# Resolved: The United States federal government should impose price controls on the pharmaceutical industry.

# PRO BLOCKS

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# \*\*\*Price of Drugs\*\*\*

# A2: Cost is Absorbed by Insurance Companies

#### 1. [TURN]: Even if insurance companies *can* absorb the cost, McDonald of Pfizer reports that 47 million Americans don’t have health insurance because they can’t afford it. When afflicted with life-threatening illnesses, these Americans are forced to pay full-price for patented drugs. As a result, Prescription Justice reports in 2017 that 45 million Americans forego life-saving medication because they can’t afford to fill it. Voting pro assists these 45 million Americans because the Jena evidence from case says that price controls make medicine six times more affordable.

#### 2. [TURN]: Voting pro brings down health insurance premiums. The McDonald evidence from case indicates that 47 million Americans can’t afford health insurance right now, meaning that they often can’t afford life-saving medication. Even worse, the Rubleski evidence from case says that the high cost of drugs drives up insurance premiums by 11.6 percent every year. Voting pro solves by making medication six times less expensive according to the Jena evidence from case, driving down health insurance premiums.

#### Reducing health insurance premiums and allowing further access to healthcare is key because the Jacobs evidence from case indicates that 18,000 people die every year from lack of access to healthcare.

Margaret McDonald. Pfizer. “A Profile of Uninsured Persons in the United States.” https://www.pfizer.com/sites/default/files/products/Profile\_of\_uninsured\_persons\_in\_the\_United\_States.pdf

Minority populations are disproportionately uninsured; Hispanics have the highest uninsured rate Among the 47 million persons who are uninsured, 45% are non-Hispanic white, 15% are non-Hispanic black, and 33% are Hispanic. A closer look reveals uninsured rates to be unevenly distributed among racial/ethnic groups. Although 66% of the US population is non-Hispanic white, only 11% of this group is uninsured. Conversely, while only 13% of the US population is non-Hispanic black and 15% is Hispanic, of these groups, their respective uninsured rates are 20% and 34%, indicating a substantial burden among Hispanics. Racial/ethnic distribution of the uninsured population.

Prescription Justice. 6 February 2017. “45 Million Americans Forego Medications Due to Costs, New Analysis Shows – 9 Times the Rate of the UK.” https://prescriptionjustice.org/press\_release/45-million-americans-forego-medications-due-to-costs-new-analysis-shows-9-times-the-rate-of-the-uk/

Litchfield, CT, February 6, 2017 – About 45 million Americans did not fill a prescription in 2016 due to the costs of pharmaceuticals, a new analysis by Prescription Justice shows, with 18% of adults reporting this problem in a recent survey. This rate of foregoing medicine due to cost is nine times higher than in the United Kingdom, where medicine is largely covered by national health insurance. The analysis conducted by Prescription Justice —a non-profit organization dedicated to tackling the crisis of high drug prices — is based on data extracted from the Commonwealth Fund’s 2016 International Health Policy Survey of Adults. “Americans cannot afford to wait a day longer for drug price relief,” said Jodi Dart, Executive Director of Prescription Justice. “Tens of millions of Americans are not taking medications because of high drug prices. We urge President Trump to keep his campaign promise to stand up to big pharma and bring relief to millions of Americans who are unduly suffering because they can’t afford the vital medications that they need.”

Dr. Anupam Jena, Harvard Medical School. The Hill. 19 January 2018. “US drug prices higher than in the rest of the world, here's why.” <https://thehill.com/opinion/healthcare/369727-us-drug-prices-higher-than-in-the-rest-of-the-world-heres-why>

Americans pay prices for prescription drugs that are two to six times the rest of the world, despite having personal incomes that are on par with many developed countries. For instance, the average price for Humira — a top-selling drug to treat rheumatoid arthritis — is nearly $2,700 per administration in the U.S., more than twice the price in the U.K. American salaries are not twice as high as British salaries. It’s not surprising that in countries with different per capita incomes (e.g., U.S. vs India), the prices of drugs are different. But why is it that in countries with similar per capita income as the U.S., drug prices are so much lower than in the U.S.?

Jeff Rubleski, Grand Valley State University. 2017. Seidman Business Review. "Prescription Drug Prices Will Drive Health Insurance Premium Increases in 2017." https://scholarworks.gvsu.edu/cgi/viewcontent.cgi?article=1200&context=sbr

The top driver of rising health insurance premiums for 2017 is the cost of prescription drugs. Medical inflation for health insurance premiums is measured by a term referred to as “trend.” In 2017, the prescription drug trend is projected to be 11.6 percent, up from 11.3 percent in 20161 . The annual prescription drug trend is alarming, considering that it is almost a 7x multiple of general inflation in our economy, represented by the Consumer Price Index (CPI).2 Based on a host of factors, including individuals being treated at an increased rate for chronic conditions and diseases, aggressive pharmaceutical price increase policies for existing drugs and the introduction of new and very expensive drug therapies, it appears that annual drug price trend increases will continue at a pace that widely exceeds the CPI for years to come. The single largest factor behind the year-over-year increase in prescription drug trend involves what are labeled as specialty drugs, which treat complex conditions such as cancer, hepatitis C, arthritis, multiple sclerosis, and a multitude of other chronic and debilitating medical conditions and diseases. Advances in complex genetic research over the past decade have served as the catalyst for the development of these drugs. Pharmaceutical companies collectively spend billions of dollars to develop specialty drugs that have a high risk of failure, as most specialty drugs do not pass stringent Food and Drug Administration (FDA) testing that is required before prescription drugs are approved to go to market. However, the relatively few specialty drugs that do pass FDA testing once introduced to consumers can produce “lottery ticket-like” revenues and profits for pharmaceutical companies. To put into context the cost impact of specialty drugs, consider that they account for less than 1 percent of all prescribed medications, yet they account for about 35 percent of total prescription drug cost trends for 2017!3

Tom Jacobs. 26 June 2017. Pacific Standard. “MORE EVIDENCE THAT HEALTH INSURANCE REALLY DOES SAVE LIVES.” https://psmag.com/news/health-insurance-saves-lives

"A mounting body of evidence indicates that lack of health insurance decreases survival," Steffie Woolhander of the City University of New York and David Himmelstein of Harvard Medical School write in the Annals of Internal Medicine. They examined research conducted since a 2002 Institute of Medicine review concluded that a lack of insurance increases mortality. It estimated that more than 18,000 American adults die annually because of a lack of insurance. The new evidence "supports and strengthens its conclusion that insurance coverage improves mortality in several specific conditions (including trauma and breast cancer), augments the use of recommended care, and improves several measures of health status," the researchers write.

# A2: Healthcare is Expensive for Alternative Causes

#### 1. [TURN]: Professor Durvasula of the University of Washington reports in April that “medications are a key driver of the increasing cost of healthcare, largely as a result of the proliferation of expensive specialty drugs.” It is increasingly obvious that the high cost of healthcare is because of expensive drugs. Voting pro solves because the Jena evidence from case says that price controls make medicine six times less expensive, decreasing the cost of healthcare.

#### 2. [TURN]: Expanding access to health insurance decreases overall healthcare costs. The Rubleski evidence from case indicates that high drug prices are the number one driver of rising insurance premiums, leading the McDonald evidence from case to conclude that 47 million Americans can’t afford health insurance. Fortunately, the Jena evidence from case says that price controls make medication six times less expensive, increasing access to health insurance. This is key because the NILC finds in 2017 that increase access to health insurance reduces the health care costs of a community by 1.6 percent overall.

Raghu Durvasula, Associate Professor of Medicine, Division of Nephrology, University of Washington Medical Center, Seattle. American Health Drug Benefits Journal. April 2018. “Standardized Review and Approval Process for High-Cost Medication Use Promotes Value-Based Care in a Large Academic Medical System.” https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5973244/

As healthcare costs rise and reimbursements decrease, healthcare organization leadership and clinical providers must collaborate to provide high-value healthcare. Medications are a key driver of the increasing cost of healthcare, largely as a result of the proliferation of expensive specialty drugs, including biologic agents. Such medications contribute significantly to the inpatient diagnosis-related group payment system, often with minimal or unproved benefit over less-expensive therapies. Objective To describe a systematic review process to reduce non–evidence-based inpatient use of high-cost medications across a large multihospital academic health system.

