We *negate*,

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

Our sole contention is the Nature of the Market.

Price controls are unlikely to tangibly hurt Big Pharma, as Feldman '17 of UC Hastings writes that pricing on pharmaceuticals is so convoluted that large corporations are always able to be a step ahead of regulators, exploiting loopholes to ensure they make a profit. Thus, Yeoh '17 of the University of Nottingham describes that price controls fall overwhelmingly on small companies who cannot adapt to these price controls the way large companies can.

Specifically, price controls would decimate two critical components of the pharmaceutical industry.

Sub-point A is a Biotechnological Collapse.

Imposing price controls would trigger capital flight from the biotech industry. Nisen '15 of Quartz writes that biotech companies are extremely reliant on high drug prices to recuperate investment costs for drug development. However, Easton '18 of Stat News continues that because price controls make pharma less profitable, venture capitalists would shift investments into other industries like high technology instead. Thus, Nisen '15 concludes that price controls would "burst the biotech bubble and bring investments crashing down."

Less investment prevents the development of necessary novel drugs. Alazreki '10 of AOL warrants that 65% of drugs developed by biotech companies are high-priority innovative drugs. Thus, Vernon '03 of the University of North Carolina quantifies that imposing price controls would reduce the number of new drugs in the coming decades by 30%.

This downsizing of innovation would have two catastrophic impacts.

First, an antibiotic-resistant nightmare.

Easton '18 of Stat News writes that there remain huge unmet needs for better treatments against drug-resistant infections. Fortunately, he continues that with sustained investment flowing into biotech companies, advances in these areas will continue to come. However, without novel, innovative drugs, Simpkin '17 of the Journal of Antibiotics writes that antibiotic resistant diseases will kill 10 million people annually by 2050.

Second, hiking overall medical costs.

Shepherd ‘16 of New York University outlines that because innovative drugs reduce medical spending on doctor visits, hospitalizations, and other medical procedures, every additional dollar spent on innovative drugs reduces total medical spending by seven dollars.

Sub-point B is a Generics Shortage.

Despite high-profile price hikes, generic drugs -- cheap, off-patent alternatives to name-brand drugs -- are becoming more prevalent, greatly improving access for patients.

Indxx ‘16, a research and analytics firm, writes that as more drug patents expire, more generics are entering the market, accounting for more than half of pharma growth globally. Indxx ‘16 concludes that by 2020, 92% of prescriptions will be filled by generic drugs. And as these drugs enter the market, they drive competition, which is why The Government Accountability Office ‘16 continues that generic drug prices have fallen by 59% since 2010. Because of this trend, Aitken ‘18 of the IQVIA Institute for Human Data Science writes that out-of-pocket drug prices are declining by 17% for consumers.

However, imposing price controls would hamper manufacturing investment by generics companies, thus creating a supply shortage.

Wechsler ‘16 of PharmTech writes that the number one cause of supply shortages of drugs is because of manufacturing failures. However, she continues that in recent years, the number of shortages has decreased due to recent investment into manufacturing.

However, imposing price controls would reverse this trend. Gottlieb ‘11 of the American Enterprise Institute writes that generic manufacturers won’t make long-term investments into improving manufacturing efficiency without being able to raise prices in the future to recuperate those costs. Problematically, Federgruen ‘12 of the Wall Street Journal writes that price controls dramatically lower profit margins of generics companies, leaving less money to make necessary investments to match demand.

Thus, Dean ‘18 of the American Society of Health Economics writes that price controls reduce the market share of generics by 14.5%. When generic manufacturers stop producing, people are left without critical medication. For example, Nix ‘11 of the Heritage Foundation writes that when the U.S. imposed price controls under Medicare, generic suppliers of cancer treatment left the market, leaving half a million people without life-saving treatment.

Thus, we negate.

