# Sjostrom/Verska – Cypress Bay Neg v2

## Contention 1 – Lobbying

#### Eric Saganowsky indicated just in October that:

Eric Sagonowsky, 10-23-2018, "As elections near, PhRMA's lobbying spend on track for potential record-breaking year," No Publication, https://www.fiercepharma.com/pharma/as-elections-near-phrma-s-9-month-lobby-spend-grows-to-21m, Date Accessed 11-1-2018 // JM

Pharma has found itself an easy political target in Washington, and as a critical election nears, the industry's lobbying spend shows drugmakers are taking the threat of pricing reform seriously—and shelling out big-time to avoid it. Through the third quarter, pharma's top trade group PhRMA has spent $21.5 million lobbying lawmakers, a 10% increase over the same period [more than] last year, according to a disclosure [form](http://disclosures.house.gov/ld/ldxmlrelease/2018/Q3/300996518.xml) released this week. The figure puts PhRMA on track to beat last year’s spending of $25.43 million, a number that itself represented a big jump from 2016. In fact, if the group keeps up the pace, it could near a record; the highest spending on record came in 2009—the beginning of the Obama administration, with healthcare reform looming—at slightly more than $27 million, according to OpenSecrets.org. In Q3, PhRMA spent nearly $6 million lobbying on a wide range of issues relating to generic drugs, patents, importation, pricing, biosimilars and more, according to the group's form.

#### This backlash is DIRECTLY related to price control policies. There are two reasons why the affirmative makes lobbying increase. First, they can reallocate money dedicated to price controls towards new efforts and second, empirically they fight harder – Saganowsky continues:

Eric Sagonowsky, 10-23-2018, "As elections near, PhRMA's lobbying spend on track for potential record-breaking year," No Publication, https://www.fiercepharma.com/pharma/as-elections-near-phrma-s-9-month-lobby-spend-grows-to-21m, Date Accessed 11-1-2018 // JM

The spending boost comes as politicians on both sides of the aisle—including President Donald Trump—rail at drug prices. The administration in May released a drug pricing blueprint that aims to increase competition and price negotiation for drugs, as well as lower list prices and out-of-pocket costs for patients. Agencies within the federal government are already making moves to bring down prices, such as the FDA's effort to boost generic approvals. More pressure could come after the November elections. Over the weekend, The New York Times [reported](https://www.nytimes.com/2018/10/20/us/politics/trump-pharmaceutical-industry-healthcare.html) that the industry is preparing for a possible worst-case scenario of Democrats and the Trump administration teaming up to lower drug prices. But PhRMA is no stranger to being a political target and often comes out victorious in policy fights. In a surprise loss this year, Congress forced the industry to pay more to make up Medicare's coverage gap, also called the "donut hole." The changes will cost certain companies billions of dollars, and the industry has been working to [reverse the loss](https://www.fiercepharma.com/pharma/lawmakers-reject-industry-effort-to-reverse-doughnut-hole-change-reports) since the change was ushered through.

#### Ben Brody indicated this week that in response to price control rhetoric:

Cynthia Koons and Ben Brody, 11-5-2018, "Pharma Makes Lobbying Push to Roll Back Seniors' Drug Discounts," Bloomberg, https://www.bloomberg.com/news/articles/2018-11-05/pharma-makes-lobbying-push-to-roll-back-seniors-drug-discounts, Date Accessed 11-7-2018 // JM

