Resolved: The United States Federal Government should impose price controls on the pharmaceutical industry.

We negate

Contention one is destroying small business.

In 1984, Congress made it much easier for pharmaceutical companies to produce copycat versions of drugs after the inventors' patents had expired. As a direct result, generics flooded the market driving out all but the most efficient manufacturers, with many merging to form monopolies.

Dolan of Barron's 17' explains that these big research-oriented pharmaceutical companies then reduced their investments in research. These big companies are now primarily marketing and advertising giants, who are in the business of buying the rights to new products from successful small businesses.

As a result **Ioannou of CNBC 18'** confirms that small businesses represent 2/3 of all medical innovations. However price controls would prevent small companies from finding the money and resources they need to kickstart R&D, harming small businesses by pricing them out.

There are two reasons why this happens,

First, **Brinkman of Harvard Law** writes that small pharmaceuticals mostly operate on a financial shoestring. They can only take risks because of the potential for large reward in the form of huge profits. She concludes that while small businesses are hurt by these restrictions, larger corporations would have the flexibility to take a hit, and could pivot to marketing copycat drugs as a response.

Second, **Beale in 2017** argues that because of the political connections of large corporations, they create loopholes to promote their own end—such as restricting competition and suppressing innovation from new firms. Small Businesses who don't have the connections would quickly find themselves on the losing side of price controls.

That's why the Citizens Petition Loophole which allows the indefinite extension of patents if a company submits a petition with a certain number of signatures. However this loophole would only help the large marketing and patenting pharmaceutical companies, while severely limiting the profits of the innovation based small businesses.

Losing small businesses would destroy livelihoods by reducing access to drugs in domestic markets.

Santerre of the University of Connecticut explains that the implementation of price controls in the 2000s would have resulted in 200 less medical innovations, with **Howard of the New York Times 15'** explaining that every 25 new drugs saves consumers **4 trillion dollars *a year*.**

Thus, **Vernon of the Manhattan Institute 04'** concludes that previous government intervention in pharmaceutical prices has directly resulted in the loss of 140 million life years.

Contention Two is Global Access.

In the status quo, branded prescription drugs are 20% to 40% cheaper in European markets while Hinnant of the Library of Congress finds that ***Critical Life saving drugs*** such as Merck Anti-AIDS are sold at ***one-tenth the price in the developing world.***

However Global Affordability and innovation is only possible because of the lack of price controls and high profit margins in the United States. **Easton of Bionest in 2018** finds that Little pharmaceutical innovation occurs in price-control countries. The United States has always, by a large margin, led the world as a source of new drugs. In fact, 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.

As a result **Whitman of International Business times 14**' quantifies almost 60% of all pharmaceutical innovation in the world occurs in the US, with 2/3rd of that coming from small businesses.

However, implementing price controls in the US would hurt global affordability in two ways:

First, through innovation loss.

Goldman of Marketwatch in 2018 finds the U.S. market accounts for as much as 78% of all global drug profits. These are the massive profits that fund innovation.

Losing the dominant source of funding for drugs would destroy innovation and ruin over 250 potential medical breakthroughs in the coming years.

Second, through revenue balancing.
Price controls decrease domestic profits, forcing pharmaceutical companies to raise prices internationally. **Boseley from the Guardian '06** finds that companies can enforce their patents on other countries, solidifying their monopolies and then price gouging as a result.

The incentive comes from **Goldman of RAND '08** who finds that each thousand dollar reduction in US comes with an 8 thousand dollar increase in other countries.

The impact is saving global lives.

Overall, the NBER '14 finds that new therapies created by American research and development have accounted for 73% of the increased life expectancies across the developing world in modern history. Since 2000 alone, Lam of the Atlantic quantifies that pharmaceutical alliances have vaccinated over 500 million children in poor countries.

Thus we negate.

Bourree Lam, xx-xx-xxxx, "Vaccines Are Profitable, So What?," Atlantic, https://www.theatlantic.com/business/archive/2015/02/vaccines-are-profitable-so-what/385214/

So while the vaccine industry is likely more profitable now than in the 1970s or 1980s, this is the result of global market forces, not a reason to skip a child's vaccinations: Pharmaceutical companies need incentives to keep producing vaccines, because regardless of profits the economic and social benefits of vaccination are huge—in lives and the billions of dollars saved**. A study released last year estimated that fully immunizing babies resulted in $10 saved for every dollar spent**, about $69 billion total. "Vaccines are one of the most cost-effective interventions we have," says Halsey.

Frontlines

Overview-Lobbying

Ismail of Public Integrity 15' writes that the pharmaceutical industry is the largest lobbying power in the United States, spending almost a billion dollars on government control and donations to 94% of the entire US congress.

The effects have been glaringly apparent. **Steven Mufson of the Washington Post 93'** concludes that price controls on pharma have had a *net zero* effect on large corporations, because of their legal and political lobbying power. In fact **Ismail** continues that the pharma lobby has watered-down and prevented numerous price control policy on both the state and federal level.

In comparison **Yeoh of the University of Nottingham 18'** writes that price controls hit small businesses the worst, simply don't have the same connections or lobby power needed to voice concerns to policymakers, whether it is to big law firms, business chambers, or politicians.

This is problematic as **Lori of CNBC 18'** confirms that 2/3 of all US medical innovation today is the result of small businesses since they're forced to take a much larger risk and innovate in order to enter the market.

Today **BIO in 2018** finds that while 70% of innovations and clinical trials are held by small businesses, adopting price controls would prevent small companies from finding the private capital they need to develop new cures.

More than 90 percent of the total was spent by 40 companies and three trade groups: the Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Industry Organization, and the Advanced Medical Technology Association.

Overview-Global Affordability

1. Prices are decreasing rn
2. 1$ increase in spending
3. Global Affordability

In the status quo, branded prescription drugs are 20% to 40% cheaper in European markets while ***Critical Life saving drugs*** such as Merck Anti-AIDS are sold at ***one-tenth the price in the developing world.***

However Global Affordability and innovation is only possible because of the lack of price controls and high profit margins in the United States. **Easton of Bionest in 2018** finds that Little pharmaceutical innovation occurs in price-control countries. 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.

As a result **Whitman of International Business times 14**' quantifies almost 60% of all pharmaceutical innovation in the world occurs in the US, with over 70% of that coming from small businesses.

However, implementing price controls in the US would hurt global affordability as Goldman of Marketwatch in 2018 finds the U.S. market accounts for as much as 78% of all global drug profits. These are the massive profits that fund innovation.