Feldman, Robin, May Your Drug Price Be Ever Green (October 29, 2017). UC Hastings Research Paper No. 256. Available at SSRN: https://ssrn.com/abstract=3061567 or http://dx.doi.org/10.2139/ssrn.3061567

Of course, some **complexity in pharmaceuticals is inevitable**. The intellectual property systems for drugs must, of necessity, interact with approval processes, and those approval processes must operate with exquisite awareness of public health and safety. These are heady responsibilities. Nevertheless, **the system has become so complex and convoluted that it threatens to collapse in on itself**. And, of course, **complexity breeds endless opportunities**.155 **It ensures that the legislators and regulators will always be at least a step behind in an endless game of cat and mouse. Year after year, government actors must attempt to block strategic behaviors that have developed, even as the industry develops new ones**.156 In such a process, it is clear that our incentive structure is badly misaligned with societal goals.

Yeoh, Tricia. "**Free Small Businesses From Price Controls**." Feb. 2017. University of Nottingham. https://www.triciayeoh.com/2017/02/free-small-businesses-from-price-controls/?fbclid=IwAR3ykNR2dWDgdos2uBYdkm-oCxczG4dPMJQYzc92XkKcewD7zfgk439kNKE//RJ

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. Thousands of stories like these mean that the country loses as much as US$12 billion a year on cumbersome business regulations, economic opportunities that we would have otherwise gained. The poorest of the poor are affected, and worse, it stifles their spirit of enterprise and efforts to get themselves out of poverty.

Nisen '15 – the current biotech bubble is being ridden on high prices; lower prices as a result of government policy could burst the bubble and bring those investments crashing down.

Nisen, Max. "Forget the tech bubble. It's the biotech bubble you should worry about." Quartz. Feb. 2015. https://qz.com/324939/biotech-valuation-bubble//RJ

Momentum and market optimism have a lot to do with these surging biotech valuations. But a more basic reason is that **major pharmaceutical companies**, the ones worth hundreds of billions of dollars, **badlyneednew drugs.Awave of patents on blockbuster drugs have expired in the past few years, hitting the industry's profits—the phenomenon known as the "patent cliff." But bringing newdrugs to market has gotten more expensive.**According to a 2012 study, pharmaceutical firms spend an average of $4 billion in R&D for each drug that gets approval. For some companies it's as much as $12 billion. (Research sponsored by the industry puts the figure at $2.6 billionper drug, but such estimates, according to the 2012 study, don't sufficiently account for high failure rates.) **Akey reason is that it'sbecome harder to findpromising substances. Pharma's traditional expertise, known assmall molecule discovery**(paywall)—screening large numbers of relatively simple chemicals to find effective ones—**is seeing rapidly diminishing returns**. Years of investment in attempting to streamline, speed up, and automate discovery haven't panned out(pdf). A newer class of medicines called biologics(paywall)—made up of giant molecules that adapt or exploit processes that already occur in the body—are more promising, but need a lot more investment. Moreover, if companies try to research a broad portfolio of potential drugs—which might seem like a prudent way to ensure a few successes—they risk ending up with spiraling costs and low returns, according to a recent report from Deloitte(pdf, p.4). The internal rate of return on research and development (R&D) has fallen over the past few years, according to Deloitte's analysis, which covers the 12 biggest R&D spenders (see chart below). On some other measures, R&D productivity has been declining for more than a decade. **As a result, Big Pharmahasbecome relianton drugsinventedelsewhere. Nearly 60% of projected pipeline revenue**—an estimate of how much income companies will get from drugs in development—**comes from externally sourced products**, according to the Deloitte survey. Last year's study was the fifth in a row by the consultancy that found external candidates were more valuable than internal ones. **It's thecreators of thesepotentialdrugsthatinvestors are excited about**. But they're risky prospects. "Most of these companies out there, most of these academic groups, they all work on the same few ideas," says Dr. Chas Bountra, the head of Oxford's Structural Genomics Consortium and a former GlaxoSmithKline executive. "They work in parallel and in secret and they spend maybe five six or seven years, coming up with a proprietary molecule. The first time they test it in