Pharma giants have been quick to tout their efforts to help the Trump administration rein in runaway drug prices, but behind the scenes the industry has been lobbying furiously to roll back recently mandated medicine discounts for U.S. seniors. [Drug companies](https://www.bloomberg.com/quote/UDG:LN) are focusing lobbying efforts to use a possible lame-duck session of Congress to peel back a legislative loss they suffered earlier this year, according to people familiar with the efforts. On the line for the drug industry is $1.9 billion next year, according to one estimate. Critics say the effort by the industry has the potential to increase costs for some of the most vulnerable and medically fragile Americans: seniors on Medicare. Medicare covers most drug costs until a patient and their plan spend $3,750. Then, coverage drops off and doesn’t pick up again until a patient’s total out-of-pocket costs, including what drug companies pay in discounts, hit $5,000. That gap between coverage is the donut hole. Almost 30 percent of seniors fell into the hole in 2014, according to data from the Medicare Payment Advisory Commission, and more are being affected as costs rise for drugs to treat conditions like diabetes, arthritis and cancer. To make the donut hole less onerous, drugmakers had been required to give a 50 percent discount on their products once seniors hit the spending threshold. A legislative change in February backed by both parties increased the industry discount to 70 percent. That extra discount is what drugmakers want to roll back, claiming that it goes too far and that the drug industry is taking too much of the expense. The lame duck session -- in between the midterm elections Tuesday when Democrats are projected by many to take the House, but before they would actually be seated and take over in January -- may be pharma’s best, last chance unless Republicans hold on. Drugmakers are up against Democrats, who oppose rolling back the larger discounts, but may also struggle with the Trump administration, which has made lowering drug costs for consumers a policy priority. In response, the industry has increased its muscle in Washington. Giants like Johnson & Johnson, [Amgen Inc.](https://www.bloomberg.com/quote/AMGN:US), [AstraZeneca Plc](https://www.bloomberg.com/quote/AZN:LN)and Eli Lilly & Co. boosted spending on lobbying by 30 percent or more in the third quarter, according to an analysis of filings by Bloomberg News. “We support reducing the manufacturer coverage gap rebate percentage,” Ruud Dobber, president of AstraZeneca U.S., said in a statement. Johnson & Johnson spent $1.98 million during that period, more than twice its expenditure during the same period a year earlier, according to lobbying disclosures filed with Congress. The company said the increase was to pay dues to trade associations. Its disclosure forms listed “issues related to Medicare Part D,” as the prescription drug program is known, as a key policy it sought to influence.

#### This influence would be exerted over Medicare – Cynthia Koons argued this week that:

Cynthia Koons and Ben Brody, 11-5-2018, "Pharma Makes Lobbying Push to Roll Back Seniors' Drug Discounts," Bloomberg, https://www.bloomberg.com/news/articles/2018-11-05/pharma-makes-lobbying-push-to-roll-back-seniors-drug-discounts, Date Accessed 11-7-2018 // JM

Pharma giants have been quick to tout their efforts to help the Trump administration rein in runaway drug prices, but behind the scenes the industry has been lobbying furiously to roll back recently mandated medicine discounts for U.S. seniors. [Drug companies](https://www.bloomberg.com/quote/UDG:LN) are focusing lobbying efforts to use a possible lame-duck session of Congress to peel back a legislative loss they suffered earlier this year, according to people familiar with the efforts. On the line for the drug industry is $1.9 billion next year, according to one estimate. Critics say the effort by the industry has the potential to increase costs for some of the most vulnerable and medically fragile Americans: seniors on Medicare. Medicare covers most drug costs until a patient and their plan spend $3,750. Then, coverage drops off and doesn’t pick up again until a patient’s total out-of-pocket costs, including what drug companies pay in discounts, hit $5,000. That gap between coverage is the donut hole. Almost 30 percent of seniors fell into the hole in 2014, according to data from the Medicare Payment Advisory Commission, and more are being affected as costs rise for drugs to treat conditions like diabetes, arthritis and cancer. To make the donut hole less onerous, drugmakers had been required to give a 50 percent discount on their products once seniors hit the spending threshold. A legislative change in February backed by both parties increased the industry discount to 70 percent. That extra discount is what drugmakers want to roll back, claiming that it goes too far and that the drug industry is taking too much of the expense. The lame duck session -- in between the midterm elections Tuesday when Democrats are projected by many to take the House, but before they would actually be seated and take over in January -- may be pharma’s best, last chance unless Republicans hold on. Drugmakers are up against Democrats, who oppose rolling back the larger discounts, but may also struggle with the Trump administration, which has made lowering drug costs for consumers a policy priority. In response, the industry has increased its muscle in Washington. Giants like Johnson & Johnson, [Amgen Inc.](https://www.bloomberg.com/quote/AMGN:US), [AstraZeneca Plc](https://www.bloomberg.com/quote/AZN:LN)and Eli Lilly & Co. boosted spending on lobbying by 30 percent or more in the third quarter, according to an analysis of filings by Bloomberg News. “We support reducing the manufacturer coverage gap rebate percentage,” Ruud Dobber, president of AstraZeneca U.S., said in a statement. Johnson & Johnson spent $1.98 million during that period, more than twice its expenditure during the same period a year earlier, according to lobbying disclosures filed with Congress. The company said the increase was to pay dues to trade associations. Its disclosure forms listed “issues related to Medicare Part D,” as the prescription drug program is known, as a key policy it sought to influence.