[US has safety net]

Losing the dominant source of funding for drugs would destroy innovation and ruin over 250 potential medical breakthroughs in the coming years.

This is key because **Cueni of IFPMA 18'** confirms that just a single US small business antiviral treatment could potentially save 21 million people from dying of HIV in southern Africa.

Overview-Affordability NU

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.

1) De-Link: **Goldberg** of the **IPI** in 2013 examines that implementing price controls in the U.S. would only save .1% of total health care costs over a 40 year period.

2) De-Link: Empirically, **Hais** of **The Heritage Foundation** in 2013 explains that in France, which has strict price controls, citizens spend significantly more on pharmaceutical drugs than American citizens because France struggles to produce new drugs.

   a. That's why **Winegarden of Forbes** (2017) finds that that generic medicines are significantly cheaper in the U.S. compared to the other major industrialized countries - pharmaceutical spending as a percentage of total health care spending is 38% lower in America than the average OECD nation.

1. Turn - relatively high drug prices in the status quo allow companies to develop better and more effective medicines, improving the quality of everyone's health to the point where they don't have to spend on other healthcare services, like hospital visits and doctors appointments. As a result, **Goldberg of the NCAP** finds every dollar spent on drugs is associated with a $4 decline in spending on hospitals.

On Affordability: price are actually going down in the status quo. **Dan Best, from Medscape** reports in May 2018 that there have been 60% fewer brand-name drug price increases and 54% more drug price decreases, in response to current legislation.

A2-Innovation Public Funded

1. Lowe of Science Translational Medicene in 2010 found in almost every country that discovered new drugs during that ten-year period, the great majority came from pharma companies.
2. As a result, the vast majority of drugs are not caused by public sector research. **HealthAffairs** finds in **2009** that only 9% of drugs approved by the FDA in the past two decades cite public-sector patents as their source.

A2-Quantity makes up for it

1. Price is 3-4 times more important than quantity

Price>Quantity Michael V. Marnrobert L. Rosiello, xx-xx-xxxx, "Managing Price, Gaining Profit," Harvard Business Review, https://hbr.org/1992/09/managing-price-gaining-profit

The leverage and payoff of improved pricing are high. Compare, for example, the profit implications of a 1% increase in volume and a 1% increase in price. For a company with average economics, improving unit volume by 1% yields a 3.3% increase in operating profit, assuming no decrease in price. But, as Exhibit 1 shows, a 1% improvement in price, assuming no loss of volume, increases operating profit by 11.1%. Improvements in price typically have three to four times the effect on profitability as proportionate increases in volume.

Derek Lowe 9 November, 2010, xx-xx-xxxx, "Where Drugs Come From: By Country," In the Pipeline, https://blogs.sciencemag.org/pipeline/archives/2010/11/09/where_drugs_come_from_by_country

And here's the last outlier that appears to tie all these together: in almost every country that discovered new drugs during that ten-year period, the great majority came from pharma companies. The only exception is the US: 60% of our drugs have the fingerprints of biotech companies on them, either alone or from university-derived drug candidates. In very few other countries do biotech-derived drugs make much of a showing at all. These trends show up in sales as well. Only in the US, UK, Switzerland, and Australia did the per-year-sales of novel therapies exceed the sales of the follow-ons. Germany and Japan tend to discover drugs with higher sales than average, but (as mentioned above) these are almost entirely followers of some sort. Taken together, it appears that the US biotech industry has been the main driver of innovative drugs over the past ten years. I don't want to belittle the follow-on compounds, because they are useful. (As

pointed out here before, it's hard for one of those compounds to be successful unless it really represents some sort of improvement over what's already available). At the same time, though, we can't run the whole industry by making better and better versions of what we already know.

Public Sector patents aren't responsible for most drugs
https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0917

We defined as public-sector patents all of those that were assigned to a government agency (which generally resulted from research conducted inside that agency) and all of those with government interest statements (most of which came from academic laboratories that had received government funding, generally through extramural research grants). The recipients of federal research grants are required to acknowledge government funding in their patent applications. These public-sector patents are the target of the recoupment and march-in strategies discussed above.

	Standard-review drugs	Priority-review drugs	All drugs
Number of drugs	224	155	379
Had public-sector patent	**3.1%**	**17.4%**	**9.0%**

A2/ Lobbying Power Decline

1) Turn this argument against them because if you decrease the power of the pharma lobby and thereby its profits, the industry will only respond with more spending on marketing to maintain its profits. That's bad for a couple of reasons:
    a) First, that means more money in politics. [general money in politics bad]
    b) Second, lobbying intensifies. **FiercePharma in 2018** reports that last year, pharmaceutical lobby spending increased 30% specifically in response to pressure on pricing.
2) Empirically, most bills limiting pharma power still fail. Luthra of the Washington Post finds that drug companies outspend their opponents 5 to 1, with a $100 million dollars spent in California, the most in state history, to defeat an initiative to cap state payments for drugs.
3) Turn because Critics see these tailored efforts as falling short or potentially opening other loopholes. For example the Citizen Petition Loophole allows a patent to be extended based on a petition arguing its social value. (Contention 2)

Shefali Luthra, 9-29-2017, "Absent federal action, states take the lead on curbing drug costs," Washington Post,
https://www.washingtonpost.com/national/health-science/absent-federal-action-states-take-the-lead-o

n-curbing-drug-costs/2017/09/29/1d346828-a4d1-11e7-ade1-76d061d56efa_story.html?utm_term=.4d23bbdfde1f

The generic-drug industry filed a lawsuit to block the statute from taking effect, arguing it's unconstitutionally vague and an overreach of state powers. A federal court judge on Friday denied that request for an injunction. The California legislature passed a bill this month that would require drugmakers to disclose when they are about to raise a price more than 16 percent over two years and to justify the hike. Gov. Jerry Brown (D) is expected to sign the measure into law. Nevada's law is like California's approach but limited to insulin prices, while Vermont's allows officials to scrutinize up to 15 drugs with rising prices for which the state spends "significant health-care dollars." Legislators have introduced similar bills in Massachusetts, Rhode Island, Tennessee and Montana. In November, Ohio voters will decide on a ballot initiative that would restrict what the state pays for prescription drugs in its Medicaid program and other state health plans. But states face a steep uphill climb in passing pricing legislation given the deep-pocketed pharmaceutical industry, which can finance strong opposition whether through lobbying, legal action or advertising campaigns. **Last fall, voters rejected a California initiative that would have capped what the state pays for drugs. Industry groups spent more than $100 million to defeat it, putting it among the state's all-time most expensive ballot fights. Ohio's measure is attracting similar heat, with drug companies outspending opponents about 5 to 1.** [Cancer drug prices are so high that doctors will test cutting doses] States also face policy challenges and limits to their statutory authority, which is why several have focused their efforts on specific parts of the drug-pricing pipeline. **Critics see these tailored efforts as falling short or potentially opening other loopholes.** Requiring companies to report prices past a certain threshold, for example, might encourage them to consistently set prices just below that level. Maryland's law is noteworthy because it includes a fine for drugmakers if price increases are deemed excessive — though a $10,000 fine is likely nominal for the billion-dollar industry, suggested Rachel Sachs, an associate law professor at Washington University, who researches drug regulations.