patients, in phase 2A, the failure rate is over 90%. I can't imagine another industry where you invest resources like that over seven years only to find out nine out of ten times you've failed." **Biotechnology companiesoften focus on so-calledspecialty drugs, which are hard to make or administer, and"orphan drugs," for treating rare diseases**. **Both are expensive to sell and lucrative to make. Orphan drugs in particular are quicker to develop because rare diseases havea small and oftengenetically homogeneous patient population**. Clinical trials are simpler, the FDA is a bit more lenient in approvals, the US's Orphan Drug Act of 1983 gives developers of such drugs longer exclusivity and price protection, and there's little or no competition, all of which gives the drug makers huge pricing power. **Thenumber of approvalsfororphandrugs has shot up in recent years**: Specialty drugs often have similar pricing power. Many work only in small populations. A lot of them are biologics, which are harder for generic manufacturers to reproduce after patents expire. Pharmaceutical companies are both buying up companies that produce these drugs, and devoting more of their own development dollars to them. From 2005 to 2013, the price of the average cancer drug in the US jumped by 10%, or about $8,500, every single year.**If prices were to drop suddenly, that could underminetheexpensiveeconomics of biotech research**. The groups that pay for drugs in the US, a patchwork of private insurers and government plans, have long been thought of as far too fragmentedto drive drug prices down. But just such a price drop is currently playing out in miniature, in the market for hepatitis C drugs. Gilead's Sovaldi and Harvoni were breakthrough treatments for the disease, but they were also the poster children of overpriced drugs. At list prices, a regimen of Sovaldi costs $84,000 for a one time course, and unlike with most specialty drugs, the potential patient population was huge—100 million or more worldwide. Sovaldi and Harvoni together accounted for $12.4 billion in sales last year, and are expected to exceed that total this year. After a rival firm, AbbVie, had a cheaper, competing drug approved late last year, Express Scripts, the US's largest pharmacy benefit manager—a company that handles prescription drug claims—said it would stop coveringHarvoni and, in most cases, Sovaldi. Such "formulary exclusion" (offering one company's drugs to patients and excluding others, often in return for a discount) is becoming more common. US pharmacy chain CVS has been a pioneer: In 2013, it excluded six drugs(pdf), last year, there were 31, and the company expects the number to rise further. Gilead's reaction was to double the discountson its hepatitis C drugs to large buyers (like government health plans and certain insurers). The company kept its upper hand in market share, but at great cost. The announcement sent share prices down for the entire sector. In some ways, the hepatitis C situation is unique. Most specialty drugs don't have this level of competition. And even if Gilead has to cut prices, it might make up for that with higher volumes: Payers (insurers *et al.*) that had restricted the treatment to the most severely ill patients because of the cost may now agree to cover more people. **But it's aconcrete and highly visible example of the sort of pricing pressureinvestors fear**. The potential savings are so big that the experience with Gilead might prompt payers to get more aggressive, and move towards all-payer rate setting, where they negotiate together to wring a uniform low price from the drug firms. **If thatwerecombined with more assertive efforts from the government, it could bring prices down for drugs more broadly**. President Barack **Obama'slatest budgetproposesallowing Medicare, the government's health-care program for seniors, to negotiate prices for the most expensive drugs**—something that's normal in other countries, where most prescription drugs are a fraction of their cost in the US. The Republican-controlled Congress is opposed, but pressure from payers and the public may force its hand. But **biotechnology companies, and theircurrent valuations, are heavily reliant on prices staying high. If more sensible pricing takes effect, itcould burst the bubble and bring those investmentscrashing down.**

Easton '18 – venture capital community would leave and invest in tech instead

Easton, Robert. "Price Controls would stifle innovation in the pharmaceutical industry." Jan. 2018. STAT News. https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry///RJ

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 worldas 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 profitabilityand value creation opportunities for new drugs declined, the appetite of the venture community forrisky, 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.

