessons involving health reform from the nation's leading policy experts). "The Need to Treat the Ailing U.S. Pharmaceutical Pricing System." Harvard T.H. Chan School of Public Health. 14 March 2019. https://www.hsph.harvard.edu/ecpe/united-states-pharmaceutical-pricing/

Prescription drug prices in the U.S. have been rising at an alarming rate, contributing to the nation's high health care costs. This concerns policy makers at the state and federal levels, prompting exploration of new options to get a better handle on costs while maintaining Americans' access to pharmacological innovations. Putting Drug Prices into Context "Pharmaceuticals are one of the fastest-growing parts of health care spending," explains John E. McDonough, DrPH, MPA, Professor of the Practice of Public Health at the Harvard T.H. Chan School of Public Health. McDonough also serves as the Program Director of the Harvard executive education program, Preparing for What's Next in U.S. Health Reform. This course helps physician leaders and health care executives stay abreast of key health policy developments—including rising drug costs—to position their organizations for success. Increased Prescription Usage in the U.S. The latest estimates from 2015 place pharmaceutical costs at about 17 percent (about $457 billion) of all health care expenditures, and this amount is expected to continue to escalate if no interventions are put into place. Other factors also contribute to overall U.S. pharmaceutical spending, according to Preparing for What's Next in U.S. Health Reform faculty member Aaron S. Kesselheim, MD, JD, MPH. Kesselheim is an Associate Professor of Medicine at Harvard Medical School and Faculty in the Division of Pharmacoepidemiology and Pharmacoeconomics at the Department of Medicine at Brigham and Women's Hospital. A 2015 RAND Corporation study shows the Affordable Care Act added health insurance for 16.9 million persons in the U.S., resulting in many more people having access to prescription medications. Kesselheim says that while this helps explain some increases in utilization, it doesn't tell the entire story. Another major factor is that drug costs have risen steeply for several years. Some employers estimate that 25 percent of their overall health spending is for employees' drug costs. And existing drug prices are continuing to rise, while new drugs come onto the market at higher prices than ever before, Kesselheim says. Americans do not consume more drugs than their non-U.S. counterparts, yet prices can be 80-150 percent more in the U.S. than elsewhere for identical drugs yielding the same results.

Adding Up the Factors Driving Pharmaceutical Pricing These factors translate into U.S. drug prices being disproportionately higher (as much as double) than in other high-income countries. Americans do not consume more drugs than their non-U.S. counterparts, yet prices can be 80-150 percent more in the U.S. than elsewhere for identical drugs yielding the same results. Higher drug pricing in America is sustained by monopolies granted by the government to brand-name manufacturers through patents, allowing manufacturers to set prices without regard to the value the product provides to patients. The U.S. also permits different drug prices for different audiences. In addition, the supply chain is complex, with pharmacies often purchasing drugs through pharmacy benefit-management companies, which negotiate pricing with pharmaceutical companies and add more costs. Further, Medicare and Medicaid have limited ability to negotiate drug-pricing arrangements, resulting in higher costs.

3.4 German Model

3.4.1 General

The German model for drug prices should be adopted. It rewards innovative drugs, provides immediate access, ensures price transparency, and limits prices.

Karl Lauterbach (member of the Deutsche Bundestag for the Social Democratic Party of Germany, former SPD Speaker for Health), **John E. McDonough** (professor of practice at the Harvard T.H. Chan School of Public Health in Boston), and **Elizabeth Seeley** (Adjunct Lecturer in the Department of Health Policy and Management at the Harvard T.H. Chan School of Public Health). "Germany's Model For Drug Price Regulation Could Work In The US." Health Affairs. 29 December 2016. https://www.healthaffairs.org/do/10.1377/hblog20161229.058150/full/

The German Model for Regulating Drug Prices If political will emerges to tackle this issue, is there a realistic and politically savvy model to use? On what basis would drug purchasers and drug makers negotiate? How would the value of new prescription drugs be determined? And how would genuine scientific innovation be encouraged and rewarded, and not stymied? We suggest that a superior model to accomplish these goals now exists and can be found in Germany's drug pricing regulatory system that has performed admirably since 2011. Called AMNOG (the Act to Reorganize Pharmaceuticals Market in the Statutory Health Insurance System or Arzneimittelmarktneuordnungsgesetz), the system has noteworthy advantages in that it: Rewards innovative drugs that provide genuine breakthrough clinical benefits; Provides immediate access to new drugs by allowing marketing, sale, and full reimbursement in the first year, during which time the drug's clinical benefits are assessed; Uses non-governmental, non-profit organizations for review and decision making, with the pharmaceutical manufacturers bearing much of the costs; Makes