#### This logically adds up since seniors have paid a certain amount they reach the “doughnut hole” of Medicare – where they had to, until recently, pay out of pocket. However, new federal regulations mean the drugmakers pay for this – however Bunis argued in 2018 that:

Dena Bunis, 6-21-2018, "AARP: Don’t Mess With Medicare Donut Hole Deal﻿," AARP, https://www.aarp.org/politics-society/advocacy/info-2018/protect-medicare-drug-donut-hole-deal.html, Date Accessed 11-8-2018 // WS

Prescription drug bills for older Americans could climb even higher if Congress reverses a budget agreement that would provide some relief from soaring costs a year earlier than expected, AARP CEO Jo Ann Jenkins [warns in a letter](https://www.aarp.org/content/dam/aarp/politics/advocacy/2018/06/aarp-letter-to-leadership-on-medicare-part-d-deal-061418.pdf) to leaders of the Senate and House of Representatives. As part of the [comprehensive budget deal](https://www.aarp.org/health/medicare-insurance/info-2018/part-d-donut-hole-closes-fd.html) earlier this year, Medicare Part D beneficiaries who have high prescription drug expenses were promised some financial relief. These older Americans currently have to pay more for the medications they rely on. That’s because of a quirky aspect of Part D called the coverage gap, also known as the donut hole. This gap has gradually narrowed since the Affordable Care Act was enacted in 2010 and was scheduled to close completely in 2020, when beneficiaries in the gap would be expected to pay 25 percent of the cost of their prescription drugs. The recent budget deal helped accelerate that process by requiring certain pharmaceutical manufacturers to pay more of the costs for enrollees who are in the coverage gap. Currently, brand-name drugmakers pay 50 percent of enrollees’ brand-name drug costs while they are in the doughnut hole. Under the budget law, they will pay 70 percent starting in 2019. The higher discounts will help push enrollees through the coverage gap more quickly and into catastrophic coverage, under which they will pay substantially less for their medications. The pharmaceutical industry has been lobbying to overturn [the discounts] this deal since it was enacted and has enlisted the support of lawmakers on both sides of the aisle. [yet] No legislation has been introduced that would overturn the agreement, but AARP is urging congressional leaders to leave the donut hole fix as is. “It is imperative that we keep in place policies that will help to lower drug costs for beneficiaries and make it easier for them to access medications they rely on,” Jenkins says in her letter. “We urge you to stand with beneficiaries and resist any attempt to undo these important reforms

#### James Zhang indicates that:

James X. Zhang & David Meltzer, 2016, "The High Cost-related Medication Non-adherence Rate Among Medicare-Medicaid Dual-Eligible Diabetes Patients," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546751/, Date Accessed 11-8-2018 // JM

Access barriers to effective medication treatment have been a persistent issue for millions of older Americans despite the establishment of Medicare Part D.[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546751/#R1) Over a third of older patients report cost-related medication non-adherence (CRN), increasing health care costs and adversely affecting patient outcomes.[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546751/#R2),[3](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546751/#R3),[4](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546751/#R4),[5](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546751/#R5) Several risk factors for CRN have been identified, including lack of health insurance coverage, high out-of-pocket payment, comorbidities, and poor mental health.[6](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546751/#R6),[7](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546751/#R7),[8](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546751/#R8),[9](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546751/#R9),[10](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546751/#R10),[11](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546751/#R11)“Dual eligibles” are beneficiaries who qualify for both Medicare and Medicaid, characterized by low income levels and a high disease burden.[12](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5546751/#R12) A common perception is that dual eligibles receive assistance from Medicaid to pay for some of the out-of-pocket costs of medical care, leading to low CRN rates. However, there has not been a comprehensive examination of risk of CRN among dual eligibles.