National Immigration Law Center. August 2017. “Increasing Access to Health Insurance Benefits Everyone Health System Impacts.” https://www.nilc.org/issues/health-care/health-system-impacts-of-increasing-access/

The loss of these vital services can have a profound effect on community health. A recent study found increased rates of deaths among inpatients in facilities located in hospital service areas where an emergency department had closed. The study, which was limited to California, found a 10 percent increase in deaths among nonelderly adults and a 15 percent increase among patients who had heart attacks.[4] Hospitals in communities with high rates are uninsurance are more likely to close. There is a national trend of acute care hospital closure, which particularly affects rural areas. Expanded access to coverage, specifically Medicaid, can help hospitals stay open. Researchers found that hospitals in states that expanded Medicaid experienced significant declines in uncompensated care costs, from 3.9 to 2.3 percent of operating costs, between 2013 and 2015. This effect was most pronounced among hospitals that cared for a disproportionate number of low-income and uninsured patients, which saw uncompensated care costs decline from 6.2 to 3.7 percent of operating costs. Hospitals in nonexpansion states experienced small declines of less than half a percentage point.[5] The reduction in uncompensated care costs could have a significant impact on hospitals’ financial sustainability; roughly 40 percent of the hospitals studied had operating margins of less than 1.6 percent of operating costs in 2011.[6]

Margaret McDonald. Pfizer. “A Profile of Uninsured Persons in the United States.” https://www.pfizer.com/sites/default/files/products/Profile\_of\_uninsured\_persons\_in\_the\_United\_States.pdf

Minority populations are disproportionately uninsured; Hispanics have the highest uninsured rate Among the 47 million persons who are uninsured, 45% are non-Hispanic white, 15% are non-Hispanic black, and 33% are Hispanic. A closer look reveals uninsured rates to be unevenly distributed among racial/ethnic groups. Although 66% of the US population is non-Hispanic white, only 11% of this group is uninsured. Conversely, while only 13% of the US population is non-Hispanic black and 15% is Hispanic, of these groups, their respective uninsured rates are 20% and 34%, indicating a substantial burden among Hispanics. Racial/ethnic distribution of the uninsured population.

Dr. Anupam Jena, Harvard Medical School. The Hill. 19 January 2018. “US drug prices higher than in the rest of the world, here's why.” <https://thehill.com/opinion/healthcare/369727-us-drug-prices-higher-than-in-the-rest-of-the-world-heres-why>

Americans pay prices for prescription drugs that are two to six times the rest of the world, despite having personal incomes that are on par with many developed countries. For instance, the average price for Humira — a top-selling drug to treat rheumatoid arthritis — is nearly $2,700 per administration in the U.S., more than twice the price in the U.K. American salaries are not twice as high as British salaries. It’s not surprising that in countries with different per capita incomes (e.g., U.S. vs India), the prices of drugs are different. But why is it that in countries with similar per capita income as the U.S., drug prices are so much lower than in the U.S.?

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The top driver of rising health insurance premiums for 2017 is the cost of prescription drugs. Medical inflation for health insurance premiums is measured by a term referred to as “trend.” In 2017, the prescription drug trend is projected to be 11.6 percent, up from 11.3 percent in 20161 . The annual prescription drug trend is alarming, considering that it is almost a 7x multiple of general inflation in our economy, represented by the Consumer Price Index (CPI).2 Based on a host of factors, including individuals being treated at an increased rate for chronic conditions and diseases, aggressive pharmaceutical price increase policies for existing drugs and the introduction of new and very expensive drug therapies, it appears that annual drug price trend increases will continue at a pace that widely exceeds the CPI for years to come. The single largest factor behind the year-over-year increase in prescription drug trend involves what are labeled as specialty drugs, which treat complex conditions such as cancer, hepatitis C, arthritis, multiple sclerosis, and a multitude of other chronic and debilitating medical conditions and diseases. Advances in complex genetic research over the past decade have served as the catalyst for the development of these drugs. Pharmaceutical companies collectively spend billions of dollars to develop specialty drugs that have a high risk of failure, as most specialty drugs do not pass stringent Food and Drug Administration (FDA) testing that is required before prescription drugs are approved to go to market. However, the relatively few specialty drugs that do pass FDA testing once introduced to consumers can produce “lottery ticket-like” revenues and profits for pharmaceutical companies. To put into context the cost impact of specialty drugs, consider that they account for less than 1 percent of all prescribed medications, yet they account for about 35 percent of total prescription drug cost trends for 2017!3

# A2: Would Raise Price of Drugs Elsewhere

#### 1. [FRAMING]: Weigh U.S.-centric impacts first because the U.S. is the actor and our policymakers would focus entirely on benefits or harms to us.

#### 2. [DELINK]: Other countries are resistant to fluctuation in U.S. drug prices because they have weaker patent laws that preclude monopolies from price gouging. For example, Long of CNN reports in 2016 that when the price of Daraprim, a pill used to treat those afflicted with AIDS, went from 13.50 to 750 dollars overnight in the U.S., it did not affect the pills price in Europe. In fact, Daraprim still only costs one dollar in international markets.

Heather Long. CNN Business. 25 August 2016. “Here's what happened to AIDS drug that spiked 5,000%.” https://money.cnn.com/2016/08/25/news/economy/daraprim-aids-drug-high-price/index.html

Outrage over the massive EpiPen price hike feels like deja vu. A year ago, America was in shock when a drug called Daraprim that's used by some AIDS and transplant patients skyrocketed overnight from $13.50 to $750 a pill. Hillary Clinton tweeted that the 5,000% spike was "outrageous" and amounted to "price gouging." Nothing about the drug itself had changed except this: a new company -- Turing Pharmaceuticals -- had bought the rights to distribute it. The Daily Beast dubbed Turing's CEO "the most hated man in America." A year later, one pill of Daraprim costs $375 for many patients. Daraprim still costs $1 or $2 outside the U.S. Daraprim still only costs $1 or $2 a pill abroad. Turing only has the U.S. rights to distribute it. Doctors around the world have flooded Dr. Aberg's inbox with offers to send her supplies from their countries. "It's not illegal what they've done [at Turing], but it's unethical and immoral," says Dr. Aberg "This is affecting patient care."

# A2: Most Americans Use Cheap Generics

#### 1. [DELINK]: Even if the price of generics is low, most new life-saving drugs are patented, meaning no generics exist and the single company that can legally produce them can price gouge whenever they want. That’s why Prescription Justice reports in 2017 that 45 million Americans forego medication they *need* because they can’t afford to fill it. Voting pro solves because the Jena evidence indicates it makes medication six times less expensive and the Kantarjian evidence says it can increase survival rates by 20 percent.

#### 2. [TURN]: Generics aren’t accessible. Fox of the Harvard Business Review explains in 2017 that because pharmaceutical companies make so much excess revenue, they often pay off generic producers not to release their medicines. That means even if these generics are cheap, they often don’t make it to market.

#### The pro solves this problem in two ways.

#### First, the Jena evidence from case indicates that price controls make medicine six times more affordable for the average Americans.

#### Secondly, Professor Sood of the University of Southern California studies price controls from 1992 to 2004 and concludes in 2009 that regulations on the pharmaceutical industry decrease revenue. By reducing the profit margin of these companies, we reduce their ability to pay off generic companies.

#### 3. [TURN]: Price controls empirically increase the number of generics drugs on the market. Dalen of the University of Oslo studies price controls on drugs from 1998 to 2004 and concludes in 2005 that price controls increase the market share of generics, meaning that more Americans can afford medicine in the pro world.

Neeraj Sood. Health Affairs. February 2009. “The Effect Of Regulation On Pharmaceutical Revenues: Experience In Nineteen Countries.” https://www.healthaffairs.org/doi/full/10.1377/hlthaff.28.1.w125

We describe pharmaceutical regulations in nineteen developed countries from 1992 to 2004 and analyze how different regulations affect pharmaceutical revenues. First, there has been a trend toward increased regulation. Second, most regulations reduce pharmaceutical revenues significantly. Third, since 1994, most countries adopting new regulations already had some regulation in place. We find that incremental regulation of this kind had a smaller impact on costs. However, introducing new regulations in a largely unregulated market, such as the United States, could greatly reduce pharmaceutical revenues. Finally, we show that the cost-reducing effects of price controls increase the longer they remain in place.

Morten Dalen, Dag “Price regulation and generic competition in the pharmaceutical market”, University of Oslo, 25 Nov 2005, https://www.researchgate.net/publication/6944913\_Price\_regulation\_and\_generic\_competition\_in\_the\_pharmaceutical\_market

“In March 2003 the Norwegian government implemented yardstick based price regulation schemes on a selection of drugs experiencing generic competition. The retail price cap, termed “index price”, on a drug (chemical substance) was set equal to the average of the three lowest producer prices on that drug, plus a fixed wholesale and retail margin. This is supposed to lower barriers of entry for generic drugs and to reduce market power. Using monthly data over the period 1998-2004 for the 6 drugs (chemical entities) subjected to the index price regulation, we estimate a structural model enabling us to examine the impact of the reform on both demand and market power. Our results suggest that the index price helped to increase the market shares of generic drugs and succeeded in reducing overall market power.”