A2/ Backlog

Rosenblatt in 2017 writes that the new FDA Commissioner has announced that the FDA will reduce the backlog of generic drug applications to speed these less expensive drugs to market and enhance competition. This is crucial as Baker with Stanford Medicine reports that competition empirically lowers health-care costs

Investor's Business Daily, 2018, https://www.investors.com/politics/editorials/drug-prices-trump-budget-medicare-price-controls/Meanwhile, the Trump administration is getting attacked because its budget plan, released last week, doesn't push to have the government set prices for Medicare drugs — something Trump himself once advocated — which would be tantamount to federal price controls on all drugs. But Trump is tackling high drug prices. Trump's FDA administrator, Scott Gottlieb, is focused on increasing price-lowering market competition. Gottlieb understands that the more choices there are, the more price competition there will be. So he's **pushed the agency to shorten approval times for generics, particularly when there's only one generic alternative on the market. He's also working to streamline the FDA's approval process for new drugs, and lifting the FDA's prejudice against so-called me-too drugs**. This sort of competition is already working. A few years ago, price-control advocates pointed to Sovaldi, a breakthrough drug that can cure hepatitis C but cost $80,000 to administer, as the poster child for price controls. Instead, the FDA last year fast-tracked approval of a second hepatitis C drug — Mavyret —which cost less than a third of Sovaldi. Suddenly, there was a price war for Hep C treatments. Competition, not price controls, cut costs overnight. **By boosting competition, Trump will be far more effective at lowering drug costs than any regime of federal price controls could ever hope to be.**

A2/ Small Business exploited by Big Business

1. Price controls destory small businesses more
2. Small Business don't always get bought out
3.

Cards

Brinkman, "DRUG PRICES", Harvard Law, 11-3-2018
https://dash.harvard.edu/bitstream/handle/1/8889453/Fiorenzo.html?sequence=2
A look specifically at the emergent biotechnology industry is also illustrative. Unlike industry giants like Pfizer and Merck, these are small companies that make even riskier bets. Although a few of these companies like Amgen and Genentech have blossomed into large players, **most are small and operate on something of a financial shoestring. The risks that these companies take is predicated on the potential for a large reward in the form of high sales and profits. Thus, they are even more dependent on superior returns from a few blockbuster drugs since their costs and their failure rate is higher. Also, the reliance by biotech firms on external financing would make them susceptible to declining innovation in a world of price controls**. The larger drug concerns do much of their R&D with retained earnings. As was argued earlier, the retained earnings would diminish under a price control regime. However, **small biotech firms might see that it was even harder to attract external investment and financing when price controls would clip returns considerably.**

No Author, "", BIO, 11-3-2018,https://www.bio.org/sites/default/files/BIO_Bayh_Dole.pdf

Approximately 70% of university innovations are licensed to small companies, and the vast majority of all clinical trials are conducted by small biotech companies. UNDERMINE BIPARTISAN CONSENSUS • On six different occasions activists have tried to force the government to exercise its march-in rights because of drug prices. All six times, those efforts have been rejected by both Democratic and Republican Administrations. • In 2012, NIH Director Francis Collins rejected a petition to exercise its march-in authority, stating the "extraordinary remedy of march-in is not an appropriate means of controlling prices of drugs broadly available to physicians and patients." WEAKEN MILITARY READINESS • The Armed Forces face myriad threats, including infectious diseases and biological and chemical weapons. The Department of Defense (DoD) relies on private-sector partnerships to supply the resources and expertise needed to research, develop and manufacture critical medical countermeasures to treat and protect those serving in uniform. • Biomedical **innovation is extremely expensive and time consuming**. Weakening patent protections and **adopting foreign price controls will make it harder for small companies to find the private capital they need to develop new cures.**

Thomas G. Donlan, 8-11-2017, "Pharmaceuticals: Dangerous Monopoly of Power," No Publication, https://www.barrons.com/articles/pharmaceuticals-dangerous-monopoly-of-power-1502507163

In 1984, Congress passed a law making it much easier for upstart companies to produce copycat versions of drugs after the inventors' patent monopolies have expired. Former Rep. Henry Waxman, a California Democrat, teamed up with Sen. Orrin Hatch, a Republican of Utah, to sponsor the law. *The copycats no longer had to spend three to five years meeting strict Food and Drug Administration requirements for new clinical trials—with paperwork to match—before bringing out cheaper, generic versions of the same drugs. The FDA established a simpler path for turning drug inventions into low-priced commodities. More than 100 drugs with patents that had already expired quickly came onto the market in generic versions, and competition pushed down prices by as much as 90%.* The generic companies had scant development costs and low production costs, so they could prosper with low prices. As Waxman, Hatch, and their allies in organized labor and consumer activism intended, their generic-drug law was for many years the most important piece of pro-consumer legislation in the field. By 2015, generic drugs accounted for 88% of all prescriptions, up from about 20% in 1983. But the expected freewheeling competition turned out to last only a relatively short time. *Competition drove down prices to a bare-minimum cost of production, but that drove out all but the most efficient manufacturers. Then, competitors sorted themselves out into specialties, seeking economies of scope, and many merged to create economies of scale.*

An unexpected result was that big inventive research-oriented pharmaceutical companies began to look like dinosaurs. They reduced their investments in research, closing labs and dismissing staff. Even monopolies couldn't create enough profit to pay for decades of research and decades of compliance with premarket regulations intended to guarantee efficacy and safety. Fortunately for the progress of science, *Wall Street moved in to finance hundreds of speculative companies, each working on one or two drugs for as long as their funding lasts.* The big companies are now primarily marketing and advertising giants, reducing their risk of failure by buying the rights to new products from the successful start-ups. Equally unforeseen was industrial shrinkage: With fewer and bigger generic-drug companies, the market for generics began to look more like the brand-name market. More than 50% of generic drugs are supplied by only one or two manufacturers, so generic prices now are often as firmly fixed and profitable as those of patented drugs. To some, this clearly inefficient market structure smelled like money. People like Martin Shkreli noticed that some drugs lose patent protection but don't attract generic competitors. Such drugs are obscure, except to those patients who need them and to the investors who want to jack up prices.