#### Jeff LeBrun quantifies that:

Jeff LeBrun, 2018, “15 Frightening Stats on Medication Adherence (Plus Infographic)," No Publication, https://www.pillsy.com/articles/medication-adherence-stats, Date Accessed 11-8-2018 // JM

Although about two-thirds of Americans have a prescription medication, approximately 50% of people do not take their medications as prescribed. This is a phenomenon known as “medication non-adherence” (MNA), or “America’s other drug problem,” and it is the cause of a huge amount of unnecessary physical and emotional suffering, financial loss, and premature deaths that cost too many people precious time that they could have with their loved ones. Another term for medication non-adherence could be “the silent killer” because of the number of people it impacts with almost zero awareness. Today, medication non-adherence leads to 125,000 preventable deaths each year, and [the risk of] about $300 billion in avoidable healthcare costs. Most people don’t realize it but of dying from your own medication non-adherence [is] are about 10 times greater than dying of homicide, or about 30 times greater for somebody who is over the age of 50.

## Contention 2 – A Crisis in Innovation

#### The US is the most productive in producing new cutting edge drugs now as Scott Atlas writes in 2018 that

Scott W. Atlas, 3-21-2018, "Soaring drug prices? Here's how to control them," CNN, https://www.cnn.com/2018/03/21/opinions/the-overlooked-ingredient-to-lower-drug-prices-atlas/index.html, Date Accessed 10-15-2018 // WS

Drugs are the most significant reason behind the past half-century gains against both chronic and life-ending disease. Policies aimed at reducing drug costs must not restrict their supply, jeopardize their quality or inhibit essential drug innovation necessary for tomorrow's cures.American patients in particular have benefited more than others from drugs. For decades, **the United States has been the most frequent country**, by far, **where new drugs are first available**. Life-saving cancer drugs, as one critical example, are at least **four times more likely** to be made first available here compared with any country, including Germany, Japan, Switzerland, France, Canada, Italy or the UK, as reported in the Annals of Oncology in 2007. Similarly, two-thirds of the [novel drugs](https://www.fda.gov/downloads/drugs/developmentapprovalprocess/druginnovation/ucm481709.pdf) OK'd in 2015 were approved in the United States before any other country. Most recently in [a 2017 study](https://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.23.2.247), of 45 new cancer drugs approved by the Food and Drug Administration from 2009-2014, all of which were covered by Medicare in the United States, only 26 were approved and covered in the UK, only 19 in France, only 13 in Canada and only 11 in Australia.

#### This is proven when Reuters reported in 2018 that:

Reuters, 1-2-2018, "2017 Saw the Most New Drugs Approved in Over 20 Years," Fortune, http://fortune.com/2018/01/02/new-drug-approvals/, Date Accessed 11-8-2018 // JM