decisions based on clear empirical evidence of clinical benefit to patients; Determines prices only after—and based on—a determination of clinical benefits, and through negotiations involving drug companies and key system stakeholders, not government bureaucrats; Avoids controversial tools such as Quality Adjusted Life Years (QALY) that place a monetary value on each additional year of life; Ensures full transparency in all key processes and steps. Historically, as with the U.S., Germany has had a reputation for high drug prices. Prior to AMNOG, drug prices in Germany were 26 percent higher than average drug prices in the European Union. Since AMNOG's 2011 launch, by August 2016, 146 new drugs have been assessed. Of the newly assessed drugs, 63 percent were determined to have an additional benefit, though half of those only for select patient groups. In 2015 alone, Germany achieved savings of $1 billion on new drug spending, with discounts averaging 21 percent in this market segment. If the U.S. cares to examine other national models, AMNOG should top the list. Because of AMNOG, the average annual growth rate in public pharmaceuticals expenditure per capita between 2009 to 2013 in Germany was -0.7 percent, as compared with +2.7 percent in the US. In a recent international comparison of health benefits assessments of pharmaceuticals, Germany showed more rigorous appraisals of new drugs than other countries in the survey. How the AMNOG process works

First, once a new drug has been demonstrated as safe and efficacious by the European Medicines Agency (the European Union's equivalent to the U.S. Food Drug Administration) or by the German Federal Institute for Drugs Medical Devices, the drug maker may introduce the product into the German market at any initial price of its choosing, fully reimbursed by all German insurance plans for the first 12 months. Second, during those 12 months, the Federal Joint Committee (G-BA), a non-governmental body of payer, provider, and patient representatives, with authority over coverage decisions for all German payers, commissions a clinical comparative effectiveness review by a non-governmental and non-profit research body known as the Institute of Quality and Efficiency in Healthcare (IQWiG). IQWiG assembles, evaluates, and reports all evidence of a new drug's clinical effectiveness and benefits compared with standard treatment and/or existing drugs, including data on benefits for different demographic groups. Drug makers must submit all their relevant data in a "Benefit Dossier," and will face sanctions for withheld information. Results are subject to an expert hearing published and used to inform both doctors and patients. Third, within six months of a drug's market introduction, and with IQWiG's report in hand, the G-BA determines the new drug's added benefit over existing drugs or treatments, including information on benefits and risks for specific patient subpopulations. New drugs are rates 1-6: Major added benefit – sustained and substantial improvement not previously achieved by current therapies; Considerable added benefit – significant improvement over current therapies; Minor added benefit – moderate improvement; Added benefit present but not quantifiable; No added benefit proven; Lower benefit than current therapies. A drug can receive differential

rankings for varied patient subpopulations. In addition, the quality of the studies and data on which the classification is based is specified in three categories: Proof of benefit Indication of benefit Hint of benefit The combination of benefit ratings and quality categories summarizes the extent and probability of additional benefits of drugs in patient groups. Fourth, if the G-BA accepts the IQWiG recommendation and the new drug is ranked in any of categories 1-2-3, then the newly established clinical value rating sets the basis for negotiations between the drug maker and the National Association of Statutory Health Insurances, the organization of all public insurance providers in Germany. If parties cannot reach agreement, the matter is submitted to an arbitration panel for a decision based on other international prices. Fifth, if a drug offers no additional value over a previously available drug, ranked in categories 4-5-6, then payers will reimburse only at prices currently paid for the older existing drugs or therapies. Drug companies can choose to sell their product at higher prices, though patients who want the newer and lower ranked drug must pay the difference out of their own pockets. Importantly, if a drug company charged an excessive rate for a lower ranked drug in the first year of availability, the extra revenues must be returned to payers. A drug company can opt for their drug to not be assessed, in which case the drug's price is set through the German reference pricing system. Under the reference pricing system, a drug's price is based on the price of other drugs in that therapeutic class, including lower priced generic alternatives.

3.4.2 US Specific

The United States should adopt it.