Alazraki '10 – biotech makes 65% of priority review drugs

Alazraki, Melly. "Where do new drugs come from? U.S. Biotechs lead the way." AOL. Nov. 2010. https://www.aol.com/2010/11/30/where-do-new-drugs-come-from-u-s-biotechs-lead-the-way//RJ

Among the drugs granted priority review because they were believed to offer substantial therapeutic benefits over currently marketed drugs, universities and biotechnology companies were credited with over half (54%), while pharmaceutical companies discovered 46%. Why lump biotechs and universities together? Because **biotechs seem to be a bridge between innovative university discoveries and downstream commercialization, either by biotechs or pharmas**(through acquisitions and licensing agreements), explains Kneller. **Not only that, but biotechs concentrated much more on this area, with 65% of the drugs attributed to them in the priority review category,** compared with 38% for pharmas. Similarly, when assessing scientific innovation, biotechs and universities are responsible for the discovery of 56% of innovative drugs. Big Pharma, with their much larger R&D budgets, are responsible for only 44% of innovative drugs. Universities and biotechs concentrated much more on innovation (nearly 70%) compared to pharmas (35%). And biotechs tended to take more risks and under-take some 70% of the early development of innovative university drugs. As for orphan drugs, which are meant to treat rare diseases and are given special incentives, here, especially, universities and American biotechs shine. Sixty percent of the orphan drugs are attributable to U.S. inventors, and almost all of the biotechs in the field are based in the U.S.

Vernon '03 – computer simulations prove: innovative output decreases by 60% and 30% less drugs will be produced

Vernon, John A. "Simulating the impact of price regulation on pharmaceutical innovation." *Pharmaceutical Development and Regulation* 1.1 (2003): 55-65. https://link.springer.com/article/10.1007/BF03257365//RJ

The implications of a system of cost-based price controls for pharmaceutical innovation(in this model) **are striking:**over a 50-year time horizon, **the annual rate of innovative output will decline by approximately 59.6 to 73.1%**(relative to the baseline scenario without price regulation). Additionally, **the cumulative effect on innovative output will be roughly 29.9 to 36.7% fewer drugsin year 50 compared with the baseline industry evolution**.

Simpkin '17 – 10 million deaths by 2050 and novel drugs are key

Simpkin, Victoria. "Incentivizing Innovation in antibiotic drug discovery and development: Progress, Challenges, and Next Steps." The Journal of Antibiotics. 2017. https://www.nature.com/articles/ja2017124//RJ

Antimicrobial resistance (AMR) is a global health crisis now. At the current rate of emergence and spread of AMR, annual loss of life is expected to reach 10 million deaths by 2050 with an estimated economic cost of $100 trillion.1 Effectively combating AMR requires a multifaceted approach that facilitates sustainable and equitable use of antimicrobials, thwarts the spread of infectious disease, preserves existing antimicrobial therapies and fosters innovation of new therapies and diagnostic tools. **A critical component of the AMR solution is the development of truly novel antibiotic drugs to cover the diminishing effectiveness of existing antibiotics that are relied on every day for essential clinical care**. However, due to a variety of inherent market failures, the present business model for antibiotics has not adequately responded to the growing demand for innovation.2, 3, 4

Shepherd '16 - $1 in R&D spending for new drugs saves $7 in total medical spending

Shepherd, Joanna. “Disrupting the Balance: The Conflict Between Hatch-Waxman and Inter Parties Review.” New York University. Fall 2016.https://www.ftc.gov/system/files/documents/public_comments/2018/08/ftc-2018-0055-d-0006-148045.pdf//RJ

A reduction in innovation will jeopardize the significant health advances that innovation achieves. Empirical estimates of the benefits of pharmaceutical innovation indicate that **each new drug brought to market saves 11,200 life-years each year**. 30 Another study finds that **the health improvements from each new drugcan eliminate $19 billion in lost wages by preventing lost work due to illness**.31 Moreover, **because new, effective drugs reduce medical spending on doctor visits, hospitalizations, and other medical procedures, data shows that for every additional dollar spent on new drugs, total medical spending decreases by more than seven dollars.**32 Brand companies, and the profit incentives that motivate them, are largely responsible for pharmaceutical innovation. Thus, actions that reduce brand profitability could have long-term negative effects on consumer health and health care spending.