Lori Ioannou, 3-28-2018, "Big Pharma's billion-dollar scramble to invest in start-ups to fuel innovation," CNBC, https://www.cnbc.com/2018/03/26/big-pharmas-scramble-to-invest-in-start-ups-to-fuel-innovation.html

In response, industry giants like Novo Holdings — which has big stakes in Danish drugmaker Novo Nordisk — Merck, Johnson & Johnson, Sanofi and others are looking to become more entrepreneurial. Increasingly, these big players are setting up venture capital funds and investing in start-ups and licensing technology to fuel their own drug pipelines. Many are also outsourcing R&D, while reducing product development efforts internally. The trend is accelerating at a rapid pace. Behind the scenes, pint-size ventures are driving pharma innovation. *The majority of drugs approved in recent years originated at smaller outfits— 63 percent of them over the last five years, according to HBM Partners, a health-care investing firm. The allure is multifaceted. Small biotech start-ups are more nimble, and many can do research and product development faster.* By investing in a broad portfolio of young ventures, a big drug company can leverage outside scientific talent and cast a wide net in order to gain access to breakthrough discoveries in areas of the company's strategic interest. For investors the sheer market size of the industry cannot be ignored. It's a global market growing at 6.5 percent compounded annually that is expected to reach $1.06 trillion by 2022, HBM forecasts.

M. Asif Ismail, 6-24-2008, "A record year for the pharmaceutical lobby in '07," Center for Public Integrity, https://www.publicintegrity.org/2008/06/24/5779/record-year-pharmaceutical-lobby-07

The spending binge last year may have also been fueled by the previous November's Democratic takeover of Congress. After the Democratic sweep of the House of Representatives, several long-standing critics of the industry, such as Representative Henry Waxman of California, assumed leadership roles of powerful committees. Intent on closer oversight of the industry, they conducted a series of hearings on issues such as drug safety, pharmaceutical pricing, and availability of generic medicines. Waxman and some fellow Democrats also tried to give more regulatory power to the Food and Drug Administration and revisit the Medicare Prescription Drug, Improvement, and Modernization Act, a law that came into being in 2003 after heavy industry lobbying. The legislation, which resulted in the largest overhaul of Medicare in its history, provides prescription drug coverage through the program. *More than 90 percent of the total was spent by 40 companies and three trade groups: the Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Industry Organization, and the Advanced Medical Technology Association.* "After the Democratic victory in November 2006, [the industry] had to scramble," says Ira Loss, a pharmaceutical analyst with Washington Analysis Corporation. "They had to hire more Democratic lobbyists." Ken Johnson, senior vice president of communications at PhRMA, acknowledged that the industry faced "a difficult political environment." But he maintained that PhRMA doesn't see having a Democratic Congress as a disadvantage. "We don't look at it through the prism of Democrats and Republicans. We look at it in terms of those who support free market policies and those who don't."

Liz Essley Whyte, 9-18-2016, "Politics of pain: Drugmakers fought state opioid limits amid crisis," Center for Public Integrity, https://www.publicintegrity.org/2016/09/18/20200/politics-pain-drugmakers-fought-state-opioid-limits-amid-crisis

Jennifer Weiss-Burke pushed for a bill limiting initial prescriptions of opioid painkillers for acute pain to seven days. The bill exempted people with chronic pain, but opponents still fought back, with lobbyists for the pharmaceutical industry quietly mobilizing in increased numbers to quash the measure. They didn't speak up in legislative hearings. "They were going individually talking to senators and representatives one-on-one," Weiss-Burke said. *Unknowingly, she had taken on a political powerhouse that spent more than $880 million nationwide on lobbying and campaign contributions from 2006 through 2015 — more than 200 times what those advocating for stricter policies spent and more than eight times what the formidable gun lobby recorded for similar activities during that same period.* The pharmaceutical companies and allied groups have a number of legislative interests in addition to opioids that account for a portion of their political activity, but their steady presence in state capitals means they're poised to jump in quickly on any debate that affects them. Collectively, the AP and the Center for Public Integrity found, the drugmakers and allied advocacy groups employed an annual average of 1,350 lobbyists in legislative hubs from 2006 through 2015, when opioids' addictive nature came under increasing scrutiny.

Robert J. Easton (Robert J. Easton is co-chairman of Bionest Partners, a global medical business consultancy serving pharmaceutical, medical device, and diagnostic firms and their investors.), 1-22-2018, "Price controls would stifle innovation in the pharmaceutical industry," STAT, https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/

Yet there remain huge unmet needs for new and better treatments for most cancers; all neurological problems, especially Alzheimer's disease; most autoimmune diseases; most major gastrointestinal disorders; macular degeneration; and diabetes — not to mention the global scourge of drug-resistant bacterial and viral infections. *Advances in these areas will come if money continues flowing to pharmaceutical companies and their primary sources of innovation, biotechnology startups.* But if U.S. drug prices come under bureaucratic control, as they have in most of Europe and Japan, it will be a different story. *Little pharmaceutical innovation occurs in price-control jurisdictions. The United States has always, by a large margin, led the world as a source of new drugs, and that lead has widened as Japan and Germany have imposed price controls over the past few decades. All major international pharmaceutical companies, without exception, have instituted R&D and commercial operations in the U.S. to take advantage of its pricing environment. e.* 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. 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.

H. Beales, Brito, et al., “Government Regulation: The Good, The Bad, & The Ugly”, released by the Regulatory Transparency Project of the Federalist Society, June 12, 2017 (https://regproject.org/wp-content/uploads/RTP-Regulatory-Process-Working-Group-Paper.pdf).

Regulation presents special issues, problems, and controversies.