U.S. drug approvals hit a 21-year high in 2017, with 46 novel medicines winning a green light—more than double the previous year—while the figure also rose in the European Union. The EU recommended 92 new drugs including generics, up from 81, and China laid out plans to speed up approvals in what is now the world’s second biggest market behind the United States. Yet the world’s biggest drugmakers saw average returns on their research and development spending fall, reflecting more competitive pressures and the growing share of new products now coming from younger biotech companies. Many of the drugs receiving a green light in 2017 were for rare diseases and sub-types of cancer, which often target very small populations, although they can cost hundreds of thousands of dollars. Significantly, the U.S. drug tally of 46 does not include the first of a new wave of cell and gene therapies from Novartis [(NVS, +0.56%)](http://fortune.com/2018/01/02/new-drug-approvals/), [Gilead Sciences](http://fortune.com/fortune500/gilead-sciences/) [(GILD, -0.52%)](http://fortune.com/2018/01/02/new-drug-approvals/) and Spark Therapeutics [(ONCE, -1.85%)](http://fortune.com/2018/01/02/new-drug-approvals/) that were approved in 2017 under a separate category. U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb has hailed these products as “a whole new scientific paradigm for the treatment of serious diseases.” However, there is debate as to how cash-strapped healthcare systems will pay for them. Under Gottlieb, the FDA has taken advantage of policy changes implemented in recent years to accelerate the drug approval process. [Recent] Procedures such as the agency’s “breakthrough therapy” designation have cut review times and helped to stimulate competition by adding multiple new drugs that often work in a similar way. A wide choice of medicines with the same mechanism of action can be a double-edged sword for manufacturers, since it gives insurers and governments ammunition to drive down prices. [Pfizer](http://fortune.com/fortune500/pfizer/) [(PFE, -0.54%)](http://fortune.com/2018/01/02/new-drug-approvals/) and Merck’s [(MRK, +0.75%)](http://fortune.com/2018/01/02/new-drug-approvals/) new diabetes drug Steglatro, for example, was the fourth product of its kind to win a green light in the United States, while Novo Nordisk’s (NOVO-NORDISK-AS) Ozempic was the sixth of its type. Both were approved in December. In cancer, AstraZeneca’s (ASTRAZENECA-PLC) Imfinzi was the fifth medicine to target a key protein found on the body’s immune cells when it won approval last May. For the current year, companies have more new products waiting in the wings, although the pace of FDA approvals may be tempered by the fact that several drugs that had been expected to be cleared in the first quarter of 2018 were actually approved in 2017. In Europe, meanwhile, the focus will be on any disruption or delays to the approval process as the European Medicines Agency prepares to relocate from London to Amsterdam as a result of Britain’s decision to leave the European Union.

#### This novel innovation is high because of high profits as Joshua Krieger of Harvard Business writes in 2017 that

Joshua Krieger, 2017, “Developing Novel Drugs,” Harvard Business School, https://www.hbs.edu/faculty/Publication%20Files/18-056\_9281482e-dc75-4fc3-a9ec-81e2fc408522.pdf, Date Accessed 11-6-2018 // WS

The fact that firm size is correlated with the likelihood to develop novel drugs suggests that financial constraints may play a role in constraining investments in novelty. Indeed, prior findings in the literature suggest that financing constraints may be an important factor limiting innovation in the pharmaceutical industry. For instance, DiMasi, Grabowski, and Hansen (2016) estimate that R&D costs are high (around $1.4 to $2.6 billion dollars per drug). Moreover, [and]returns to developing new drug candidates are skewed and uncertain (since fewer than 20% of drug candidates ever reach approval). Further, intellectual property—even when protected by patents—is difficult to value or collateralize, making access to external finance more difficult. Berndt, Nass, Kleinrock, and Aitken (2015) find that sales of newly-approved drugs are so volatile that returns are often insufficient to cover R&D costs A firm that anticipates greater revenue in 2 to 3 years may choose to push its more novel discovery-stage candidates into the preclinical testing knowing that it would not need to pay for the bulk of development costs for another few years and, moreover, would only need to make these payments if the drug candidate actually shows promise. Third, it is possible that firms could increase their borrowing in response to this increase in expected cashflows. We explore this idea further in Section 3.5. Finally, we note that some firms may have seen actual cashflow increases as a result of Medicare’s Drug Discount and Transitional Assistance Programs, which operated from 2004 to 2006. These programs spent about $1.5 billion over an 18 month time period (Huh and Reif, 2017).