Indxx ’16 – 92% of prescriptions will be generics by 2020

Indxx. “Generic Drugs: Revolutionary Change in the Global Pharmaceutical Industry.” NASDAQ.com, Nasdaq, 8 Feb. 2016, www.nasdaq.com/article/generic-drugs-revolutionary-change-in-the-global-pharmaceutical-industry-cm576603. Accessed 6 Nov. 2018.

Over the last few years, generic drugs - low-cost copies of branded drugs - have been gaining in volume[i]and market share.[ii]Typically priced at significant discounts (50%-70%) to their branded counterparts, health plans and governments around the world, which are dealing with rapidly increasing costs and aging populations, have actively encouraged and promoted their use. **Today in the US, generic drugs account for 88% of all prescriptions filled and according to latest IMS report, generics may account for 91%-92% of prescription volumes by 2020.According to a report by IMS Health, from 2013-2018 generic drugs are expected to account for 52% of global pharmaceutical spending growth, compared to 35% for branded drugs.**Overall, sales of generic drugs are forecast to increase from $267 billion in 2013 to $442 billion in 2017, an annualized growth rate of 10.6%. **Major factors driving this growth include popular branded drugs losing their patent protection (known as a “patent cliff”), support for generics from governments, new complex generics coming into the market, and industry consolidation.**

GAO ’16 – generic prices fell 59% since 2010.

Government Accountability Office. “Generic Drugs Under Medicare.” August 2016. https://www.gao.gov/assets/680/679022.pdf//RJ

Generic drug prices declined overallunder Medicare Part D—the voluntary outpatient prescription drug program administered by the Centers for Medicare & Medicaid Services within the Department of Health and Human Services (HHS)—**since 2010.Specifically,generic drug prices fell 59 percent from the first quarter of 2010 through the second quarter of 2015**. **This decline reflects a changing basket of 2,378 unique generic drugs, including those that came into or exited the market during this period.**GAO also analyzed an established basket of 1,441 generic drugs that were present during the entire period of analysis. Unlike the larger changing basket of drugs, prices of established generics decreased moderately and then increased slightly (see figure). **The steeper price decrease for the changing basket of generic drugs is at least partially attributable to more rapid price declines among new generic drugs as they enter the market.**

Aitken ’18 – final prices of drugs fell by 17% and adherence improved.

Aitken, Murray. “Medicine Use and Spending in the U.S.” IQVIA Institute for Human Data Science. Apr. 2018. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf?_=1542082789524//RJ

The usageof medicines by patients has continued to rise. In 2017, there was a significant increase within chronic, 90-day prescriptions which can be linked to efforts to improve adherence. Every year, there are hundreds of billions of dollars in avoidable healthcare costs, with the largest portion of these relating to non-adherence to drug therapy and its associated complications.1 Hypertension affects nearly one-third of Americans, and new guidelines recommend treating nearly half of the population, which could further increase the prescription volume in the largest therapy area by volume. The greatest decline in treatment volumes in 2017 was for prescription opioids, which saw its largest decline ever as greater restrictions, patient awareness and responsible treatment decisions reduced usage by over 12% of morphine milligram equivalents (MMEs). The highest doses of prescription opioids declined by over 33% during the past two years. List prices at pharmacies rose by 58% over the past five years, while **final out-of-pocket costs declined by 17%**. These divergent trends reflect the complex dynamics determining how much patients pay for their medicines and the influence those costs have on whether they fill their prescriptions.