Karl Lauterbach (member of the Deutsche Bundestag for the Social Democratic Party of Germany, former SPD Speaker for Health), **John E. McDonough** (professor of practice at the Harvard T.H. Chan School of Public Health in Boston), and **Elizabeth Seeley** (Adjunct Lecturer in the Department of Health Policy and Management at the Harvard T.H. Chan School of Public Health). "Germany's Model For Drug Price Regulation Could Work In The US." Health Affairs. 29 December 2016. https://www.healthaffairs.org/do/10.1377/hblog20161229.058150/full/

Results and Implications for the United States As mentioned, in 2015 alone, Germany achieved savings of $1 billion on new drugs, with discounts averaging 21 percent in this pharmaceutical market segment. This savings estimate does not include a calculation for drugs that were placed in categories 4-6, so full savings would be significantly larger. Rather than stifling innovation, in AMNOG's first four and one half years, 124 new products had completed assessments and launches, and only 13 were withdrawn from consideration. Though some American policymakers suggest that the U.S. has little to learn from other nations, Germany may be an exception. Unlike single payer systems in Canada and the United Kingdom, Germany has a private multi-payer system where more than 90 percent of the insurance market is

managed by non-profit "sickness funds." Public anger led to AMNOG's establishment as drug prices began to skyrocket in the last decade, reaching a growth rate of over 6 percent by 2009. Growth rates in the U.S. were 12.2 percent in 2014 and 8.1 percent in 2015. In the U.S., the Patient Centered Outcomes Research Institute (PCORI), established under the Affordable Care Act, was created to commission clinical-effectiveness research to provide evidence to support patient-centered care, evaluating drugs and medical therapies. Like PCORI, IQWiG in its early days chose research targets on its own initiative. Under AMNOG, IQWiG now systematically reports on all new drugs and also may assess the effectiveness of older ones, including medical devices, plus surgical and screening procedures. PCORI may be well positioned to review manufacturers' comparative-effectiveness documents as IQWiG now does. In the U.S. pharmaceutical industry and elsewhere, a growing movement among some drug makers proposes payment based on the "value" of their products rather than on arbitrary price setting. This new "pay-for-value" movement, of course, now extends far beyond the pharmaceutical sector through initiatives such as accountable care organizations, bundled payments, and hospital readmission penalties set in motion by the Affordable Care Act. AMNOG represents a scientific and evidence-based way to pay for drugs based on their value. For sure, the AMNOG system faces challenges, as any new and complex policy would. At times, the G-BA has chosen comparator drugs about which manufacturers disagree, that have resulted in negative benefit ratings. Parties have disagreed about appropriate end points that manufacturers must include in disclosed studies, especially in domains such as oncology where surrogate endpoints may not reflect ultimate clinical outcomes. However, the G-BA works extensively with manufacturers up front during the assessment process to communicate their choice of comparators and endpoints, allowing manufacturers a hearing or appeals process in which they disagree or develop new data. Germany's AMNOG system is value and evidence-based, transparent, non-governmental, publicly managed, and innovation embracing. If the U.S. wants to create an evidence and value-based system to pay for prescription drugs, we could not start at a better place than emulating the AMNOG model.

3.5 Alternatives

3.5.1 CAP

Comprehensive legislation that includes value-based pricing, as well as indexed limits on price gouging, solves price concerns. We endorse the Center for American Progress' plan.

Madeline Twomey (special assistant for Health Policy at the Center for American Progress). "Comprehensive Reform to Lower Prescription Drug Prices." Center for American Progress. 29 January 2019. https://www.americanprogress.org/issues/healthcare/news/2019/01/29/465621/comprehensive-reform-lower-prescription-drug-

