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

Contention 1 is Delays

Varol from the London School of Economics in 2011

Pharmaceutical price regulation has been used in major pharmaceutical markets to correct market imperfections and contain rising healthcare costs. But regulations can affect the adoption of innovations, especially in highly regulated industries such as the pharmaceutical industry where products and processes are protected by intellectual property rights. Lags in adoption of new pharmaceutical innovations may affect consumer welfare through impaired access to new drug products, in particular cost-effective products. Thus, price regulation is contentious. There is some evidence to suggest that **price regulation can delay launch of new drugs,**. This delay stems **from the inevitable price and reimbursement negotiation processes**, with governments' and firms' strategies combining to cause delay or even a non-launch of new drugs in low-priced markets (Danzon et al. 2005, Kyle 2007). From a health-policy perspective, such delays and non-adoptions can compromise health outcomes and the quality of healthcare. It can also lead to dependency on older pharmaceutical molecules that exhibit lower therapeutic value or cost-effectiveness (Danzon and Ketcham 2004, Schoffski 2002, Kessler 2004, Wertheimer and Santella 2004).

Furthering that

Figure 2 illustrates the pattern of delay for the biggest seven price-regulated markets. In Italy, France and Spain, for example, **introductions [in price-controlled markets] lag about 1.6 to 2.6 years behind free-priced markets** (US, UK and Germany). The Japanese market exhibits a highly paradoxical behaviour with a substantial delay of 6.5 years. This anomaly results from the fact that the Japanese pharmaceutical industry remains predominantly domestic and is still uncompetitive.

Unfortunately, Spiegel from the Hill in 2017 writes

This delay can be deadly, especially for colon cancer patients. The drug industry has invented advanced drugs proven to beat back this disease, including specialty chemotherapy agents such as panitumumab and "angiogenesis inhibitors," which prevent colon cancer cells from growing by cutting off their blood supply. Obviously, these drugs can only help patients if regulators approve them. Too often, that approval is slow to come. And such delays are now common across a wide variety of drug classes, leading to serious carnage: some **600,000 European deaths could be avoided each year if the continent's healthcare systems simply offered "timely and effective medical treatments,"** according to the European Union's own data.

Contention 2 is Cutting off Access

Sullivan of Policy & Medicine in 2018

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 **[and] eliminate the rationale for investments in better manufacturing technologies and processes,** as shown in a 2009 study conducted by the author and published in the Journal

of Management Science. Government **[since] price controls** on generic drugs **limit the manufacturers'[profit] margin to 6% in many cases.**

This is empirically proven

Ridley from dUkE University in 2016 writes

Low prices for products **reduce the incentive for manufacturers to invest in quality and reliability**.5 **Indeed, manufacturing problems** were reported to be **[are] the main cause of** vaccine **shortages** in our sample. Furthermore, low prices for products reduce the incentive for manufacturers to stay in the market. Consistent with this, we found that lower prices were associated with higher probabilities of vaccine shortages

Finding, that In 2004 an Institute of Medicine report warned of vaccine shortages, raising concerns about disease outbreaks. More than a decade later, we looked for progress in reducing vaccine shortages. We analyzed data on vaccine sales and shortages reported by practitioners and patients to the Food and Drug Administration and the American Society of Health-System Pharmacists in the period 2004–13. We found that the number of annual vaccine shortages peaked in 2007, when there were shortages of seven vaccines; there were only two shortages in 2013. There were no shortages of vaccines with a mean price per dose greater than $75 during the study period. Furthermore, we found that a 10 percent increase in price was associated with a nearly 1 percent decrease in the probability of a shortage. Government payers should carefully consider the benefits of averting shortages when evaluating prices for vaccines, including older vaccines whose prices have been subject to congressional price caps.

The Access to Medicine Foundation in May **adds**

an explosion at a Chinese factory in 2016 triggered a n ongoing **global shortage**

Gulland from The Telegraph in June furthers

A new ~~report~~ warns that **antibiotic supply chains are on the "brink of collapse**", with many countries experiencing shortages of key drugs such as penicillin. Doctors are either forced to treat patients with inferior second choice treatments, switch to a lower dose or delay treatment – all of which can fuel the rise in antibiotic resistance.