#### Unfortunately price controls lessen the incentives for novel innovation. Winegarden furthers that

Wayne Winegarden, Jul 15, 2016, "How To Encourage Pharmaceutical Innovation And Why It Is Important," Forbes, https://www.forbes.com/sites/econostats/2016/07/15/regulating-short-term-volatility-will-harm-pharmaceutical-innovation/#6f19f42b566c, Date Accessed 11-7-2018 // WS

In light of these data, price control proposals are particularly troubling. Pharmaceutical price controls will lessen the incentives for future drug innovation. The likelihood that new therapies will be created to address diseases, such as Alzheimer’s, cancer and diabetes will significantly diminish. Pharmaceutical price controls will also not address the problems plaguing the U.S. healthcare system, therefore the problems of declining care, rising overall healthcare costs, and declining healthcare accessibility will continue unabated. Calls to target pharmaceutical drugs with price controls are misplaced. There are many problems with our current healthcare system that must be addressed. Setting long-term healthcare policies based on short-term price volatility will not effectively address these problem, however.

#### Easton explains in 2018 that this happens because

Robert J. Easton, 1-22-2018, "Price controls would stifle innovation in the pharmaceutical industry," STAT, https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/, Date Accessed 10-15-2018 // WS

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. 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. 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. But if U.S. drug prices come under bureaucratic control, as they have in most of Europe and Japan, it will be a different story. Little pharmaceutical innovation occurs in price-control jurisdictions. The United States has always, by a large margin, led the world as a source of new drugs, and that lead has widened as Japan and Germany have imposed price controls over the past few decades. All major international pharmaceutical companies, without exception, have instituted R&D and commercial operations in the U.S. to take advantage of its pricing environment. If price controls pressure the U.S. industry into a more conventional process industry model, like that of the chemical industry, pharmaceutical R&D budgets would be slashed. To achieve the chemical industry’s rate of R&D spending, as would be required to achieve profitability competitive with the chemical industry, top pharmaceutical companies would have to reduce their R&D budgets by 80 percent — almost $50 billion in total. This reduction in spending would take a few years to realize, but would be completely evident by 2023 or earlier. An important corollary is that, if profitability and value creation opportunities for new drugs declined, the appetite of the venture community for risky, long-term biopharmaceutical investments would shrink exponentially. Price controls on drugs would have the surprising effect of accelerating the flow of investment into high technology, where timelines to market are shorter, less regulated, and less risky. The venture capital community is flush with cash and anxious to invest where high returns can be achieved — ideally within a much shorter time than is typically possible in the realm of drug R&D. As a society, if we force pharma into a chemical industry model, where there is no biotech equivalent and no venture investing, we will be trading better and sooner effective drugs for better and sooner virtual reality devices and self-driving cars. Squeezing pharmaceutical R&D spending down to one-fifth of what it is today would also have an enormous impact on the problems that drug developers often choose to address. Orphan diseases would be deprioritized, as the returns under price controls would not warrant the investment. Complex diseases would also be deselected. While Alzheimer’s disease and diabetes have huge patient populations, the extremely high cost of conducting the difficult research and the need for huge and complex clinical trials would dissuade all but the largest companies from pursuing those illnesses if the potential pricing upside was to be significantly constrained. Moreover, for difficult diseases like schizophrenia, where today’s treatments are mostly inadequate, the flow of more effective new treatments would slow from a trickle to a rivulet, depriving those with these conditions from the possibility of relief. 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.

#### That’s important because external funding is the vital internal link to innovation. Bruce Booth explains that:

Bruce Booth, 12-16-2016, "Positive Impact Of External Sourcing On Pharma R&D Productivity," Forbes, https://www.forbes.com/sites/brucebooth/2016/12/16/positive-impact-of-external-sourcing-on-pharma-rd-productivity/, Date Accessed 11-9-2018 // JM