While the goals of most regulatory programs enjoy broad public support, in practice regulation usually comes down to detailed rules and lots of paperwork that can be highly costly and burdensome to those who must comply with them. This includes not only large corporations but small businesses, nonprofit organizations, schools, state and local governments, farms, and consumers and citizens. Some sectors of the economy bear the heaviest burdens, such as manufacturing, automobiles and transportation, energy and power, banking and finance, and health care and pharmaceuticals. But all of us pay for federal regulations through higher prices, fewer available products, services, and opportunities, and stifled wages or job opportunities. The costs of regulation are never “absorbed” by businesses; they always fall on real people. In our democracy, citizens express their views at election time by voting for candidates and parties that stand for broad menus of policy positions. Between elections, choices on controversial subjects are made through presidential leadership, voting in Congress, court rulings on specific disputes, and “checks and balances” among the three constitutional branches. For citizens to intelligently hold elected officials accountable, however, policies’ benefits and costs must be visible. While policies effected through both spending and regulatory programs provide benefits to Americans, the costs associated with regulatory programs are much less transparent than their on-budget counterparts. To implement spending policies, presidents send proposed budgets each year to Congress, and Congress must both authorize activities and appropriate necessary funds to implement them. Spending agencies are generally enthusiastic about their programs and want more resources to pursue them, but the available funds are necessarily limited and must be allocated to the highest priorities by Congress and the President in a much-debated, highly-publicized, annual budget process. These checks and balances make elected officials accountable to citizens. Regulatory policies cannot be measured in the same way, however; and there is nothing equivalent to the fiscal budget to track regulatory costs. These costs are like stealth taxation, and because they are assumed to fall on businesses (even though individual consumers and workers ultimately bear them), regulatory tools may seem preferable to direct spending programs for accomplishing an agency’s policy objectives. Further, regulations have the force of law, but Congress usually just sets broad regulatory goals by statute, and delegates the power to write and enforce detailed rules to specialized regulatory agencies. This means that Congress gets credit for popular regulatory goals while the often-unpopular rules are blamed on “unelected bureaucrats.” This criticism often comes not only from citizens and businesses but also from the legislators who voted for the regulatory statutes in the first place Regulatory costs are large, but invisible. As the size and reach of the government has grown dramatically over the last century, so too have concerns about the costs and unintended consequences of regulatory programs. At the end of the nineteenth century, government accounted for less than ten percent of the U.S. economy. Today, government consumes or directs nearly half of the economy, with direct government spending alone reaching on the order of one-third of U.S. gross domestic product.4 Regulatory costs, while off-budget and less visible, are no less real.5 At the federal level alone, there are over 70 federal regulatory agencies, employing hundreds of thousands of people to write and implement regulations.6 Every year, they issue about 3,500 new rules, and the regulatory code now is over 168,000 pages long.7 Because regulatory impacts are diffuse and hard to measure, no estimates of the actual costs of regulation are completely reliable, but some researchers peg the total annual cost at more than $2 trillion.8 Other research suggests the drag on economic growth could be twice that much, about $4 trillion per year, or $13,000 for every man, woman, and child in the United States.9 And we will never know the other costs, such as the value of jobs never created, factories never built, medicines never discovered, or entrepreneurial ideas never realized. Regulatory mandates often are very costly—for example, for expensive pollution control equipment, extensive testing of new drugs, and collection of detailed information from consumers. As noted, these costs are not controlled as they are for spending programs. Federal spending is limited by the available revenues, and by budgeting among many competing programs. But regulatory costs are born outside the government, by those who must comply with the rules, their customers, and their employees. Additionally, lacking the budget constraint of spending agencies, regulatory agencies are prone to excess. They often pursue their specific mission with zeal, but this results in too little regard for other legitimate goals, such as a strong and growing economy. This “tunnel vision” can result in rules that impose costs greater than the benefits they provide.10 Regulation faces fewer checks and balances.Spending programs, like regulatory programs, often are authorized with broad aspirational language that everyone can support, like the ‘War on Cancer’ or ‘No Child Left Behind.’ But funds for those programs must be appropriated as well as authorized, and it is there in the budget process that we confront the necessary tradeoffs among competing priorities. In contrast, regulatory programs never realistically adjust to the reality that our country’s resources are limited. Both types of programs may claim dramatic benefits from eliminating disease, or crime, or pollution, but such claims often lack credibility and accountability. We would never allow the spending agencies to collect their own taxes from the public, in whatever amounts they feel they need. Yet regulatory agencies effectively do just that. While many regulatory costs initially fall on regulated businesses, those costs are necessarily passed on—to consumers in the form of higher prices, to employees in the form of lower wages, and to investors in the form of lower returns on investment. For this reason, regulation can produce not only large social benefits but also large negative effects on prices, wages, business investment, and job opportunities. As mentioned earlier, regulation functions essentially as stealth taxation. The balance is often ignored in political debate—when it is assumed, incorrectly, that regulation is a “free lunch. The regulatory dilemma is this: On the one hand, regulation can be critically important to our welfare. Federal and state regulatory agencies have contributed to great improvements in air and water quality, highway safety, public health, honest commerce, racial and gender equality, and many other central aspects of American life. On the other hand, regulatory actions often have come at a cost that exceeds their benefits and sometimes actually have been counterproductive. These failures are abetted by the structure of the regulatory process: regulation operates outside our usual system of checks and balances, where policies are enacted directly by our elected representatives and disciplined by taxing and budgeting. Regulatory agencies have too often fallen short of public expectations and disappointed public trust.Precisely because of its importance, regulation deserves constructive criticism and earnest efforts at improvement. In the following pages, we attempt to show how regulation can be reformed to achieve its valuable goals more thoroughly, more effectively, and at lower cost. Insiders gain advantage. Regulatory programs are sometimes captured by businesses and other “interest groups,” who use them to promote their own end—such as restricting competition and suppressing innovation from new firms and business methods, or advancing their market power or political agendas. And even where regulations are well intended, they can produce unintended negative consequences. For example, drug regulation may delay the introduction of new, life-saving pharmaceuticals. The well-connected—those who can