prices/

Comprehensive drug pricing legislation

First and foremost, legislation should lower costs for all payers and benefit all Americans. It should address the problem of stratospheric prices for seniors, as well as for middle-class and lower-income families. Private insurance, which covers 56 percent of the U.S. population, accounts for 42 percent of drug spending and is one of the main drivers of premium increases. Therefore, a comprehensive solution cannot focus solely on Medicare; it must also take private insurance into account. In addition, the following principles would ensure that prices for new drugs reflect their value and that price gouging on existing drugs is eliminated. Prices that reflect value and innovation All payers—public and private—should pay prices that reflect value and innovation. The federal government should negotiate these prices with drug manufacturers. They could measure the value of a drug using two metrics. First, value could be measured by a drug's cost-effectiveness, meaning its value based on the cost for each quality-adjusted life year (QUALY) gained by patients using the drug. Second, the value of a drug could be measured by its comparative clinical effectiveness, which sets the cost in proportion to its effectiveness relative to existing treatments. CAP's Negotiation Plus plan proposes using comparative effectiveness research to inform negotiations between payers and manufacturers, which would then determine the prices of prescription drugs. According to this plan, the price recommendations would vary depending on whether the new product "provides no added benefit, minor added benefit, or significant added benefit compared with alternative treatments. Added benefits would include improved health status, shortened disease duration, extended life expectancy, reduced side effects, and improved quality of life." Independent and fair assessments of value Under the Negotiation Plus framework, negotiations would be informed by independent assessments of value and innovation. Congress would set standards for U.S. nonprofit organizations to assess the value of drugs, ensuring that these parties are free of conflicts of interest, have transparent methodology, and enforce board representation standards as well as clear priorities for which drugs to assess. Examples of such organizations might include the Institute of Medicine (IOM), the Patient-Centered Outcomes Research Institute (PCORI), or the Institute for Clinical and Economic Review (ICER). There are a number of real-world examples that the United States can draw from. Several countries in Europe already assess value when regulating drug prices and, as a result, see far lower prices than the United States. For example, Germany imposes a thorough assessment process when a new drug hits the market. The analysis measures whether the new medicine has an "added therapeutic benefit" over other medicines treating the same condition. If it does, then the reimbursement price is negotiated based on the price of these existing treatments. If no added benefit is found, the new drug is given a "reference price," meaning it will not be reimbursed at a rate higher than comparable treatments. Strong enforcement mechanism In

order for drug prices to be negotiated effectively, there must be an enforcement mechanism in place to ensure that all payers have leverage. If a drug manufacturer sets a price for a drug that is higher than its value—as determined by independent assessments or an international pricing index—then one or more of the following enforcement mechanisms should be triggered: Tax on corporate profits Noncoverage of all the manufacturer's products under public programs, including Medicare and Medicaid Binding arbitration, where an arbitrator—selected from a list provided by the Government Accountability Office—would determine the price of a drug using all available cost-effectiveness and transparency data International reference pricing, where the price of a drug would be measured based on the average price of another country's or a group of countries' list prices Compulsory licensing, where other manufacturers would be allowed to sell their own versions of the drug, creating competition that would lower prices Elimination of price gouging Congress must also limit price increases for existing drugs based on health care inflation or the medical consumer price index (CPI-M). Price increases that exceed a limit linked to these measures should trigger reporting by the manufacturer, as well as civil penalties, a tax on corporate profits, or rebates. Manufacturers already pay additional rebates to the Medicaid program when their prices rise faster than general inflation. The Medicaid Drug Rebate Program guarantees that, in exchange for covering a manufacturer's drugs, the Medicaid program receives the lowest net prices available to private payers. Proposed legislation has expanded on this idea. For example, in May 2017, Rep. Jan Schakowsky (D-IL) introduced legislation that would address price gouging by requiring manufacturers of certain drugs and biological products to report significant price increases to the Department of Health and Human Services. This would apply to any drugs with a wholesale cost of at least $100 per month that see price increases of 10 percent or more over a 12-month period, or an increase of 25 percent or more over a 36-month period. Manufacturers that fail to report such increases would be subject to a civil penalty. Conclusion It is critical for Congress to put an end to skyrocketing drug prices. The drug industry has gone unchecked for far too long, and Americans are hurting because of it. In addition to giving patients better access to lifesaving treatments, lowering prescription drug prices would help bring down health insurance premiums and better ensure families' financial security. By following the principles listed above, comprehensive legislation can provide all Americans with access to affordable prescription drugs.

3.5.2 Comparative Effectiveness

Comparative effectiveness solves.

Xenia Shih Bion (engagement specialist at CHCF, where she oversees social media and analytics to amplify the programmatic work of the foundation). "The Human Cost of Soaring Prescription Drug Prices." California Health Care Foundation. 30 November 2018. https://www.chcf.org/blog/the-human-cost-of-soaring-

prescription-drug-prices/

Another Tool: Comparative Effectiveness Comparative effectiveness research could also help reduce drug costs. "Efforts to constrain prices by aligning them with clinical value would not stifle innovation," write Steven Pearson, MD, (founder and president of the Institute for Clinical and Economic Review), Len Nichols, PhD (professor of health policy and director of the Center for Health Policy Research and Ethics at George Mason University), and Amitabh Chandra, PhD (professor of social policy and director of health policy research at the Harvard Kennedy School of Government). In Health Affairs, they argue that "measures to enhance competitive market forces and to leverage comparative effectiveness to achieve value-based pricing would provide more explicit incentives for the kind of innovation that should be rewarded handsomely within the US health care system." California is implementing mandatory drug price transparency measures. In 2017, Governor Jerry Brown signed into law SB 17, which requires drug companies planning significant price increases to give 60 days' notice to health insurers and the state. Starting next year, the state's Office of Statewide Health Planning and Development will begin collecting information related to new drugs and significant price increases of existing drugs. That information will be published four times a year on its website.