I’m convinced these efforts are likely to increase the overall R&D productivity of the industry. Precisely defined, R&D productivity involves both risk and spend. The risk part of the equation is particularly impactful–thousands of molecules are made to prepare a candidate for development, and only one in ten make it from IND to market. While there are clear cost-benefits of working with leaner and more capital-efficient partners (who lack the burden of large fixed-legacy R&D infrastructure) especially as variable costs), I believe this risk component to the R&D productivity equation is where external R&D efforts are likely to have a big impact. Here’s some historic and recent data to support that conclusion: over the past 20 years, externally sourced programs (“in-licensed”) have delivered almost a twofold higher rate of success in development versus in-house programs. This was true in the 1990s (Figure 6b here), and its true more recently (here). Why is this? It’s certainly not the quality of the science itself. Lots of good science, worked on by good scientists, exists inside large pharma organizations as “in-house” projects. We and others have successfully “externally sourced” great programs from pharma as the substrate for startups in biotech–and this is happening across many companies and disease areas today. The differential success rate of externally sourced programs is more likely a reflection of the sociology of organizations and the diligence process: the higher bar that an external asset must go through in order to find a place in a pharma company’s R&D pipeline. An externally sourced project has to displace other programs. It’s also competing with hundreds of other “external” projects for those limited licensing or partnership slots. Beyond the operational and financial aspects driving this level of diligence, it’s also reinforced by conventional behaviors: the increased process rigor can be from paranoia (“these guys are hiding something, I should diligence harder”), internal career pressure (“I really don’t want to be the person that recommends buying a bad project”) or a host of other social factors (e.g., remnants of NIH syndrome--not invented here). Overall, this competitive pressure around externally sourcing creates a level of stringency and discipline in the diligence process that leads to, in general, the onboarding of higher-quality assets. These data suggest the delta is considerable, and hasn’t greatly diminished in two decades. These data are part of what underpins the differential in FDA approvals: two-thirds of the last five years of new drugs originated from smaller companies, but two-thirds are launched by the larger companies. External sourcing has clearly been a big part of R&D success--and will likely be increasingly important going forward. Lastly, are there things that can be done to improve internal R&D to shrink the gap in clinical success rates? BCG’s recent report on R&D performance highlighted operational effectiveness as a key distinguisher of the best organizations. I’d like to call attention to the last of the “imperatives” they highlight as part of truly effective R&D: “Promote truth-seeking behavior rather than progression-seeking behavior.” This is a critical point: it’s a culture change for many organizations, but super-impactful. As they suggest, productivity might improve if a better advancement process was “implemented for evaluating internal assets, similar to the evaluation that is typically made on possible external assets.” There’s certainly a good deal of merit behind this recommendation. These data, and the sociology they reflect, are further evidence for why the open-source models of pharma R&D are not only important today but likely to be even more important in the future.

#### There are two impacts to losing this innovation. The First is Life expectancy as Aaron Carroll writes in 2017 that due to innovation

Aaron E. Carroll and Austin Frakt, 10-9-2017, "Can the U.S. Repair Its Health Care While Keeping Its Innovation Edge?," No Publication, https://www.nytimes.com/2017/10/09/upshot/can-the-us-repair-its-health-care-while-keeping-its-innovation-edge.html, Date Accessed 10-23-2018 // WS

This is not mere theory, economists have shown. [Daron Acemoglu and Joshua Linn](http://economics.mit.edu/files/4464) found that as the potential market for a type of drug grows, so do the number of new drugs entering that market. [Amy Finkelstein showed](http://www.jstor.org/stable/25098693?seq=1#page_scan_tab_contents) that policies that made the market for vaccines more favorable in the late 1980s encouraged 2.5 times more new vaccine clinical trials per year for each affected disease. And [Meg Blume-Kohout and Neeraj Sood](http://www.sciencedirect.com/science/article/pii/S0047272712001119#!) found that Medicare’s introduction of a drug benefit in 2006 was associated with increases in preclinical testing and clinical trials for drug classes most likely affected by the policy. Health care innovation can have direct benefits for health, well-being and longevity. [A study](http://www.nejm.org/doi/full/10.1056/NEJMsa054744) led by a Harvard economist, David Cutler, showed that life expectancy grew [has grown] by almost seven years in the second half of the 20th century at a cost of only about $20,000 per year of life gained. The vast majority of gains were because of innovations in the [care for high-risk, premature infants and for cardiovascular disease](http://theincidentaleconomist.com/wordpress/to-what-extent-is-health-care-responsible-for-our-longer-lives/). These technologies are expensive, but other innovation can be cost-reducing. For instance, in the mid-1970s, new dialysis equipment [halved treatment time](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1808299/), saving labor costs.