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

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

Dr. Anupam Jena, Harvard Medical School. The Hill. 19 January 2018. “US drug prices higher than in the rest of the world, here's why.” <https://thehill.com/opinion/healthcare/369727-us-drug-prices-higher-than-in-the-rest-of-the-world-heres-why>

Americans pay prices for prescription drugs that are two to six times the rest of the world, despite having personal incomes that are on par with many developed countries. For instance, the average price for Humira — a top-selling drug to treat rheumatoid arthritis — is nearly $2,700 per administration in the U.S., more than twice the price in the U.K. American salaries are not twice as high as British salaries. It’s not surprising that in countries with different per capita incomes (e.g., U.S. vs India), the prices of drugs are different. But why is it that in countries with similar per capita income as the U.S., drug prices are so much lower than in the U.S.?

Hagop Kantarjian, U.S. News, "The Harm of High Drug Prices to Americans – A Continuing Saga | Policy Dose | US News", December 12, 2016, https://www.usnews.com/opinion/policy-dose/articles/2016-12-12/the-harm-of-high-drug-prices-to-americans-a-continuing-saga

Under criticism, the drug industry repeats the same arguments: 1) high cost of research and development; 2) benefit justifies price; 3) market forces; and 4) regulating prices stifles innovation. But all four arguments lack validity. The cost of [research and development](http://onlinelibrary.wiley.com/doi/10.1002/cncr.28321/pdf) is [only 10 percent](http://www.pharmamyths.net/files/Biosocieties_2011_Myths_of_High_Drug_Research_Costs.pdf) of the [$1-2.6 billion](http://www.nejm.org/doi/full/10.1056/NEJMp1500848) figure that is claimed in industry-supported studies. More than 50 percent of important discoveries are made in independent academic centers, funded by taxpayers, and 85 percent of basic research is conducted in academic centers. The drug industry spends [1.3 percent](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1261198/) of its budget on basic research, but 20-40 percent on advertisements and related activities. Some [studies](http://ascopubs.org/doi/pdf/10.1200/JCO.2008.21.0534) show no relationship between drug benefits and price. Drug companies enjoy monopoly-like conditions that discourage competition based on price. Finally, innovation is driven by independent investigators who will continue to conduct research even if drug prices fall. High drug prices are harmful. Medical costs and out-of-pocket expenses result in high rates of [bankruptcies,](http://www.amjmed.com/article/S0002-9343%2809%2900404-5/pdf) and 10-25 percent of patients either [delay](http://ascopubs.org/doi/pdf/10.1200/JCO.2013.52.9123), abandon or [compromise treatments](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3639525/)because of financial constraints. Survival is also compromised. For example, in chronic myeloid leukemia, the 8-10 year [survival rate](http://jnci.oxfordjournals.org/content/103/7/553.full.pdf%2Bhtml) is 80 percent in Europe (where treatment is universally affordable); in the U.S., where finances may limit access to drugs, the 5-year [survival is 60 percent.](http://www.tandfonline.com/doi/full/10.3109/10428194.2012.745525) In surveys, 78 percent of Americans worry most about costs of drugs. Sadly, three years after the issue was raised, there has been little progress. The problem is compounded by 2 additional factors. First is the increasing shift in the cost of care and drugs to patients. Insurers justify this "skin-in-the-game" strategy as effective in reducing costs, but the high out-of-pocket expenses have turned this into "deterrence-in-the-game," discouraging patients from seeking care or purchasing drugs. In a recent survey, one-third of insured Texans delayed or did not pursue care because of high out-of-pocket expenses. Second is the spill-over of high drug prices to [generics](http://www.bloodjournal.org/content/bloodjournal/127/11/1398.full.pdf?sso-checked=true). Complex regulatory issues and shortages allow companies to increase prices of generics to levels as high as patented drugs. The latest scandals – Turing, Valiant and Mylan – are only the most extreme examples of a [common strategy](https://www.bloomberg.com/news/articles/2015-10-02/pfizer-raised-prices-on-133-drugs-this-year-and-it-s-not-alone) in pricing drugs. Generic Imatinib to treat chronic myeloid leukemia is priced at $5,000-8,000/year in Canada, $400/year in India, but [$140,000/year](http://www.nature.com/nrclinonc/journal/v13/n5/full/nrclinonc.2016.59.html) in the U.S. For generic drugs to be priced low, [four to five generics](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm) have to be available. The [average cost](http://www.wsj.com/articles/how-obamas-fda-keeps-generic-drugs-off-the-market-1471645550) of filing for FDA approval of a drug is $5 million in 2016, and the average time to approval is 4 years. There are currently more than 3,800 generic drug applications awaiting FDA action. The FDA should overhaul its procedures to reduce the cost of filing to less than $1 million per drug, reduce the timeline to approval to 6-12 months and monitor for the availability of multiple generics at all times.

Prescription Justice. 6 February 2017. “45 Million Americans Forego Medications Due to Costs, New Analysis Shows – 9 Times the Rate of the UK.” https://prescriptionjustice.org/press\_release/45-million-americans-forego-medications-due-to-costs-new-analysis-shows-9-times-the-rate-of-the-uk/

Litchfield, CT, February 6, 2017 – About 45 million Americans did not fill a prescription in 2016 due to the costs of pharmaceuticals, a new analysis by Prescription Justice shows, with 18% of adults reporting this problem in a recent survey. This rate of foregoing medicine due to cost is nine times higher than in the United Kingdom, where medicine is largely covered by national health insurance. The analysis conducted by Prescription Justice —a non-profit organization dedicated to tackling the crisis of high drug prices — is based on data extracted from the Commonwealth Fund’s 2016 International Health Policy Survey of Adults. “Americans cannot afford to wait a day longer for drug price relief,” said Jodi Dart, Executive Director of Prescription Justice. “Tens of millions of Americans are not taking medications because of high drug prices. We urge President Trump to keep his campaign promise to stand up to big pharma and bring relief to millions of Americans who are unduly suffering because they can’t afford the vital medications that they need.”

# \*\*\*Innovation\*\*\*

# A2: Reduces Capital for R&D

### Six reasons this argument is untrue on the link level:

#### 1. [DELINK]: Kantarjian of Rice University explains in 2016 that companies only spend 1.3 percent of their budgets on innovation. At that point, even if price controls reduced the profit margin of pharmaceutical companies, they would still have plenty of money left for research and development.

#### 2. [DELINK]: A study from the American Medical Association finds that the true cost of producing a new drug is 650 million dollars, just 24 percent of the 2.7-billion-dollar benchmark cited by the industry, making it obvious these companies don’t need as much money as they’re bringing in.

#### 3. [DELINK]: Companies will still innovate because there is still profit to be made. Goozner of the Harvard Health Policy Review explains in 2016 that the pharmaceutical industry posted a 25 percent profit in 2016. Reducing this profit margin slightly by imposing price controls would still leave plenty of funding to run as usual.

#### 4. [DELINK]: Past precedence shows their argument is false. Edwards of CBS News reports in 2011 that companies in countries with strict price controls actually spend more on R&D than U.S. companies do. For example, U.S. companies spend 19 percent of sales on R&D, but in countries like the U.K. and Switzerland, companies spend 42 and 120 percent, respectively. At worst this is a delink on their case, at best it’s a reason to vote for us.

#### 5. [DELINK]: Viki of Forbes does a 12-year study of the 1000 most innovation companies in the pharmaceutical industry and finds that R&D spending has no statistically significant relationship to innovation because there are too many variables involved, such as market and technical risk.

#### 6. [DELINK]: McCaughan of Health Affairs reports in 2017 that even if there is less financial incentive to innovate, companies are going to do it anyway because the 1983 Orphan Drug Act provides legislative incentivizes to innovate such as tax credits.

### But even if you still believe that companies are going to lower important R&D, two levels of mitigation on the link level.

#### 5. [MITIGATE]: Kantarjian of Rice University explains in 2016 that 85 percent of research happens in academic centers at public universities, which are completely untouched by price controls, meaning the majority of innovation can continue. Moreover, we’d say that this is the majority, if not all, of the life-saving innovation that is actually important because universities foster environments of collaboration and discovery to actually help people rather than chasing profit like corporations do.

#### 6. [MITIGATE]: Science News reports in March that Trump’s 2018 budget gave 6.3 billion extra dollars to publicly-funded research, meaning now more than ever we can rely on public R&D rather than private corporations.

### On the impact level. Even if you still believe that pharmaceutical companies are key to R&D:

#### 7. [DELINK]: The innovation happening at corporations doesn’t matter. Hollis of the University of Calgary writes in 2014 that private research is driven by profit, not social value. That means they make useless treatments for things like cosmetic problems because they’re cheap to make and can be sold to a larger population rather than focusing on expensive, but life-saving treatments that affect smaller population groups. That means it doesn’t really matter if this R&D exists anyway.