Aitken ’18 – 69% of brand name price growth is solved by rebates

Aitken, Murray. “Medicine Use and Spending in the U.S.” IQVIA Institute for Human Data Science. Apr. 2018. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf?_=1542082789524//RJ

Net price spending growth was driven by autoimmune, multiple sclerosis (MS) and oncology while at the same time offset by price declines in diabetes and respiratory therapies. • **Discounts, rebates and other price concessions offset protected brands price growth by 69% in 2017**. • The difference between invoice-price sales and manufacturer net revenues averaged 34% for protected brands and 28% for the market overall including off-patent brands and generics. • Some therapy areas like diabetes, respiratory, central nervous systems and hepatitis C have seen invoice to net differences exceeding 40%, while other areas such as oncology are typically less than 10%.

Aitken ’18 – costs for prescription drugs holistically have declined by 17%, resulting in $1.54 less per drug on average

Aitken, Murray. “Medicine Use and Spending in the U.S.” IQVIA Institute for Human Data Science. Apr. 2018. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf?_=1542082789524//RJ

• Pharmacy prices have increased by 58% since 2013, while **costs for retail prescription drugs of all types have declined by 17%, as a combination of greater generic use and the use of coupons have lowered patient costs**. • Pharmacy prices for brands increased from an average $231 to an average $364, but final out-of-pocket costs were unchanged at around $30 for the past five years. • **Patient out-of-pocket costs for brands and generics in total have decreased by $1.54 since 2013.**

Aitken ’18 – brands and generics costs have declined by 17%.

Aitken, Murray. “Medicine Use and Spending in the U.S.” IQVIA Institute for Human Data Science. Apr. 2018. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf?_=1542082789524//RJ

Patient final out-of-pocket costs for dispensed prescriptions were $8.69 on average in 2017, reflecting the use ofcoupons to lower costs, the use of**generics where available**, and not including prescriptions abandoned by patients. **• Generic costs declined by 7%**from $6.98 on average to $6.48, **and out-of-pocket costs for brands and generics declined by 17% as greater generic use drove average cost reductions**. • Deductibles have been very effective at influencing patient behavior, and arguably rising deductibles and the rising percentage of workers who have them, are limiting use of products where cost exposure is high.

Aitken ’18 – the aff evidence misses the point and only looks at list prices

Aitken, Murray. “Medicine Use and Spending in the U.S.” IQVIA Institute for Human Data Science. Apr. 2018. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf?_=1542082789524//RJ

While wholesaler acquisition cost (WAC), commonly referred to as list prices, are the most easily researched by patients, the average prices at pharmacies before discounts and coupons are lower.

•**The gap between WAC and pharmacy prices has been influenced by the rising percentage of patients with deductible plans**, with out-of-pocket costs linked to list prices, but potentially much lower if patients reach their deductible or out-of-pocket maximum spend.

Wechsler ’16 – drug shortages are getting better, but manufacturing failings remain the lead cause

Wechsler, Jill. “Quality Manufacturing Key to Stemming Drug Shortages.” PharmTech. Aug. 2016. http://www.pharmtech.com/quality-manufacturing-key-stemming-drug-shortages//RJ

Drug shortages have lessened in the past two years, but remain sufficiently prevalentto raise serious concerns about ensuring patient access to crucial therapies. **Ongoing shortages dropped from nearly 100 at the end of 2013 to approximately 60 a year ago**, according to FDA’s Center for Drug Evaluation and Research (CDER). The American Society of Health-System Pharmacists (ASHP), which compiles data from the University of Utah Drug Information Service, similarly reports **a notable decline in new shortages over the past five years**(1). A main turning point was the enactment of legislation in 2012 that requires manufacturers to notify FDA in advance of likely supply problems for critical medicines. The legislation has helped the agency prevent and resolve such issues. **The drug shortage situation “now is in a better place**,” commented CDER deputy director Douglas Throckmorton at the ISPE/FDA/PQRI quality manufacturing conference in June 2016. He credited expanded international cooperation and aggressive action by FDA’s Drug Shortages Staff (DSS) in identifying alternative sources for scarce critical drugs. **But supply problems still are “way toomany,”**he said, noting that **quality manufacturing failings remain the lead cause of supply disruptions, particularly with sterile injectables**.