3.5.3 Foreign Price Refencing

Foreign price referencing solves.

Xenia Shih Bion (engagement specialist at CHCF, where she oversees social media and analytics to amplify the programmatic work of the foundation). "The Human Cost of Soaring Prescription Drug Prices." California Health Care Foundation. 30 November 2018. https://www.chcf.org/blog/the-human-cost-of-soaring-prescription-drug-prices/

Where Do We Go from Here? The silver lining to the drug pricing problem — yes, there is one — is that Congress has bipartisan agreement to cut costs as soon as possible. Sarah Karlin-Smith reports for POLITICO that "Senator Bernie Sanders and Donald Trump are on the same page on drug pricing once again." Sanders, an independent from Vermont who caucuses with the Democrats, and Representative Ro Khanna (D-California) introduced bills in their respective chambers to lower drug costs by relying on price controls set by other countries. Karlin-Smith explains that if US pharmaceutical companies don't charge prices comparable to those paid in countries like Canada and the United Kingdom, "the federal government could intervene to allow generic companies to produce cheaper knockoffs." The Sanders-Khanna plan complements a recent proposal from the Trump administration. Vox's Dylan Scott writes, "The administration wants Medicare Part B, which covers hospital and cancer drugs, to start paying a price based on an average of what certain European countries pay for specific medications." Though similar to the Sanders-

Khanna plan, the administration proposal only addresses drug costs in Medicare, not the private market. The Trump administration has also released a proposal for changes to Medicare Advantage and Medicare Part D. Max Nisen opines in a column for Bloomberg that the proposed rules "would make it easier for drug plans to require that patients obtain prior approval for treatments in [the six protected classes of drugs in Part D] before they are dispensed, and that patients try lower-cost options before moving on to more expensive drugs." The protected classes include cancer drugs, antidepressants, and antipsychotics. Though policymakers appear to be reaching across the aisle to curb drug costs, they will also have to reach out to seniors whose access to necessary drugs may be affected by their actions. Nisen warns, "The past history of this kind of effort is fraught. The Obama administration attempted to end the protected status for two of the six classes but saw its effect flounder under withering criticism from industry and patient groups." Additionally, 55 conservative groups and activists submitted a letter opposing the Part B proposal to Health and Human Services Secretary Alex Azar. They argue that importing price controls "will inevitably suppress innovation and harm American competitiveness."

3.5.4 Halpenny

We endorse the drug pricing plan described below.

Genevieve M. Halpenny (PhD in Chemistry, Attorney at Newman Lickstein). "High Drug Prices Hurt Everyone." ACS Medicinal Chemistry Letters. 3 May 2016. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4904249/

At least one scholar proposes incorporating an excessive pricing doctrine into antitrust law.10 Because antitrust law aims to protect consumers, adding protections against price gouging is a natural extension of existing law. To succeed, this approach requires access to information regarding RD costs, so reasonable and excessive prices can be determined. Representative Lloyd Doggett sent a letter to the Secretary of Heath and Human Services and the Director of the National Institutes of Health, asking them to exercise march-in rights provided by the Bayh-Dole Act of 1980.11 The letter asked the administrative agencies to demand licenses to medicines developed with federal funding when the prices of such medicines exceed the prices in seven of the ten largest countries, i.e., reference pricing. Although this administrative action would require a departure from current NIH precedent, it is an option the United States cannot continue to overlook. Improving access to medicines and decreasing pharmaceutical expenditures are related problems that require a multifaceted solution that includes elements of developing preventative programs that decrease the prevalence of heart disease, diabetes, and other preventable chronic conditions; increasing pharmaceutical coverage; working with doctors and patients to obtain data regarding patient outcomes and encouraging doctors to prescribe generic medicines when new drugs fail to offer improved patient outcomes; increas-

ing transparency regarding the price of pharmaceutical RD and determining what drug prices fairly compensate pharmaceutical companies for RD; increasing transparency regarding pharmaceutical price negotiations and pooling market power to obtain fair prices in negotiations; and prohibiting excessive prices and exploiting licensing rights retained by federal funding agencies. Pharmaceutical spending increases are unsustainable, and pharmaceutical pricing policies that increase patient access to medicines need to be developed now.