Don’t read this! It’s not as good as that ^!

1. [DELINK]: R&D costs do not explain the astronomical costs of drugs. Goozner of the Harvard Health Policy Review explains in 2016 that pharmaceutical companies only spend 20% of their revenue on R&D. That means that narrative that drug price need to be high to fund innovation is incorrect.

4. [DELINK]: The best drugs are produce from publicly-funded research, meaning that profit margin of private corporations doesn’t matter. Professor Kesselheim of Harvard Medical School explain in 2016 that “important innovation that leads to new drug[s] is often performed in academic institutions supported by investment from public sources such as the National Institutes of Health. A recent analysis of the most transformative drugs of the last 25 years found that more than half their origins in publicly funded research.” The most important drugs are a result of public funding because this allows for more collaboration between experts; this will be entirely unaffected by price controls on PRIVATE companies.

## A2: Monopolies

### The monopolies can’t form in the first place.

#### 1. [DELINK]: Any monopoly formed would be broken up by the government. The Balance reports in October that any monopoly that provides unfair product prices is illegal and would be broken apart.

### But secondly, mergers and acquisitions are happening anyway.

#### 2. [NON-UNIQUE]: Lo of Pharmaceutical Technology reports in 2015 that mergers and acquisitions are already happening at record pace in the pharmaceutical industry because it is a good way to cut costs in an expensive industry. Indeed, the number of major pharmaceutical companies has reduced from 42 to just 11 in the last 20 years because of mergers and acquisitions. This is already happening at record pace–there’s no way the pro makes it worse.

### But even if you believe that mergers and acquisitions increase in our world, this is actually a good thing:

#### [LINK]: Wieczner of Fortune explains in 2015 that slowed revenue growth causes investors and companies to form monopolies to boost profit.]

### Two reasons to vote for us here:

#### 3. [TURN]: Dorfman of the University of Georgia warrants in 2017 that mergers are beneficial for consumers because it incentivizes startups in the industry to create more innovative products because they want to bought out by big companies.

#### 4. [TURN]: Mergers increase productivity and drug development. Ringel of Stat News reports in 2017 that mergers increase innovation in two ways: first by bringing together experts and knowledge from both organizations and second by triggering reviews of each project so that only viable projects are pursued and ones likely to fail are scrapped. Ringel concludes that on net, mergers increase the number of innovative therapies brought to patients. [Empirically, Li of the Asian Development Bank Institute studies more than 1000 mergers and acquisitions in 2017 and finds that firms tend to have higher innovation quality after a merger.]

## A2: Produce Generics Instead

#### 1. [DELINK]: Companies are never going to produce generics because it’s not profitable. Sanders of the Huffington Post reports in 2015 that generics are 33 times cheaper than brand-named drugs. Companies would never switch to generic production because it destroys their revenue.

#### 2. [NON-UNIQUE]: Companies produce at their profit-maximizing equilibrium anyway. So, if generics will truly give them more revenue, the companies would already be producing them, meaning the problem can’t get worse when you vote pro.

McCaughan, Mike. “Pricing Orphan Drugs.” The Physician Payments Sunshine Act, 21 July 2017, www.healthaffairs.org/do/10.1377/hpb20170721.588081/full/.

A 1983 law created incentives to develop drugs to treat rare diseases that might otherwise not justify commercial investment. Many of the drugs developed by companies relying on incentives created by the Orphan Drug Act have high prices. This has made the law controversial, though the relationship between those high prices and the incentives in the law is not always clear. One prominent incentive in the Act is a special period of market exclusivity that prohibits the Food and Drug Administration (FDA) from approving a competing version of the drug for seven years--in essence, a

Bernie Sanders. The Huffington Post. 29 August 2015. “High Drug Prices Are Killing Americans.” https://www.huffingtonpost.com/bernie-sanders/high-drug-prices-are-kill\_b\_8059526.html

We should penalize drug companies that commit fraud. They seem to feel the same way big banks do: that paying fines and settlements is simply part of the cost of doing business. That needs to change. We should pass legislation which says that drug companies lose their government-backed monopoly on a drug if they are found guilty of fraud in the manufacture or sale of that drug. We should end “pay for delay.” That’s the collusion which takes place between drug companies when the holder of a brand-name patent pays another drug company to hold off on manufacturing a generic substitute. Brand-name drugs cost ten times as much as generics, on average, and can cost as much as 33 times as much. We should also demand transparency from drug companies, who have been concealing the true cost of their research and development while at the same time taking tax breaks for it and using biased figures as an excuse for price gouging.

Jen Wieczner. Fortune. 28 July 2015. “The real reasons for the pharma merger boom.” <http://fortune.com/2015/07/28/why-pharma-mergers-are-booming/>

For a company like Teva, cost cuts are a primary motivation for dealmaking. The world’s largest drug manufacturer is facing steep competition from a slew of smaller generic players, and the recent loss of patent protection on its major branded drug, Copaxone, is threatening Teva’s profit margins. By acquiring a rival generic maker, Teva can claim more market share in the industry and also slash any overlapping divisions (and their staff): After absorbing Allergan’s generics business, it expects to save $1.4 billion annually. (Teva had said it would have saved $2 billion annually had it bought Mylan.) But growth is the main driver for M&A deals: Not just growth in drug distribution scale or earnings growth through cost-cutting, but in revenues—and especially share price. Revenue growth has slowed as many companies sink more resources into developing the next blockbuster drug; what’s more, the “patent cliff” for the last round of megabillion-dollar drugs—when generics firms typically see a sales spurt—happened a few years ago. Investors have recently rewarded both targets and acquirers upon pharma deal announcements (whereas in the past, shares of the acquirer would often sink due to the supposed transaction costs). Because of the likelihood that pursuing an acquisition will boost a company’s revenue growth and thus its share price, investors have increasingly been [pressuring pharmaceutical firms such as Gilead Sciences](http://fortune.com/2015/05/23/can-gilead-grow-without-a-deal/) [(GILD, +1.11%)](http://fortune.com/2015/07/28/why-pharma-mergers-are-booming/) and Teva to strike deals. Shares of Teva, for instance, rose nearly 17% on Monday after the Allergan transaction was announced, while shares of Allergan rose 6%. Consider also a company like Horizon Pharma [(HZNP, -0.67%)](http://fortune.com/2015/07/28/why-pharma-mergers-are-booming/), a biopharmaceutical firm that has acquired three other pharma firms since September of 2014. Horizon says acquiring other medicines is as much as part of its strategy as R&D. The company expects its revenues and profits to roughly double this year, and it recently launched an unsolicited takeover bid for Depomed [(DEPO, +1.19%)](http://fortune.com/2015/07/28/why-pharma-mergers-are-booming/). Horizon’s stock price is up more than 250% since September.

Michael Ringel. Stat News. 24 July 2017. “A new wave of pharma mergers could put innovative drugs in the pipeline.” https://www.statnews.com/2017/07/24/mergers-pharma-drug-development/

To determine whether mega-mergers benefit patients, we looked at what happened to research and development productivity in all of the major mergers going back to 2001, including the last big wave in 2009 that brought together Merck & Co. and Schering-Plough, Pfizer and Wyeth, and Roche and Genentech. As expected, the results varied from year to year and company to company. But our report in Drug Discovery Today showed that mergers generally appeared to drive productivity up — and did so significantly. Why might this be so? While mergers undoubtedly bring disruption to research and development, they also can be catalysts for addressing the fatal flaw of most research and development enterprises: the high cost of failure. More than 90 percent of pharmaceutical industry spending on research and development goes into projects that never reach the market. Any intervention that helps reduce this waste can be a real boon to productivity. There are really only two ways to fix the industry’s cost-of-failure problem: 1) start with better science, so you have fewer failures; and 2) employ better decision-making about when to stop projects so you can reallocate that capital to more-promising opportunities. Mergers can help with both of these dimensions. They bring the best combined science of the merged organizations to bear on the difficult questions of which pathways, modalities, and molecules to pursue. Mergers also trigger reviews that drive the leadership of the new company to take a fresh look at research and development. These reviews can offer the leadership an opportunity to soberly and objectively reassess its scientific hypotheses in each disease area and reevaluate the combined research and development portfolio, eliminating those projects least likely to produce advances in treatment. This spring cleaning can have a cathartic effect. The combination of the two factors — fresh science and a fresh look at the portfolio — can create a renewed research and development enterprise better able to bring new medicines to patients. Our analysis doesn’t suggest that all mergers are good. Even from the perspective of research and development productivity, some mergers in our study appeared to have depressed the flow of new medicines to patients by slowing down or stopping promising projects. And there are considerations beyond the scope of our analysis, such as jobs or drug prices, that may be equally valid inputs to views about mergers and acquisitions. Overall, however, the evidence indicates that large mergers increase, not decrease, the productivity of pharmaceutical research and development — good news for those in need of new therapies.