Gottlieb ’18 – empirics prove: our 2003 price controls force companies out of the market when they can’t raise prices to match increasing production costs

Scott Gottlieb, 11-5-2018, "Solving the Growing Drug Shortages," WSJ, https://www.wsj.com/articles/SB10001424052970203716204577015702644712634//TP

The bigger problem is that **manufacturers can't easily raise prices to meet the resulting increased costs of production**. **A 2003 law fixes the price Medicare will pay for injected drugs to an "average sales price" that is at least six months old at any given time. This flawed concept means even if a generic firm raises its price to reflect increased production costs, the new price won't get paid by Medicare—meaning purchasers would be losing money for months at a time. The result is that generic prices can't rise to reflect changing demand or the need for bigger investments in manufacturing.Branded drugs have faced similar production (and FDA) issues, and they are paid for under the same flawed scheme. But they have larger profit margins to offset the cost of plant upgrades**. **Among the generics makers—whose much smaller profits have been eroded away by production costs—more and more are choosing to exit product lines rather than invest money to meet steadily higher standards.To fix this, we should lift existing price controls when it comes to critical injectable drugs that are generic. First, Medicare can be directed to ditch the flawed "average sales price" and reimburse manufacturers**

for these drugs according to the price that is paid by wholesalers on the open market and already reported to Medicare. Then generic firms could adjust prices to match rising production costs and meet demand.These drugs should also get a holiday from other Medicaid price-control schemes that serve to distort market prices. Sen. Orrin Hatch, the ranking member of the Senate Finance Committee, is working on a legislative proposal to ease the regulatory and pricing burdens facing this market. Better still, Medicare can move the reimbursement of these drugs from its price-controlled "Part B" scheme and into its "Part D" drug program, which already pays for the pills that senior citizens get from pharmacies. Part D is run like a real marketplace, where drug makers compete to sell their medicines to large purchasers. **Allowing generic injectables to be priced competitively would allow manufacturers to recoup the costs of production and bring shortages to an end.**

Federgruen ’12 – manufacturing capacity shifts towards more profitable, patented pharmaceuticals

Federgruen, Awi. “The Drug Shortage Debacle—and How to Fix It.” Wall Street Journal. 2012. https://outline.com/KZ7Xqu//RJ

Behind both problems are the government's tight price controls for generic drugs, especially when purchased by Medicare and Medicaid. **Low prices induce drug makers to exit various markets, or at least to reallocate their manufacturing capacity toward more profitable, patented pharmaceuticals.Low prices also tend to eliminate the rationale forinvestments in better manufacturing technologies and processes**, as shown in my 2009 study in the Journal of Management Science. **Government price controls on generic drugs limit the manufacturers' margin to 6% in many cases**. In the case of vaccines, for example, the Centers for Disease Control and Prevention pays as little for generics as it can negotiate. This results in an average reduction of 40% off the catalog price that applies to sales in the private sector, according to a 2006 study in the journal Clinical Infectious Diseases. As that study noted, the federal government's own National Vaccine Advisory Committee identified price controls as the primary reason for the dramatic decline in the number of suppliers. Second, the government's oversight of manufacturing safety and quality is unnecessarily contributing to shortage problems. The pharmaceutical industry generates many applications for new manufacturing facilities and manufacturing processes within existing facilities. The government has failed to allocate the money to hire enough reviewers to analyze the applications or inspectors to visit the facilities. The backlog of applications for new generic drug facilities and manufacturing processes at the FDA remains a year long, according to the Generic Pharmaceutical Association, and generic drug reviews take 15 months longer on average than evaluations of brand-name products. The generic drug industry, tired of the government's inability to execute, has proposed providing the agency with $299 million in annual fees. **It is clear that the way to resolve the shortage of critical drugs is to relax or eliminate government price controls**, and to increase the FDA's review and inspection capacities. In the latter case the generic drug industry is willing to foot most or all of the bill. Unfortunately, the Obama administration has thus far pursued the opposite objective, at least as far as price controls are concerned. Last November, it issued an executive order instructing the FDA to report any violations of price controls to the Justice Department.