3.6 High Prices

3.6.1 Market Solutions Fail

Market based solutions fail — there's only a risk that price control works.

Joyce Frieden (News editor, Medpage). "Price Controls Best Way to Cut Health Costs, Economists Say." MedPage, 10 July 2019
https://www.medpagetoday.com/publichealthpolicy/healthpolicy/80935

WASHINGTON – Are price controls really the best solution to lower healthcare costs? "I'm a card-carrying economist – my card may be revoked, [but] I'll just say 'Yes,'" said Dan Polsky, PhD, professor of health economics at Johns Hopkins University in Baltimore, speaking Monday at an event on U.S. health spending sponsored by the Robert Wood Johnson Foundation and Altarum, a health policy think tank. "We've tried market-based methods," said Polsky. "The assumptions one makes in economics class about how a market functions – none of them exist in healthcare ... it's not working. I'm all for giving price controls a try." Other economists agreed. "We don't let PEPCO just run wild and charge whatever rates they want for electricity," said Chapin White, PhD, an adjunct senior policy researcher at the RAND Corporation, a policy analysis firm here, referring to the local electric utility. "The regulation of prices follows the features of that industry. I feel like in the healthcare industry, on the Medicare and Medicaid side we're doing price controls and – news flash – they work. They constrain spending growth ... On the private side, we've done a massive experiment in letting private health plans and providers negotiate without price controls, and we've seen the result: it's incredibly expensive, and it's unsustainably expensive." The discussion continued during the question-and-answer session. "My bias is that the healthcare market is screwed up," said audience member Bob Murray, MBA, former executive director of the Maryland Health Services Cost Review Commission, which sets payment rates under that state's unique all-payer hospital rate system. "The rest of the world has figured this out ... if [price controls] are the conclusion we ultimately get to, where do we start? There is a range of options from setting limits to doing benchmarks, which a number of states are looking to do, or hard-core rate-setting like Maryland," Murray said.

The private market fails — the market is fundamentally un-free and only price controls solve.

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). "Drug Price Controls Are Vital in a Market That's Not Free." New York Times. 29 June 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.

The drug industry has a mix of odd and perverse incentives that cause spiking prices.

Xenia Shih Bion (engagement specialist at CHCF, where she oversees social media and analytics to amplify the programmatic work of the foundation). "The Human Cost of Soaring Prescription Drug Prices." California Health Care Foundation. 30 November 2018. https://www.chcf.org/blog/the-human-cost-of-soaring-prescription-drug-prices/

How Did Commonly Used Drugs Get So Expensive? "This country's shadowy and byzantine system for negotiating drug prices and rebate deals" is the cause of such illogical price movements, said Robin Feldman, a law professor at UC Hastings and director of the Institute for Innovation Law. In the Washington Post, Feldman explains that a maze of "odd and perverse incentives" allows more expensive drugs to receive more favorable reimbursement positions that reward doctors and hospitals for prescribing those drugs. Additionally, strong patent protections help drug companies shut out competition. "The 1984 Drug Price Competition and Patent Term Restoration Act gave pharmaceutical companies exclusive protections for innovating a new drug," writes Erin Fox, PharmD, BCPS, FASHP, an adjunct associate professor of pharmacotherapy at the University of Utah, in the Harvard Business Review. "If they brought a new therapy to life, they enjoyed patent protection to effectively monopolize the market." The federal law also attempts to encourage competition by allowing other companies to manufacture generic versions of a drug once its patent expires. But drugmakers have numerous tactics up their sleeves to thwart generic competition. They can introduce incremental changes to a drug to extend a patent. They can even hatch costly but legal "pay for delay" agreements with generic drug companies to block competition. "In the short term, society pays more in the form of higher prices," Feldman writes. "In the long term, society pays more in the form of fewer competitors to offer lower-priced drugs." The short-term cost is evident in the historical pricing of EpiPen, which injects the drug epinephrine to halt a life-threatening allergic reaction known as anaphylactic shock. EpiPen is a product of the American pharmaceutical company Mylan. According to an editorial in The Lancet Child Adolescent Health, a pack of two EpiPens cost $100 when Mylan purchased the brand in 2007. By 2016, the cost of a pack had increased six-fold even though the manufacturing costs remained the same. Mylan responded to backlash over the high drug costs by introducing a generic version of the EpiPen for $300. Then, in August 2018, the Food and Drug Administration (FDA) approved a