Chris Lo. Pharmaceutical Technology. 6 January 2015. “Pharma mergers: big business, bad science?” https://www.pharmaceutical-technology.com/features/featurepharma-mergers-big-business-bad-science-4467897/

Like any major industrial sector, the pharmaceutical industry is vulnerable to the vagaries of the free market. Balancing the demands of cutting-edge research with the need to make a healthy return on investment and satisfy shareholders is a tricky tightrope for pharma companies to walk, particularly at a time when the pipeline for innovative new blockbuster drugs is slowing to a trickle and patent expiries are biting deep into the sales of drugs that have provided a massive and steady stream of revenue for decades. The result of the modern squeeze on pharmaceutical innovation has been the rise of a risk-averse mentality among pharma companies and a greater tendency to hold huge amounts of cash on hand, coupled with a surge of mergers and acquisitions (M&A) as the industry consolidates and firms endlessly restructure and realign their portfolios. The era of M&A M&A activity in the pharmaceutical industry is showing no signs of slowing down. According to data compiled by Bloomberg, the month of April 2014 saw more than $118bn worth of pharma deals proposed or announced, a figure not too far off the $174bn spent on M&A in the industry during the whole of 2013. In the US, sustained consolidation over the last 20 years has meant that only 11 original members of the Pharmaceutical Research and Manufacturers of America industry lobby still remain in operation today, compared with 42 in 1988. Pfizer, at the head of the M&A pack by a country mile, has spent more than $219bn since 1994 on large-scale takeovers of rivals like Warner-Lambert, Pharmacia and Wyeth – an already eye-watering sum that could have been much higher if its aborted takeover bid for UK pharma company AstraZeneca had gone ahead earlier this year.

The Balance. 21 October 2017. “How Monopolies Impact the Economy.” https://www.thebalance.com/monopoly-4-reasons-it-s-bad-and-its-history-3305945

He goes on to say, "All happy companies are different: Each one earns a monopoly by solving a unique problem. All failed companies are the same: They failed to escape competition." He suggests entrepreneurs focus on "What valuable company is nobody building?" (Source: "Three Cheers for 'Creative Monopolies,'" The Wall Street Journal, October 13, 2014.) Monopolies in the United States Monopolies in the United States aren't illegal. But the Sherman Anti-Trust Act prevents them from using their power to gain advantages. Congress enacted it in 1890 when the monopolies were Trusts. A group of companies formed a trust to fix prices low enough to drive competitors out of business. Once they had a monopoly on the market, they would raise prices to regain their profit. The most famous trust was Standard Oil Company. John D. Rockefeller owned all the oil refineries, which were in Ohio, in the 1890s. His monopoly allowed him to control the price of oil. He bulliod the railroad companies to charge him a lower price for transportation. When Ohio threatened legal action to put him out of business, he moved to New Jersey. He also set up the first trust. He bought up the majority share of former competitors' stock certificates of trust. (Source: "The Sherman Anti-Trust Act," American.gov archive.)

Jeffrey Dorfman, 4-10-2017, "Can Mergers Cause Mergers? Yes, And It Can Be A Good Thing," Forbes, https://www.forbes.com/sites/jeffreydorfman/2017/04/10/can-mergers-cause-mergers-yes-and-it-can-be-a-good-thing/#187c5fee6c53

A recent [paper](https://academic.oup.com/ajae/article-abstract/98/5/1360/2415569/Concentration-Product-Variety-and-Entry-for-Merger?redirectedFrom=fulltext) in the American Journal of Agricultural Economics by Haimanti Bhattacharya and Rob Innes examined the effect of concentration on new product introductions in the food industry. They find that higher levels of concentration lead to a larger number of new products, partly from small firms hoping that a successful product will lead to a large firm buying them. This entry-for-merger strategy is not confined to the food industry; for example, it is also a common strategy in the tech sector. As [reported](https://techcrunch.com/2015/04/25/is-seattle-silicon-valleys-next-favorite-stop/) by Hadi Partovi, many tech start-ups have located in Seattle with a business plan of becoming just successful enough for Microsoft to buy them out. In addition, this entry-for-merger behavior leads to even more concentration as the biggest firms buy up the best new products and ideas, gaining even more market share as they do so. Yet, new product innovation increases simultaneously because entrepreneurs and innovators see the success of the entry-for-merger strategy. This creates a positive feedback loop: concentration leads to more innovation, which leads to more concentration, and on and on. Thus, high industry concentration does not necessarily lead to stodgy firms stuck in their ways, but can instead lead to a dynamic industry burgeoning with innovation by a swarm of small start-ups. Interestingly, under such a scenario, concentration even leads to somewhat lower prices than if the big firms themselves were developing the new products. If incumbent industry leaders do the innovating, their customers must pay the full cost of their R&D programs. In contrast, when innovation comes from small start-ups, only the successful ones are bought out by the big firms. The cost of failed products is borne by those start-ups’ investors and any lenders. Therefore, entry-for-merger can deliver not only plenty of innovation but also does so at a lower price for the customers of the successful new products. A highly concentrated industry in which entry-for-merger is a common strategy is also likely to be more competitive than might be indicated by its concentration ratio. Certainly, entry-for-merger implies there are not high barriers to entry for new products which can help a merger partner take market share away from competitors. This ease of entry makes the industry what economists call [contestable](https://en.wikipedia.org/wiki/Contestable_market). Contestability means concentration does not automatically lead to higher prices because if the big existing firms raise prices too high, it just encourages more entrants, potentially both entrants-for-merger and big firms from other industries who could buy a bunch of small innovators to suddenly join the industry with size and scale. All this means that the increasing concentration we see in the food industry (and others) should not be assumed to be a bad thing too quickly. Concentration when combined with high barriers to entry can lead to anticompetitive behavior, high prices, and disadvantaged consumers. However, in more and more industries these days we are observing higher concentration even without barrier to entry, thanks to mergers. The research by Bhattacharya and Innes gives us reason to hope that in many such cases, concentration can leave consumers both with low prices and lots of new products. When entry-for-merger is a viable strategy, concentration actually can bring consumers multiple benefits rather than harm. Jeffrey Dorfman is a professor of economics at The University of Georgia. His last popular press book is an e-book, [Ending the Era of the Free Lunch](https://www.amazon.com/Ending-Free-Lunch-Jeffrey-Dorfman-ebook/dp/B006TO6T1A). You can follow him on Twitter [@DorfmanJeffrey](http://twitter.com/DorfmanJeffrey)

Li, Kai. Asian Development Bank Institute. "Mergers and Acquisitions and Corporate Innovation." (2017).

Hall’s (1988) is one of the first large-sample studies on the relationship between M&As and corporate R&D (without using patent data), and it examines the ex ante selection effect of corporate R&D on M&As and the impact of target R&D on the valuation premium at the time of the takeover. The sample comprises 2,519 US manufacturing firms in Compustat between 1976 and 1985, when around 600 of the firms were acquired. Using a logit regression, the author finds that high R&D intensity (i.e., R&D expenditures/sales) is associated with a lower likelihood of becoming acquirers, and is not significantly associated with the likelihood of becoming targets. Matching each acquirer with six randomly drawn firms and using a conditional logit model to study the likelihood of pair formation, the author finds that intra-industry mergers tend to take place between pairs of similar size and with similar R&D intensity, and that the valuation premium at the time of the takeover is positively related to the target firm’s R&D stock. Zhao’s (2009) is one of the first large-sample studies to use patent data to examine whether technological innovation drives firms’ acquisition decisions and how an acquisition affects technological innovation in subsequent years. Using a sample of 1,053 US M&A deals by public acquirers from 1984 to 1997 and 7,798 industry- and size-matched non-bidding firm-year observations, the author first shows that compared to other firms, bidders tend to have lower innovation quality measured by the number of patent citations (i.e., citation counts) before acquisition, while they have similar innovation quantity measured by the number of patents (i.e., patent counts). Further, bidders are more likely to complete the deal if their citation counts are low, whereas there is no significant relationship between bidder patent counts and the likelihood of deal completion. Finally, using a different matched sample based on a long list of firm characteristics, including sales, market-to-book (M/B) ratio, R&D, profitability, returns, market leverage, and industry, as well as patent counts and citation counts in the year of deal completion, the author shows that after deal completion, formerly less innovative bidders experience significantly greater improvement in patent counts, citation counts, and stock performance compared to non-bidding peers; formerly more innovative bidders do not behave differently after the acquisition compared to 4 ADBI Working Paper 789 K. Li non-bidding peers. Finally, bidders with failed bids have fewer patent counts and citation counts than their peers during the subsequent three years. The author concludes that acquisition could be one way of remedying firms’ innovation deficiencies, particularly for less innovative firms. The paper does not differentiate innovation at different stages of development, such as unrealized innovation (i.e., R&D) vs. realized innovation (i.e., patents), nor does it establish a causal relationship between M&As and subsequent innovation outcomes, leaving some gaps for future work in the area to fill