#### Not only do these years directly benefit the people but it also boosts the economy as the CMPI writes in 2013 that

Center for Medicine in the Public Interest. 2013 "Innovative Medicines Impact Life Expectancy, More Cancer Survivors," Value of Medical Innovation, http://valueofinnovation.org/power-of-innovation/, Date Accessed 11-7-2018 // WS

Between 1990 and 2011, death rates from all cancers fell from 216 per 100,000 Americans to 168.7—a 22% decrease. At the same time, the number of people surviving cancer and living longer more than doubled, from 6.5 million to 13.8 million. To begin with, the cost of lost productivity from cancer death is about $124 billion each year. Conversely, increasing life-years saved and cancer survivorship has an opposite, stimulating impact on our economy. Over $127 billion in additional productivity is attributed to the 15% decline in cancer deaths between 2000-2011.

#### Second is preventing cures for chronic deseases as the National Health Council writes in 2014 that

National Health Council, 7-29-2014, “About Chronic Diseases,” <http://www.nationalhealthcouncil.org/sites/default/files/NHC_Files/Pdf_Files/AboutChronicDisease.pdf>, Date Accessed 10-30-2018 // JM

Generally incurable and ongoing, chronic diseases affect approximately 133 million Americans, representing more than 40% of the total population of this country.2 By 2020, that number is projected to grow to an estimated 157 million, with 81 million having multiple conditions.3 About half of all adults have a chronic condition, and approximately 8 percent of children ages 5 to 17 were reported by their parents to have limited activities due to at least one chronic disease or disability.4,5 More and more people are living with not just one chronic illness, such as diabetes, heart disease or depression, but with two or more conditions. Almost a third of the population is now living with multiple chronic conditions. 6 In 2009, 7 out of 10 deaths in the U.S. are due to chronic diseases. Heart disease, cancer and stroke account for more than half of all deaths each year.7 According to the New England Journal of Medicine, people with chronic conditions receive only 56% of recommended preventive health care services.

#### The only chance at saving these lives is by voting neg

## Extra Cards

#### And Wayne Winegarden corroborates this when he writes that we have seen a

Wayne Winegarden, Jul 15, 2016, "How To Encourage Pharmaceutical Innovation And Why It Is Important," Forbes, https://www.forbes.com/sites/econostats/2016/07/15/regulating-short-term-volatility-will-harm-pharmaceutical-innovation/#6f19f42b566c, Date Accessed 11-7-2018 // WS

But, any investor during that period would surely feel less confident. After all, following the 36% decline in stock prices in 2008, a nervous investor might inaccurately conclude that the future is grim and that stock prices will never grow again. Alternatively, following the over 32% price surge in 2014, an overly exuberant investor might feel that prices can now only go up–only to be disappointed by the meager 1% growth in 2015. The lesson here is that drawing long-term implications from short-term fluctuations will often lead to inaccurate answers. The same is true in the pharmaceutical market. In misplaced attempts to address the problems with the U.S. [health](http://www.forbes.com/health/)care industry, many analysts point to specific list price increases on specialty pharmaceutical drugs to claim that high drug prices are driving overall healthcare costs ever higher. Such proclamations misdiagnose the problem with the healthcare industry and risk future innovations that can address pressing healthcare needs. It is true that the average price of medicines grew faster than average over the past two years. Over these two years, there was also a significant increase in new medicines. In 2015, 73 new brand name drugs were introduced, 43 of which were novel therapies. This followed 74 new brand name drugs being introduced in 2014, 45 of which were novel therapies. It is also clear that many of these new drug innovations, such as Sovaldi and Harvoni, provide immense medical benefits to patients. Patients with hepatitis C now have access to a 12-week treatment with a 90% cure rate–prior to these drugs, there was no cure.