Dean ’18 – price controls reduce market share of generics by 14.5%

Dean, Emma, “Who Benefits from Pharmaceutical Price Controls?” American Society of Health Economics, 13 June 2018,

https://ashecon.confex.com/ashecon/2018/webprogram/Paper6815.html//EK

With the goal of driving down drug costs, governments across the globe have instituted various forms of pharmaceutical price control policies. Understanding the impacts of such policies is particularly important in low- and middle-income countries, where lack of insurance coverage means that prices can serve as a barrier to access for patients. In this paper, I examine the theoretical and empirical effects of one implementation of pharmaceutical price controls, in which the Indian government placed price ceilings on a set of essential medicines. I find that the legislation resulted in broadly declining prices amongst both directly-impacted products and competing products. However, **the legislation** also **led to decreased sales of price-controlled and closely related products, preventing trade that would have otherwise occurred**. **The sales of small, local generics manufacturers were most impacted by the legislation, seeing a 14.5% decrease in market share and a 5.3% decrease in sales.**These products tend to be inexpensive and important for consumer access, but I

use novel data to show that they are also of lower average quality. I provide evidence that the legislation impacted consumer types differentially. The benefits of the legislation were largest for quality-sensitive consumers, while the downsides largely affected poor and rural consumers, two groups already suffering from low access to medicines.

Nix '11 – shortages in 2011 under price controls in America pushed half a million to lack access.

Nix 11(Kathryn Nix, writer for the Heritage Foundation, 21 December 2011, "How Medicare Price Controls Have Contributed to Drug Shortages"https://www.heritage.org/health-care-reform/report/how-medicare-price-controls-have-contributed-drug-shortagesDOA 10/22/18) MDS

According to the Food and Drug Administration (FDA), **there were 178 drug shortages reported in 2010, 132 of which were sterile injectable drugs, which are administered by health care providers.[1] Shortages increased in 2011 and will continue to grow**. **Oncology has the largest share of shortages, affecting more than half a million cancer patients**.[2]Reasons behind the drug shortages are complex and vary from drug to drug, but one of the biggest problems is that Medicare drug reimbursement under Part B keeps prices low. At the same time, drug manufacturers face increasing production costs but cannot easily adjust prices, leading many to halt production. Reasons behind the drug shortages are complex and vary from drug to drug, but **one of the biggest problems is that Medicare drug reimbursement under Part B keeps prices low. At the same time, drug manufacturers face increasing production costs but cannot easily adjust prices, leading many to halt production.Medicare price fixing for outpatient drugs covered under Part B is one of the major reasons for shortages**. **The program pays based on the average sales price**(ASP) **posted for more than six months.**This scheme was enacted in response to the consequences of price controls that preceded it. Before passage of the Medicare Modernization Act of 2003, Medicare payments were based on drugs' average wholesale price (AWP), a suggested retail price set by manufacturers completely independent of what providers actually paid to acquire the drugs.

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Instead, Congress should apply the market forces that have successfully contained costs and maintained access to prescription drugs in Medicare Part D to the rest of Medicare. When it comes to drug coverage, combining Part B and Part D would go a long way to restoring access and appropriate pricing for drugs currently covered under Part B.[11]Short of the necessary structural reform, Congress should change Part B drug payments to reflect the actual acquisition costs for individual drugs. **Ultimately, drug shortages are just one of the consequences of decades of government price controls in programs like Medicare.[12]A rethinking of health care entitlements is necessary to restore robust and well-functioning markets for health care goods and services.**