hire lobbyists and know the right people in Washington—can gain at the expense of ordinary citizens. For example, large, established interest groups, such as large companies and trade associations, environmental groups, trial lawyers, unions, and state, local, and tribal governments, **generally have much better access to legislators and regulatory officials, and can influence how regulations are designed and enforced. They often have Washington offices dedicated to ensuring their interests are reflected in regulations. This can disadvantage everyone else—ordinary consumers, taxpayers, workers, small businesses, the middle class, and the poor. Businesses who ignore Washington, and just concentrate on competing for customers in the marketplace, can quickly find themselves on the losing side of trade policy, or tax policy, or some other regulatory tilt of the playing field. Large businesses also have advantages over smaller entities in that they have systems in place to handle the burdens of regulatory compliance, and can spread those costs over more employees and products. In heavily regulated industries like medical care or consumer finance, it becomes difficult, if not impossible to be successful by attending only to the needs of consumers. Catering to the whims of the regulators can dominate other considerations.** C. The vulnerable shoulder many of the costs. The real costs of regulation are passed on to all Americans, who are generally unaware of these costs because they are hidden in lower wages, higher prices for consumer goods and services, and fewer products and opportunities made available. Often, those least able to represent themselves shoulder the greatest burdens. For example, many regulations lead to higher energy and transportation costs, raising product prices on almost everything we buy. These regulations may lead to some benefits, but is it really fair to ask low-income families to pay a larger share of their income for these benefits than wealthier families? Products standards that may make sense for many may also price low income consumers out of the market entirely. Higher prices for new cars to incorporate backup cameras, for example, make them less affordable to lower income consumers who end up driving older, less safe cars longer. Some have suggested that wireless carriers offering certain programming for free or without counting against data limits would violate "net neutrality," but this could potentially preclude an offering likely to be especially attractive to lower income consumers. Regulations in the workplace may keep the workplace safer, but they limit worker flexibility, and can dampen wages, or discourage employers from hiring less-experienced or lower-skilled workers. **Lengthy drug approval processes not only increase the cost of new drugs but discourage investment in potentially life-improving products. Consumers may face absurdly high drug prices, not because the drug is new or expensive to produce, but because it enjoys a monopoly protected by regulatory barriers.** Only those pharmaceuticals with the potential to earn the highest profits can afford to go through the expense of decades' long scrutiny. **And, patients are prevented from getting access to promising products during the bureaucratic delay, even those with terminal illnesses.**[20] **Small, pioneering companies cannot afford the costs and time required to get approval of innovative new products, and often sell out to larger companies with the expertise and resources to obtain government approvals. It is then up to the larger company whether to market the new product or crush it. This reduces competition and innovation, and ultimately increases prices.**

Elizabeth Whitman @Elizabethwhitty, 9-24-2015, "How The US Subsidizes Cheap Drugs For Europe," International Business Times, https://www.ibtimes.com/how-us-subsidizes-cheap-drugs-europe-2112662

These price discrepancies and their implications are well known throughout the industry but rarely discussed outside of it. Pharmaceutical companies have long defended the high price of drugs as necessary to pay for the research and development of new drugs, but the differences in pricing essentially means that consumers in the U.S. are contributing more than those in other countries. *The U.S. accounted for 46 percent of global life sciences research and development--the vast majority of which is in biopharmaceuticals--according to the December 2013 issue of R&D Magazine.*

"60%" Stewart Lyman, 9-2-2014, "Xconomy: Which Countries Excel in Creating New Drugs? It's Complicated," Xconomy, https://xconomy.com/seattle/2014/09/02/which-countries-excel-in-creating-new-drugs-its-complicated/?single_page=true

Let's dive in a little deeper. Consider the data in the table below (from the Milken Institute report, The Global Biomedical Industry: Preserving U.S. Leadership). The table purports to show how the number of drugs produced within certain countries has changed over time. The take home message: drug discovery efforts have moved in large part from Europe and Japan to the U.S. over the past 30 years. But these numbers are difficult to interpret due to the frequent acquisition of both companies and products during this time period. **The percentage of all NCE's (New Chemical Entities) that originated from U.S.-based companies rose from about 31 percent in the '70s and '80s to 42 percent in the '90s to 57 percent in the 2000s. These data raise three important questions:**

Lori Hinnant, 3-8-2001, "Merck lowers price of AIDS drugs in Africa," Daily Local News, https://www.dailylocal.com/business/merck-lowers-price-of-aids-drugs-in-africa/article_701b7728-ddcb-51d6-a856-452cf3d5c2ee.html

In a statement Wednesday, the company said it will make no profit when selling the two protease-inhibitor drugs in developing countries. The drugs will be made available at about one-tenth of their U.S. price. Merck and other drug companies have come under sharp criticism from various governments and relief groups, which accuse them of keeping patented lifesaving medicines beyond the reach of the world's poor. "The reason we did this is we're trying to speed the process of access to these medicines," said Merck spokesman Greg Reaves. "We thought it would now spur other entities to get involved." More than 25 million of the 36 million people infected with HIV live in sub-Saharan Africa, one of the world's most impoverished regions. Developing countries in other areas will be evaluated for the reduced-price program on a case-by-case basis, Reaves said. Reaves said the company is looking in particular at "those countries where clearly the disease is most devastating, and also where economic conditions are devastating." *Merck, one of the world's biggest manufacturers of AIDS drugs, makes Crixivan and Stocrin, which suppress HIV levels in the body and can be used alone or drug combinations known as AIDS cocktails. Crixivan, which sells for $6,016 per patient per year in the United States, will be sold in developing countries for $600 a year; Stocrin, whose U.S. equivalent Sustiva costs $4,730 per patient per year, will be sold for $500 a year.* Merck said the treatments will be available at a reduced price to governments, relief agencies and others who can provide them to patients, on the condition that the drugs be used only in the countries where they are sold. Protease inhibitors, introduced in the mid-1990s, revolutionized AIDS treatment, transforming the disease from a death sentence into a manageable chronic ailment for many patients. The drugs typically are mixed with two other, older medicines such as AZT and 3TC. Officials with Doctors Without Borders, the Nobel Peace Prize-winning relief agency, welcomed Merck's announcement but cautioned that the reduced price could still leave the drugs out of reach for many of Africa's AIDS patients.

Lori Hinnant, 3-8-2001, "Merck lowers price of AIDS drugs in Africa," Daily Local News, https://www.dailylocal.com/business/merck-lowers-price-of-aids-drugs-in-africa/article_701b7728-ddcb-51d6-a856-452cf3d5c2ee.html

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Thomas, Cueni, International Federation of Pharmaceutical Manufacturers & Associations, 05-13-18, https://www.ifpma.org/wp-content/uploads/2018/05/IFPMA_50Years_of_Global_Health_Progress.pdf

*Of the 37 million people globally living with HIV, 21 million have access to ARV therapy – and more year-on-year. Yet, millions still lack access to therapy, many in LMICs. It is estimated that just 12 million of the 25 million living with HIV/AIDS in Africa receive ARV therapy.*177 UNAIDS estimates the funding gap for HIV in LMICs over the 2015 to 2020 period stands at USD 26 billion, and it looks to public and private partners to ensure the gains in R&D innovation do not exclude those in need of existing or older treatments.178 Individual R&D-based pharmaceutical manufacturers – through licensing, pricing initiatives and various partnerships – continue to seek to improve access for LMICs, alongside critically needed interventions in prevention, diagnosis and broader health system strengthening. Only a holistic approach will ensure critical treatments are available to all people in need.