Merrill Goozner. Harvard Health Policy Review. 22 December 2016. “Drug Prices Are Unrelated to Research and Development Costs.” http://www.hhpronline.org/articles/2016/12/21/drug-prices-are-unrelated-to-research-and-development-costs

For the winners, those returns have been substantial. The financial filings of the major pharmaceutical companies, who continue to fund the vast bulk of R&D or buy drugs in the late stages of their development from start-ups and experienced drug development firms that make up the biotechnology industry, are the envy of Wall Street. In fact, they are consistently higher than banking and other financial institutions. While total industry spending on R&D equaled nearly 20% of sales in 2015 and averaged between 16% and 18% for most of the past two decades, 9 profits have been even higher. The pharmaceutical and biotechnology industries are projected to post profit margins around 25% in 2016. The only sectors earning higher margins, according to a recent analysis in Forbes Magazine, were investment managers, the tobacco industry and, highest of all, generic drug makers at a 30% margin. 10 Despite the industry’s substantial spending on R&D, which grows or shrinks in lockstep with total sales, there is rising concern about declining return from research. One study projected falling, even negative returns and predicted the “rewards for innovation” would be insufficient “to sustain biomedical innovation.” 11

Richard Harris. NPR. 11 September 2017. “R&D Costs For Cancer Drugs Are Likely Much Less Than Industry Claims, Study Finds.” https://www.npr.org/sections/health-shots/2017/09/11/550135932/r-d-costs-for-cancer-drugs-are-likely-much-less-than-industry-claims-study-finds

Cancer drugs cost far less to develop than industry-backed research asserts, an analysis published Monday asserts. Research and development costs are a major reason that drug companies justify high prices, so this dispute has a direct bearing on the cost of medical care. The analysis, published in the current issue of JAMA Internal Medicine, concludes that it costs, on average, $650 million to develop a new cancer drug. The authors add in another $100 million or so to account for income those companies could have had if that money had been invested in the stock market instead of in new products. That total is far lower than the $2.7 billion figure that the drug industry frequently points to when it justifies the soaring cost of medicine. (It's far higher than $320 million — an inflation-adjusted figure from a 2001 study by the consumer group Public Citizen). To arrive at this new figure, cancer physicians Vinay Prasad, at Oregon Health and Science University, and Sham Mailankody, at the Memorial Sloan Kettering Cancer Center, took a novel approach. They identified 10 companies that each had a single cancer drug on the market. They looked up the companies' research and development costs, as reported in their federal stock reporting paperwork, to come up with the average figure of $650 million.

James Thomas. Science-Based Medicine. 15 October 2016. “R&D and the High Cost of Drugs.” https://sciencebasedmedicine.org/rd-and-the-high-cost-of-drugs/

Kesselheim counters: First, important innovation that leads to new drug products is often performed in academic institutions and supported by investment from public sources such as the National Institutes of Health. A recent analysis of the most transformative drugs of the last 25 years found that more than half of the 26 products or product classes identified had their origins in publicly funded research in such nonprofit centers. Other analyses have highlighted the importance of small companies, many funded by venture capital. These biotech startups frequently take early-stage drug development research that may have its origins in academic laboratories and continue it until the product and the company can be acquired by a large manufacturer, as occurred with sofosbuvir. Arguments in defense of maintaining high drug prices to protect the strength of the drug industry misstate its vulnerability. The biotechnology and pharmaceutical sectors have for years been among the very best-performing sectors in the US economy. The proportion of revenue of large pharmaceutical companies that is invested in research and development is just 10% to 20% (Table 4); if only innovative product development is considered, that proportion is considerably lower. The contention that high prescription drug spending in the United States is required to spur domestic innovation has not been borne out in several analyses. A more relevant policy opportunity would be to address the stringency of congressional funding for the National Institutes of Health, such that its budget has barely kept up with inflation for most of the last decade. Given the evidence of the central role played by publicly funded research in generating discoveries that lead to new therapeutic approaches, this is one obvious area of potential intervention to address concerns about threats to innovation in drug discovery.

Science News Staff. Science Magazine. 23 March 2018. “Trump, Congress approve largest U.S. research spending increase in a decade.” https://www.sciencemag.org/news/2018/03/updated-us-spending-deal-contains-largest-research-spending-increase-decade

It took an extra 6 months, but Congress has finally completed its work on a spending plan for the 2018 fiscal year, which began last October. And the delay was good news for many federal science agencies. President Donald Trump today signed into law a $1.3 trillion spending package that largely rejects deep cuts to research agencies proposed by the White House and, in many cases, provides substantial increases. When it comes to federal research spending, there are “some silly good numbers in here,” tweeted Matt Hourihan, who analyzes U.S. science spending patterns for AAAS (publisher of ScienceInsider) in Washington, D.C., when the deal was released this past Wednesday. In an analysis, Hourihan and his colleague David Parkes note that the research spending increase is the largest in more than a decade. They estimate R&D spending in 2018 will reach “$176.8 billion, an increase of 12.8% or $20.1 billion above FY 2017 estimated R&D. … [T]otal federal R&D spending would reach its highest point ever in inflation-adjusted dollars. … Basic and applied research funding would receive its largest year-over-year increase since” the 2009 economic stimulus package. The increases were made possible, in large part, by an agreement reached earlier this year to raise mandatory caps on civilian and military spending that gave lawmakers an additional $300 billion to spend this year and next. Here’s a look at some of the top line numbers for key science agencies: The National Institutes of Health (NIH) in Bethesda, Maryland, receives a $3 billion, 8.3% increase to $37 billion. That is well above the increase proposed by either the House of Representatives or the Senate in their versions of the spending bills, and a blunt rejection of the 22% cut proposed by the White House. Included is an additional $414 million for Alzheimer’s disease research, for a total of $1.8 billion, and a $27 million boost, to $543 million, for clinical and translational science funding. The NIH increase is “beyond words, folks,” tweeted Benjamin Corb, director of public affairs at the American Society for Biochemistry and Molecular Biology in Rockville, Maryland. The National Science Foundation in Alexandria, Virginia, would get $7.8 billion, a 3.9% or $295 million increase. The agency’s research account would grow by about 5%, to $6.3 billion. The bill notes "this strong investment in basic research reflects the Congress' growing concern that China and other competitors are outpacing the United States in terms of research spending." It also endorses the Senate’s call to build three new oceanographic research vessels. The Department of Energy’s Office of Science in Washington, D.C., would receive $6.26 billion, an $868 million increase. That is roughly a 15% increase, rather than the 15% cut the White House proposed. Lawmakers also rejected Trump’s proposal to eliminate the Advanced Research Projects Agency-Energy, and instead gave it a $47 million boost, to $353 million. A $457 million, 7.9% increase for NASA science programs, to $6.2 billion. The bill increases the agency’s planetary science program by some 21%, or $382 million, to $2.2 billion. NASA’s earth science programs remain flat at 2017 levels, but the bill rejects the proposed elimination of several earth science missions and maintains funding for the troubled Wide Field Infrared Survey Telescope. Overall, NASA gets $20.7 billion, $1.1 billion above 2017. Spending at the National Oceanic and Atmospheric Administration in Silver Spring, Maryland, would grow by $234 million, to $5.9 billion overall. Funding for climate research would remain flat, but the final bill rejects cuts proposed by Trump and the House. The National Institute of Standards and Technology ​in Gaithersburg, Maryland, would get $1.2 billion, $247 million above 2017 levels. The U.S. Geological Survey in Reston, Virginia, gets $1.1 billion, $63 million above 2017 levels. The bill preserves the agency’s eight climate science centers; the White House had proposed cutting that number in half. Research programs at the U.S. Department of Agriculture in Washington, D.C., would grow by $33 million, to $1.2 billion. The budget of the Environmental Protection Agency ​in Washington, D.C., remains flat at $8.1 billion, as lawmakers rejected deep proposed cuts.