generic version of the EpiPen from Teva Pharmaceutical. FDA Commissioner Scott Gottlieb, MD, said, "This approval means patients living with severe allergies who require constant access to life-saving epinephrine should have a lower-cost option." This week, Teva announced the cost of its generic epinephrine auto-injector: $300, the same as Mylan's generic EpiPen. "File this under 'When is a bargain not really a bargain?'" Ed Silverman wrote in STAT. The pricing is a clear example of the long-term cost society pays when there are few competitors in the drug market. When pressed on the not-quite-bargain cost of Teva's generic drug, Gottlieb said, "We have found that having three or more generic competitors brings prices down more sharply than with only one or two generic competitors."

3.6.2 Impact

High drug prices deny people access to life-saving medicine.

Genevieve M. Halpenny (PhD in Chemistry, Attorney at Newman Lickstein). "High Drug Prices Hurt Everyone." ACS Medicinal Chemistry Letters. 3 May 2016. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4904249/

Hard cases may make bad law, but a closer look at the ability of patients to access life-saving medicines reveals that these cases are hardly exceptional. The United States ranks first in per capita expenditures on pharmaceuticals and medical nondurables (FigureFigure11). In 2014, the Centers for Medicare and Medicaid Services (CMS) paid $140 billion on prescription drugs for seniors, the working poor, and people with disabilities.4 This figure does not include amounts paid by other state and federal programs, insurance, and individuals. CMS spending on medicines increased 13% in 2014 as compared to 5% in healthcare spending overall. Greater consumption of pharmaceuticals accounts for some of the differences in pharmaceutical spending between different countries. Another factor is that pharmaceutical prices are consistently greater in the United States than abroad. There is no satisfactory justification for the pricing disparity. Every American should be concerned about the accessibility of medicines that reduce suffering and save lives. Some surveys report that up to one in four patients cannot afford and do not fill their prescriptions. The patients who suffer most under the current regime are the elderly and patients with chronic conditions. In addition to escalating pharmaceutical expenditures increasing the burden on taxpayers, we are all in the process of aging and face the risk of catastrophic illness. Medication accessibility is a problem for each American.

3.6.3 Launch Prices

Monopolies result in steep launch prices for drugs unrelated to their value.

Madeline Twomey (special assistant for Health Policy at the Center for American

Progress). "Comprehensive Reform to Lower Prescription Drug Prices." Center for American Progress. 29 January 2019. https://www.americanprogress.org/issues/healthcare/news/2019/01/29/465621/comprehensive-reform-lower-prescription-drug-prices/

Drug prices are too high As it stands, drug manufacturers enjoy monopolistic market power and set prices as high as they possibly can. As a result, many of their drugs launch with huge price tags despite little added innovation. Even when manufacturers do account for the value of their drugs, it is largely based on their own studies and data—which are often not made public. There are two main problems that comprehensive legislation should address. Steep launch prices of new drugs First, launch prices of new drugs—and specialty drugs in particular—are often exorbitant and unrelated to their added value. Specialty drugs are medications that treat complex, chronic, or life-threatening conditions, such as autoimmune diseases and many cancers. They are often more complex to manufacture than other prescription drugs, require special handling or administration, or require ongoing monitoring and clinical support. While manufacturers cite these challenges to justify specialty drugs' sky-high prices, launch prices are still excessive: On average, they are 37 times more expensive than traditional prescription drugs. Even when comparable treatments are already available, many specialty drugs enter the market at unreasonably high prices. For example, the pharmaceutical company Amgen initially released its cholesterol drug Repatha at a list price of $14,100 per year. However, the Institute for Clinical and Economic Review (ICER) found that, given the availability of lower-cost treatments with similar effects, the drug should cost about 85 percent less than this list price. Amgen subsequently announced that it would be reducing the price of Repatha by 60 percent, to $5850, indicating that the initial price did not actually reflect the drug's value—as ICER determined. Sovaldi—a hepatitis C drug—offers another example of inflated launch prices. When initially approved, its manufacturer—Gilead Science—priced the drug at a staggering $1,000 per pill, or $84,000 per treatment. This decision ultimately spurred an 18-month Senate investigation, which revealed that Gilead set the price for Sovaldi based on factors such as how high the price could be increased before attracting the attention of Congress; of course, the manufacturer misjudged its ability to remain unexposed.