Rexford Santerre, xx-xx-xxxx, "(PDF) Assessing Consumer Gains from a Drug Price Control Policy in the U.S," ResearchGate, https://www.researchgate.net/publication/254072188_Assessing_Consumer_Gains_from_a_Drug_Price_Control_Policy_in_the_US

This paper uses national data for the period 1960 to 2000 to estimate an aggregate private consumer demand for pharmaceuticals in the U.S. The estimated demand curve is then used to simulate the value of consumer surplus gains from a drug price control regime that holds drug price increases to the same rate of growth as the general consumer price level over the time period from 1981 to 2000. Based upon a 7 percent real interest rate, we find that the future value of consumer surplus gains from this hypothetical policy would have been $319 billion at the end of 2000. *According to a recent study, that same drug price control regime would have led to 198 fewer new drugs being brought to the U.S. market over this period.* Therefore, we approximate that the average social opportunity cost per drug developed during this period to be approximately $1.6 billion. Recent research on the value of pharmaceuticals suggests that the social benefits of a new drug may be far greater than this estimated social opportunity cost.Institutional subscribers to the NBER working paper series, and residents of developing countries may download this paper without additional charge at www.nber.org.

Vernon, John, University of Conneticut/Manhattan Institute, Nov 1, 2004, https://www.manhattan-institute.org/pdf/mpr_01.pdf

Using the predicted trend in pharmaceutical prices without government influence and an established elasticity of R&D spending with respect to drug prices from prior research, we determined that the resulting government-induced loss of capitalized pharmaceutical R&D expenditures was $188 billion (in 2000 dollars) from 1960 to 2001. **This "lost" R&D may be translated into human life years "lost"—literally, increased pain and suffering and shorter lives caused by the absence of new medicines and future research—by using results from recent econometric work on the productivity of pharmaceutical R&D in the U.S. over the same period. We conclude that the federal government's influence on real drug prices cost the U.S. economy approximately 140 million life years between 1960 and 2001.** Applying this same analysis to the future, we predict that the increased government influence on drug purchases under the MMA will dramatically reduce both real drug prices and R&D spending. We estimate that real drug prices will decline by 67.5 percent (or about 49 percent lower than pre-MMA levels) if purchases under the MMA are treated in the same manner as drug purchases under Medicaid and the VA iii Medical Progress Report 1 iv December 2004 have been treated historically. We further estimate that this decline will reduce R&D spending by 39.4 percent, or $372 billion over the lifetime of the act. This translates into a reduction of 277 million life years.

Howard, Paul 9-23-2015, "To Lower Drug Prices, Innovate, Don't Regulate," No Publication, https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/to-lower-drug-prices-innovate-dont-regulate

Better prices can be enjoyed today without compromising tomorrow's cures. But instead of exercising greater control over the industry, reformers should opt for less — focusing instead on efficiency, innovation and competition. First, modernize the drug development process to ensure that companies can develop safe and effective medicines for Food and Drug Administration approval faster and at less cost than is currently possible. Getting more drugs to market means more competition between producers. As we've seen from new medicines combating hepatitis C, the emergence of multiple drugs has helped insurers negotiate up to 50 percent price cuts. **And because the health benefits of new medicines are so large, advancing one generation of F.D.A. drug approvals (or 25 new drugs) by a just a single year would generate $4 trillion in benefits to U.S. patients.** Second, Congress should retool entitlement programs to encourage greater competition among providers and insurers based on real health outcomes. Ground level efficiency in patient care, not top-down price controls, will ensure consumers and taxpayers get the maximum value for their health care dollars without dampening innovation. Price controls sacrifice the health of future generations in exchange for a short-term fix. They remain a poor choice for any policymaker with a holistic view of American health care.

Tricia Yeoh, "Column", PhD University of Nottingham, 11-2-2018, 11-2-2018, http://www.thesundaily.my/node/427968

Price Controls will have serious consequences on people's lives, and already has. In May 2016, it was reported that a 32-year-old retail store operator in Kuantan was fined RM8,000 for failing to respond to a notice issued by the ministry. He had been asked to justify why he sold a packet of laundry detergent for RM10.60 instead of RM9.90, which the government said was more justified – just a price difference of 70 sen. **A fine of RM8,000 may not sound like much to a big business, but it could definitely eat into the business savings of a small kedai runcit.** One wonders whether his shop survived after having to pay the hefty amount. **Policies like these hit the small businesses the worst, because they do not have the resources, infrastructure or economies of scale to adapt as quickly as big businesses. They do not have the same connections needed either to voice out these concerns to policymakers, whether it is to big law firms, business chambers or politicians**.

Innovation on horizon:

Royal Engineering, "", No Publication, 11-2-2018, xx-xx-xxxx https://www.raeng.org.uk/publications/reports/nov-13-innovation-in-medical-technologies

The aim of health technology horizon scanning is to systematically identify new and emerging technologies that have the potential to impact health, health servicty; and which might be considered for health technology assessment. Horizon scanning can inform strategic priorities, help priorities research, inform guidance development and support innovation. It is a big task. Dr Alison Cook, Associate Director of the National Institute for Health Research (NIHR) Horizon Scanning Centre, is part of an academic unit that is monitoring more thanes, and/or socie **250 medical technologies with the aim of identifying which innovations are close to reaching the market,** in order to help those who will be affected to prepare for them. Examples of innovation that she sees **within the next few years include the development of systems – in part putting together existing technologies – that could create an artificial pancreas to tackle type 1 diabetes, and work on visual prosthetics that could make artificial sight a reality.** Further out, there is the potential for **stem cell-based therapies** to expand to the point where cells can be 'reprogrammed' to overcome faults. If this kind of technology horizon scanning is essentially an academic exercise, then the other constituencies identified as **central to the medical technology innovation** process by Professor Lionel Tarassenko in the keynote address also have their individual perspectives on future innovation directions:

Price control loopholes:

Steven Mufson, "PRICE CONTROLS: PAST AS HEALTH CARE PROLOGUE", Washington Post, 11-2-2018, 3-14-1993 https://www.washingtonpost.com/archive/business/1993/03/14/price-controls-past-as-health-care-prologue/bcf61ebd-5549-492a-a210-08c3fe54bc7b/

The Nixon administration, for example, slapped wage and price controls on the entire economy in 1971 in an attempt to slow down inflation. The controls were supposed to last 90 days. Instead, they went on for nearly three years.