Hagop Kantarjian. U.S. News. 12 December 2016. “The Harm of High Drug Prices.” https://www.usnews.com/opinion/policy-dose/articles/2016-12-12/the-harm-of-high-drug-prices-to-americans-a-continuing-saga

Despite protests, prices continue to escalate. In 2015, the average price of a new cancer drug was $145,000/year. The price per year of life gained increased from $54,000 in 1995 to $207,000 in 2013, while real median American household income rose by seven percent. Unlike in Europe and elsewhere, the prices of older drugs in the U.S. continue to increase by an average of 8-12 percent annually, allowing new cancer drugs to be launched at higher prices every year, in lockstep with the rising prices of older drugs. Under criticism, the drug industry repeats the same arguments: 1) high cost of research and development; 2) benefit justifies price; 3) market forces; and 4) regulating prices stifles innovation. But all four arguments lack validity. The cost of research and development is only 10 percent of the $1-2.6 billion figure that is claimed in industry-supported studies. More than 50 percent of important discoveries are made in independent academic centers, funded by taxpayers, and 85 percent of basic research is conducted in academic centers. The drug industry spends 1.3 percent of its budget on basic research, but 20-40 percent on advertisements and related activities. Some studies show no relationship between drug benefits and price. Drug companies enjoy monopoly-like conditions that discourage competition based on price. Finally, innovation is driven by independent investigators who will continue to conduct research even if drug prices fall. High drug prices are harmful. Medical costs and out-of-pocket expenses result in high rates of bankruptcies, and 10-25 percent of patients either delay, abandon or compromise treatments because of financial constraints. Survival is also compromised. For example, in chronic myeloid leukemia, the 8-10 year survival rate is 80 percent in Europe (where treatment is universally affordable); in the U.S., where finances may limit access to drugs, the 5-year survival is 60 percent. In surveys, 78 percent of Americans worry most about costs of drugs.

Jim Edwards. CBS News. 28 June 2011. “Hey, Whaddya Know -- Drug-Price Controls Don't Kill Medical Innovation.” https://www.cbsnews.com/news/hey-whaddya-know-drug-price-controls-dont-kill-medical-innovation/

Drug price controls will punish innovation and drive down R&D spending -- that's the familiar mantra of the pharmaceutical industry. But a new report from Canada, which has strict price controls, shows no relationship between R&D spending and price regulation. The report, by Canada's Patented Medicine Prices Review Board, says that drug prices in the U.S. are about twice as high as most other countries, and that U.S. drug companies spend less on R&D in the U.S. than they do in many countries with strict price regulation. Drug sales are growing faster in Canada despite price controls, and Canadians spend about the same on drugs as a percentage of GDP as Americans do, the report shows. It's all statistics, of course, and thus should be taken with a pinch of salt. Plus, the geographic location of drug R&D spending is unrelated to sales, as companies move their labs and testing facilities to the cheapest countries, such as China and India. In terms of delivering cheaper drugs, price controls work, the report says: The U.S. is the only major Western country that has no formal system of controlling prices or bargaining with drug companies for supplies. And it shows, with drug prices roughly twice in the U.S. what they are elsewhere: Critics might point to the fact that in Canada, drug companies spend only 8.1 percent of their sales on R&D while in the U.S companies spend 19.4 percent. But those same critics are unlikely to point out that in the U.K., which like Canada has a fully public system, R&D spending is 42.3 percent of sales. In Switzerland -- home of Novartis (NVS) and Roche (RHBBY) -- R&D is apparently 120 percent of sales. Switzerland has a three-yearly cycle of government price controls: The flow of new drugs seems uninterrupted, unless you're only willing to look at the numbers since 2006:

Aidan Hollis. June 2014. University of Calgary. “An Efficient Reward System for Pharmaceutical Innovation.” http://www.who.int/intellectualproperty/news/Submission-Hollis6-Oct.pdf

It is well known that monopoly exploitation of innovations under the patent system can reduce the benefits or “surplus” available to society from an innovation. This inefficiency is tolerated because the monopoly profits create an incentive to innovate, and in the absence of innovation, even less social surplus is created. Underlying this trade-off between high prices and innovation is the understanding that if people are willing to pay high prices for a good, that indicates that it is a valuable innovation. The greater the value to consumers, the higher the price the innovator can charge, and the greater the profits. This means, in turn, that the incentive for innovators is to undertake research that is valuable to society, since such innovations will earn high rewards. If rewards are not proportional to the social value, then the patent system cannot work well: it will lead firms to invest in innovations which have little social value, while ignoring avenues of investigation which could be of immense social value. Unfortunately, pharmaceutical markets are among the least well functioning of all markets, undermining the connection between value and reward. Doctors prescribe medications based on their beliefs as to the best medicine, somewhat influenced, presumably, by the extensive detailing and advertising focused on them. Since doctors do not pay for the medicines they prescribe, price is not an important component of their decision-making process. Consumers are typically ignorant of possible choices, and of the differences between various therapies and medicines and how these would relate to their own physiology, and may be paying only a fraction of the price of any medicine, or may pay nothing at all. The other part will be paid for by an insurer – possibly government or a private company – which has limited influence over the medicine prescribed.6 In these circumstances, price is a relatively unimportant strategic variable for competition between drugs – detailing of doctors may be more important. In addition, prices in many countries are regulated by government. The result is that prices may be either too high or too low compared to the ideal market (one in which consumers are informed about the choices they make and then bear the full cost of those choices).

Tendayi Viki. Forbes. 21 August 2016. “Why R&D Spending Is Not A Measure Of Innovation.” https://www.forbes.com/sites/tendayiviki/2016/08/21/why-rd-spending-is-not-a-measure-of-innovation/#1cd1c3dcc77d

However, leaders may be asking the wrong questions here. A focus on R&D spending might be a good way to gauge best practice within an industry, but it is not a measure of how innovative any company really is. Having a great R&D process and achieving market success with the technologies we invent are two different things. Strategy&, a business unit within PriceWaterhouseCoopers, has b”een publishing an annual report of the top 1000 most innovative companies in the world for over 12 years now. In that time, it has found no statistically significant relationship between R&D spending and sustained financial performance. Its findings apply to total R&D spend, as well as R&D spending as a percent of revenues. Spending on R&D is not related to growth in sales or profits, increases in market capitalization or shareholder returns. In every single annual report that Strategy& has published, the top 10 most innovative companies are rarely the top 10 spenders on R&D. Strategy&’s research makes it clear that it is not the amount of money spent on R&D that produces innovation success. But why might this be the case? Steve Blank distinguishes between technical risk and market risk. Technical risk is about whether a company is capable of creating new technologies and making them work. In contrast, market risk is about whether customers will buy and use the product, even if the technology works. Innovation is about solving for both technical and market risk. The challenge with R&D labs is that they have traditionally focused on solving for technical risk only. While this might increase a company’s number of patentable technologies, it does not guarantee the success of those technologies in the market. To solve for market risk, companies need innovation frameworks and processes that allow them to search for sustainable business models.

# \*\*\*Government\*\*\*

# A2: Will Cause Political Backlash

#### 1. [DELINK]: Pharmaceutical companies don’t really have political power anyway. Weixel of The Hill reports last month that combatting high drug prices is a bipartisan issue. Thus, pharmaceutical companies can’t really buy out senators or representatives because there is no political risk is voting against high drug prices.

#### 2. [DELINK]: Their argument is historically untrue. Manning of the Washington Examiner reports in May that Trump has been able to roll out a plan called “American Patients First” that aims to combat high prescription drug prices. There’s been no retaliation against this plan, meaning their argument isn’t true.

Nathaniel Weixel. The Hill. 17 October 2018. “Trump officials ratchet up drug pricing fight.” https://thehill.com/policy/healthcare/411755-trump-officials-ratchet-up-drug-pricing-fight

President Trump vowed on the 2016 campaign trail to take on high drug prices, and Azar’s proposal comes with just three weeks left before the November midterm elections. Drug prices have spiked over the last decade, putting a pinch on consumers who have not seen wages keep pace with the hikes. Polls consistently show significant voter outrage over drug prices, and it’s a bipartisan issue. That support makes it a tougher fight for the drug industry.

Hadley Manning. Washington Examiner. 15 May 2018. “Trump tackles soaring prescription drug prices.” https://www.washingtonexaminer.com/opinion/trump-tackles-soaring-prescription-drug-prices

The Trump administration has just rolled out an ambitious regulatory framework for combating high prescription drug prices, called American Patients First. This plan identifies four key problem areas for drug costs today: high list prices for drugs, a lack of negotiation tools in government programs, increasing out-of-pocket costs, and foreign governments free-riding on American innovation. And in response, the administration lays out four solutions or goals: increased competition, better negotiation tools for government programs, incentives for lower list prices, and reduced out-of-pocket costs. While this new plan is the most comprehensive effort any administration has made in this issue area, and while it’s attractive to hone in on just a few key areas, it’s worth remembering that drug policy, like the rest of our health policy, is very complicated. Lowering prescription drug costs is not going to be straightforward or easy (it’s not just a four-item checklist). But this is a helpful framework, and we should applaud the administration’s efforts and focus on the issue.