3.6.4 Price Gouging

Existing drugs are subject to price gouging — this is unrelated to innovation because the drugs have already been developed.

Madeline Twomey (special assistant for Health Policy at the Center for American Progress). "Comprehensive Reform to Lower Prescription Drug Prices." Center for American Progress. 29 January 2019. https://www.americanprogress.org/issues/healthcare/news/2019/01/29/465621/comprehensive-reform-lower-prescription-drug-prices/

Price hikes on existing drugs The second problem that meaningful drug legislation must address is drug manufacturers boosting their profits through price gouging of existing drugs. By definition, these price increases are largely unrelated to value or innovation because the drugs have already been developed. Some of these price increases are for brand-name drugs that still have patent protection; others are for generic drugs—often in cases where only one or two generic manufacturers have entered the market. Insulin, for example, has seen price hikes year after year. A recent study by the University of Pittsburgh found that Lantus insulin saw a 49 percent price increase in 2014, despite being on the market for more than 10 years.

3.6.5 Politically Popular

Everyone loves price controls!

Michael Wornow (PhD student in Computer Science, Stanford University). "Just What the Doctor Ordered: The Case for Drug Price Controls." Harvard Political Review. 2 December 2018.https://harvardpolitics.com/united-states/just-what-the-doctor-ordered-the-case-for-drug-price-controls/

Even though independent analyses have largely favored price controls, without political backing there is little hope for achieving real-world change. Fortunately, drug price controls are one of the increasingly rare issues where both President Trump and Democrats share the same goals, and for good reason — as previously mentioned, unfilled drug prescriptions are one of the leading causes of death in America despite (from a biological standpoint) being the most preventable. This crisis is incredibly unique in the healthcare space, for instead of requiring a costly, decades-long process of developing and testing possible drugs, this far-reaching issue can be addressed with straightforward legislation. This solution, moreover, does not seem to be too far out of reach, as Trump advanced an "aggressive" proposal to closely tie domestic U.S. drug prices to their prices in foreign markets in October 2018. While the regulations fall short of what some had hoped, many political commentators view the issue as a promising and rare "area of cooperation" between Democrats and Trump. It is therefore imperative that the surprising political consensus that has emerged on the issue and public outcry over recent drug price hikes continue to gain momentum for the sake of patients' lives, producing legislation that meaningfully impacts the healthcare market while resulting in fewer unfulfilled prescriptions.

3.6.6 AT: Finances Innovation

Even if drug prices finance innovation, US prices are still extreme.

Ezekiel J. Emanuel (oncologist, a bioethicist, and a vice provost of the University of Pennsylvania). "Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up." The Atlantic. 23 March 2019. https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/

Abiraterone is manufactured under the brand name Zytiga by Johnson Johnson. To justify the price, the company pointed me to its "2017 Janssen U.S. Transparency Report," which states: "We have an obligation to ensure that the sale of our medicines provides us with the resources necessary to invest in future research and development." In other words, the prices are necessary to fund expensive research projects to generate new drugs. This explanation is common among industry executives. To many Americans, it can seem plausible and compelling. It's easy to conjure images of scientific researchers in their protective gear and goggles carefully dropping precious liquids into an array of Erlenmeyer flasks, searching for a new cure for cancer or Alzheimer's. But invoking high research costs to justify high drug prices is deceptive. No matter the metric, drug prices in the United States are extreme. Many drugs cost more than $120,000 a year. A few are even closing in on $1 million. The Department of Health and Human Services estimates that Americans spent more than $460 billion on drugs—16.7 percent of total health-care spending—in 2016, the last year for which there are definitive data. On average, citizens of other rich countries spend 56 percent of what Americans spend on the exact same drug. Excessive drug prices are the single biggest category of health-care overspending in the United States compared with Europe, well beyond high administrative costs or excessive use of CT and MRI scans. And unlike almost every other product, drug prices continue to rapidly rise over time. HHS estimates that over the next decade, drug prices will rise 6.3 percent each year, while other health-care costs will rise 5.5 percent. Basic economic principles suggest that drug prices should be going down, not up: For most drugs, manufacturing volumes are increasing, and little new research is being conducted on those already on the market.