Throughout that period of wage-price controls, American ingenuity thrived in finding ways around the rules.

Faced with price controls on all the usual cuts of beef, **grocers invented new cuts**, such as the "watermelon roast," that would be uncontrolled. **When companies realized that the prices of imports were exempt, they**

shipped lumber to Canada and imported it again. Taking advantage of a loophole for customized work, contractors drilled holes in plywood and filled the holes back up to create customized products.

"I was sympathetic to {price controls} all through the 1970s," said Barry Bosworth, a Brookings Institution fellow who was director of President Jimmy Carter's Council of Wage and Price Stability for two years. But "**when we actually did it," he said, "you just never would have believed so many things could go wrong."**

Nonetheless President Clinton and his health advisers are considering imposing price controls on the health care industry to slow down the 12 percent inflation in that area, a rate roughly four times the rate in the overall economy. Doctors' fees, hospital charges, pharmaceutical prices and other medical services could be hit by government dictates of the sort that have not been used in the United States since the 1970s.

People who implemented wage and price controls during the 1970s warn that the Clinton efforts could be futile.

"As I think back on that period," said Herb Stein, who was chairman of President Richard M. Nixon's Council of Economic Advisers. "We didn't do much good. **The trend of prices ... slowed down, but within a few months after controls were over we were back to the previous trend."**

"It would be a mistake to underestimate the ingenuity of people in the private sector to take advantage of discrepancies in a system of price controls," said Marvin Kosters, who was chief economist for Nixon's wage and price control council in the early 1970s and who now is a fellow at the American Enterprise Institute.

The story of Nixon's imposition of wage and price controls shows just how tempting such a policy can become, even for Republican free marketers.

Steven Mufson, "PRICE CONTROLS: PAST AS HEALTH CARE PROLOGUE", Washington Post, 11-2-2018, 3-14-1993
https://www.washingtonpost.com/archive/business/1993/03/14/price-controls-past-as-health-care-prologue/bcf61ebd-5549-492a-a210-08c3fe54bc7b/
"You can't tell me that a 12 percent overall price increase is all because of inefficiencies," Bosworth said. "Some is new technology, new tests that never existed before, new drugs that never existed before. How do you set a price on a new product? You don't."

In addition to breakthroughs in technology, **price fixers in health care face the "watermelon roast" problem.** People will "**create new products trivially different from old products" to circumvent controls**, Bosworth said.

Of all the problems Clinton's advisers face in fixing prices for health care, Bosworth said, "**the new product problem is most relevant. And they'll be killed by it."**

Beware of Increases In Procedures "**If you don't give a surgeon an acceptable price for taking out a kidney, he'll take out two,**" said Stein, only half in jest.

In fact, said Bosworth, who sits on the board of Blue Cross-Blue Shield of Maryland, **when the big insurance company lowered fees on doctors, doctors billed for more work. When Blue Cross in Maryland tried to**

squeeze charges for hospital stays, the costs of outpatient care shot up. As a result, Maryland hospital care costs less than the national average; Maryland medical care does not.

"Price controls could work for a few months," Bosworth said. "But if you are going to have them in place for a year or more, don't underestimate the ingenuity of people to get around them. Their livelihoods are at stake."

M. Asif Ismail, "Drug lobby second to none", Center for Public Integrity, 11-2-2018, 7-7-2005 https://www.publicintegrity.org/2005/07/07/5786/drug-lobby-second-none
The pharmaceutical and health products industry has spent more than $800 million in federal lobbying and campaign donations at the federal and state levels in the past seven years, a Center for Public Integrity investigation has found. Its lobbying operation, on which it reports spending more than $675 million, **is the biggest in the nation. No other industry has spent more money to sway public policy** in that period. Its combined political outlays on lobbying and campaign contributions is topped only by the insurance industry.

The drug industry's huge investments in Washington—though meager compared to the profits they make—have paid off handsomely, resulting in a series of favorable laws on Capitol Hill and tens of billions of dollars in additional profits. They have also **fended off measures aimed at containing prices,** like allowing importation of medicines from countries that cap prescription drug prices, which would have dented their profit margins.Pfizer, the world's largest drug company, made a profit of $11.3 billion last year, out of sales of $51 billion.

The industry's multi-faceted influence campaign has also led to a more industry-friendly regulatory policy at the Food and Drug Administration, the agency that approves its products for sale and most directly oversees drug makers.

Most of the industry's political spending paid for federal lobbying. Medicine makers hired about 3,000 lobbyists, more than a third of them former federal officials, to advance their interests before the House, the Senate, the FDA, the Department of Health and Human Services, and other executive branch offices.

Old impact shits
Easton 17' continues that when Germany and Japan instituted price controls, businesses rapidly shifted their headquarters to the US to find a safe haven for innovation. As a result, over the past 30 years, the US has been the global leader in medical innovation, with **Whitman of International Business times 14'** quantifying that 46% of all new biopharmaceuticals and almost 60% of chemical pharmaceuticals are innovated in the US.

With US price controls, other countries who rely on US innovation to subsidize medication will have no way of helping their poor.

Goldman of Marketwatch in 2018 finds the U.S. market accounts for as much as 78% of all global drug profits. These are the massive profits that fund innovation.

As a result, **Hinnant of the Library of Economics** explains that after Merck created anti-AIDS drugs, it was able to be sold for 10 times less the cost in *international markets*, preventing millions of dying from a rampant disease.

With the current trajectory of innovation the **Royal Academy of Engineering** finds that over 250 potential medical innovations, each with the capacity to save an entire generation of people, will be released to the market in the coming years.

Losing this would be devastating as **Cueni in 18'** confirms that just a single US small business antiviral treatment could potentially save 21 million people from dying of HIV in southern Africa.

Overall, the NBER '14 finds that new therapies created by American research and development have accounted for 73% of the increased life expectancies across the developing world in modern history. Since 2000 alone, Lam of the Atlantic quantifies that pharmaceutical alliances have vaccinated over 500 million children in poor countries.

Thus, we negate.