# \*\*\*Economy\*\*\*

# A2: Disrupts Supply and Demand

#### 1. Supply and demand only makes drugs more affordable when multiple companies sell the same product because this allows consumers to choose the most affordable of all the market options, coercing companies to decrease their prices to be competitive. However, the pharmaceutical industry does not follow this narrative because a single company has a monopoly on any patented drug, meaning they are the only ones that can legally produce it. This forces consumers to pay whatever astronomical price that company demands. That means supply and demand doesn’t regulate the pharmaceutical industry anyway.

# A2: PC Encourage Illegal Market

#### 1. [DELINK]: People will only turn to the illegal market if they are either a. getting better quality drugs or b. there is a shortage in the formal economy. Neither of these things is going to happen:

#### First, the quality of drugs will remain the same because innovation will continue. Two warrants:

#### First, Kantarjian of Rice University explains in 2016 that companies only spend 1.3 percent of their budgets on innovation. At that point, even if price controls reduced the profit margin of pharmaceutical companies, they would still have plenty of money left for research and development.

#### But second, Viki of Forbes does a 12-year study of the 1000 most innovation companies in the pharmaceutical industry and finds that R&D spending has no statistically significant relationship to innovation because there are too many variables involved, such as market and technical risk.

#### Because innovation remains the same, the quality of medicine will too.

#### Secondly, there won’t be a shortage because pharmaceutical companies will still produce enough drugs because there is still profit to be made. Goozner of the Harvard Health Policy Review explains in 2016 that the pharmaceutical industry posted a 25 percent profit in 2016. Reducing this profit margin slightly by imposing price controls would still leave an incentive for production.

#### Ultimately, because the variables that cause movement towards the illegal market won’t play out, this isn’t going to be a problem.

#### 2. [TURN]: Edwards of Orion College reports in 2017 that high prices of medicine have forced patients to turn to the illegal market, which they find to be riskier, but cheaper. This means that patients are getting lower quality, potentially deadly, drugs that could cost them their life.

Hagop Kantarjian, U.S. News, "The Harm of High Drug Prices to Americans – A Continuing Saga | Policy Dose | US News", December 12, 2016, https://www.usnews.com/opinion/policy-dose/articles/2016-12-12/the-harm-of-high-drug-prices-to-americans-a-continuing-saga

Under criticism, the drug industry repeats the same arguments: 1) high cost of research and development; 2) benefit justifies price; 3) market forces; and 4) regulating prices stifles innovation. But all four arguments lack validity. The cost of [research and development](http://onlinelibrary.wiley.com/doi/10.1002/cncr.28321/pdf) is [only 10 percent](http://www.pharmamyths.net/files/Biosocieties_2011_Myths_of_High_Drug_Research_Costs.pdf) of the [$1-2.6 billion](http://www.nejm.org/doi/full/10.1056/NEJMp1500848) figure that is claimed in industry-supported studies. More than 50 percent of important discoveries are made in independent academic centers, funded by taxpayers, and 85 percent of basic research is conducted in academic centers. The drug industry spends [1.3 percent](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1261198/) of its budget on basic research, but 20-40 percent on advertisements and related activities. Some [studies](http://ascopubs.org/doi/pdf/10.1200/JCO.2008.21.0534) show no relationship between drug benefits and price. Drug companies enjoy monopoly-like conditions that discourage competition based on price. Finally, innovation is driven by independent investigators who will continue to conduct research even if drug prices fall. High drug prices are harmful. Medical costs and out-of-pocket expenses result in high rates of [bankruptcies,](http://www.amjmed.com/article/S0002-9343%2809%2900404-5/pdf) and 10-25 percent of patients either [delay](http://ascopubs.org/doi/pdf/10.1200/JCO.2013.52.9123), abandon or [compromise treatments](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3639525/)because of financial constraints. Survival is also compromised. For example, in chronic myeloid leukemia, the 8-10 year [survival rate](http://jnci.oxfordjournals.org/content/103/7/553.full.pdf%2Bhtml) is 80 percent in Europe (where treatment is universally affordable); in the U.S., where finances may limit access to drugs, the 5-year [survival is 60 percent.](http://www.tandfonline.com/doi/full/10.3109/10428194.2012.745525) In surveys, 78 percent of Americans worry most about costs of drugs. Sadly, three years after the issue was raised, there has been little progress. The problem is compounded by 2 additional factors. First is the increasing shift in the cost of care and drugs to patients. Insurers justify this "skin-in-the-game" strategy as effective in reducing costs, but the high out-of-pocket expenses have turned this into "deterrence-in-the-game," discouraging patients from seeking care or purchasing drugs. In a recent survey, one-third of insured Texans delayed or did not pursue care because of high out-of-pocket expenses. Second is the spill-over of high drug prices to [generics](http://www.bloodjournal.org/content/bloodjournal/127/11/1398.full.pdf?sso-checked=true). Complex regulatory issues and shortages allow companies to increase prices of generics to levels as high as patented drugs. The latest scandals – Turing, Valiant and Mylan – are only the most extreme examples of a [common strategy](https://www.bloomberg.com/news/articles/2015-10-02/pfizer-raised-prices-on-133-drugs-this-year-and-it-s-not-alone) in pricing drugs. Generic Imatinib to treat chronic myeloid leukemia is priced at $5,000-8,000/year in Canada, $400/year in India, but [$140,000/year](http://www.nature.com/nrclinonc/journal/v13/n5/full/nrclinonc.2016.59.html) in the U.S. For generic drugs to be priced low, [four to five generics](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm) have to be available. The [average cost](http://www.wsj.com/articles/how-obamas-fda-keeps-generic-drugs-off-the-market-1471645550) of filing for FDA approval of a drug is $5 million in 2016, and the average time to approval is 4 years. There are currently more than 3,800 generic drug applications awaiting FDA action. The FDA should overhaul its procedures to reduce the cost of filing to less than $1 million per drug, reduce the timeline to approval to 6-12 months and monitor for the availability of multiple generics at all times.

Merrill Goozner. Harvard Health Policy Review. 22 December 2016. “Drug Prices Are Unrelated to Research and Development Costs.” http://www.hhpronline.org/articles/2016/12/21/drug-prices-are-unrelated-to-research-and-development-costs

For the winners, those returns have been substantial. The financial filings of the major pharmaceutical companies, who continue to fund the vast bulk of R&D or buy drugs in the late stages of their development from start-ups and experienced drug development firms that make up the biotechnology industry, are the envy of Wall Street. In fact, they are consistently higher than banking and other financial institutions. While total industry spending on R&D equaled nearly 20% of sales in 2015 and averaged between 16% and 18% for most of the past two decades, 9 profits have been even higher. The pharmaceutical and biotechnology industries are projected to post profit margins around 25% in 2016. The only sectors earning higher margins, according to a recent analysis in Forbes Magazine, were investment managers, the tobacco industry and, highest of all, generic drug makers at a 30% margin. 10 Despite the industry’s substantial spending on R&D, which grows or shrinks in lockstep with total sales, there is rising concern about declining return from research. One study projected falling, even negative returns and predicted the “rewards for innovation” would be insufficient “to sustain biomedical innovation.” 11

James Thomas. Science-Based Medicine. 15 October 2016. “R&D and the High Cost of Drugs.” https://sciencebasedmedicine.org/rd-and-the-high-cost-of-drugs/

Kesselheim counters: First, important innovation that leads to new drug products is often performed in academic institutions and supported by investment from public sources such as the National Institutes of Health. A recent analysis of the most transformative drugs of the last 25 years found that more than half of the 26 products or product classes identified had their origins in publicly funded research in such nonprofit centers. Other analyses have highlighted the importance of small companies, many funded by venture capital. These biotech startups frequently take early-stage drug development research that may have its origins in academic laboratories and continue it until the product and the company can be acquired by a large manufacturer, as occurred with sofosbuvir. Arguments in defense of maintaining high drug prices to protect the strength of the drug industry misstate its vulnerability. The biotechnology and pharmaceutical sectors have for years been among the very best-performing sectors in the US economy. The proportion of revenue of large pharmaceutical companies that is invested in research and development is just 10% to 20% (Table 4); if only innovative product development is considered, that proportion is considerably lower. The contention that high prescription drug spending in the United States is required to spur domestic innovation has not been borne out in several analyses. A more relevant policy opportunity would be to address the stringency of congressional funding for the National Institutes of Health, such that its budget has barely kept up with inflation for most of the last decade. Given the evidence of the central role played by publicly funded research in generating discoveries that lead to new therapeutic approaches, this is one obvious area of potential intervention to address concerns about threats to innovation in drug discovery.

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

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