Price controls would push the global market over this brink

The AMF continues

Shortages are symptoms of fragile supply chains – **[supply chains are fragile] because there are few competitors** at different stages of the chain, **the failure or exit of even one** factory,[or] **manufacturer** or middle-man **can lead the entire supply chain to collapse.**

The impact is antibiotic shortages

The AMF Furthers

Supply chain collapse leads to **antibiotic shortages**, which **are linked to disease outbreaks** and antimicrobial resistance

As historically

[an antibiotic]shortage coincided with a syphilis outbreak that, as a result, could not be brought under control. Between 2012 and 2015, **[doubled]the number of babies born in Brazil with congenital syphilis** has more than doubled.

Hirschler from Reuters in 2017 writes

But **antibiotic shortages** can **have** especially **dire consequences, since doctors have to resort to sub-optimal treatments that are less efficient at killing specific pathogens,** leading to the rise of

resistant bacteria or so-called superbugs. An estimated 70 percent of bacteria are already resistant to at least one antibiotic that is commonly used to treat them, making the evolution of such superbugs one of the biggest threats facing medicine today.

Ashiru of Public Health Matters in 2015 finds [for just TB,] 37 million lives worldwide have been saved by antibiotic treatment for TB **since 2000**

Contention 3 is Impeding Investment

Ian Lloyd writes for PharmaProjects that

As of October 2016, a total of 4,549 **[more than 4,000] drugs are** now **in development for** at least one of **447 rare diseases**. This is an increased drug count of 56% and 23% more rare diseases after nearly three years, **demonstrating** ongoing interest and seemingly **increased** enthusiasm for **research within** these **areas of** high **unmet needs [such as cancer]**.

However, Easton of Stat News 2018 finds

Consumer access to affordable and effective medicines is an important issue. As the cost of many drugs continues to rise, sometimes astronomically, some have suggested **imposing price controls on the U.S. pharmaceutical industry.** Doing that **risks crippling our only hope of curing the many serious diseases that still plague us.**

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.

Thus, Vernon 2004 concludes that

> **regulating** pharmaceutical **prices in the U.S. could lead to a decline in R&D** intensity **of [up to]** between 23.4 and **32.7% .**

Easton furthers

Squeezing pharmaceutical R&D spending down to one-fifth of what it is today would also have an enormous impact on the problems that drug developers often choose to address. Orphan diseases would be deprioritized, as the returns under price controls would not warrant the investment. **[would cause]Complex diseases** would also **[to] be deselected**. While Alzheimer's disease and diabetes have huge patient populations, **[due to]the extremely high cost of conducting** the **difficult research and the need for huge and complex clinical trials** would dissuade all but the largest companies from pursuing those illnesses if the potential pricing upside was to be significantly constrained. Moreover, for difficult diseases like schizophrenia, where today's treatments are mostly inadequate, the flow of more effective new treatments would slow from a trickle to a rivulet, depriving those with these conditions from the possibility of relief.

There is historical precedent for this.

Milliman 2009 writes that

> An example of the powerful impact that price control legislation has upon R&D spending occurred between 1992 and 1993, **when the Clinton Administration proposed a** healthcare **plan that would have placed caps on the price of** breakthrough **drugs**. During that time period, the market value of the industry plunged, and a 2005 study estimated that **the industry reduced** overall **R&D spending by 1.6 billion [it was not until companies were sure the plan had failed that R&D spending returned to previous levels].**

If price controls had been successfully implemented in this time period, Santerre finds that drug **price controls would have led to 198 fewer new drugs being brought to the U.S. market from 1981 to 2000**, at a societal cost of about $100 billion more than the estimated savings from those price controls.

The Impact Is less treatments

Shin of Pharma Intelligence in 2017 concludes that

while individual rare diseases may only affect a small pool of patients, **rare disease patients as a whole are quite numerous at an estimated 350 million people worldwide**. Perhaps most troubling is the fact that **about half of these patients are children, 30% of whom will not live to see their fifth birthday**

The impact is not limited only to the US, as the ITIF finds that

> **Pharmaceutical Innovation Accounted for 73 Percent of the Increase in Life Expectancy [worldwide].**

FL: Other companies enter market to end shortages

James Lowe Newsmax September

The explanation is basic economic theory. **Price controls reduce profits below "normal" economic levels, the margins that people consider worth the work required to produce a good. This, in turn, prompt[ing] firms to exit the market [and] reducing supply. [however, because] Prices stay at the government-set limit, there's no incentive for others to pick up the slack**. Voila, a shortage is born!

FL:The Turn that says AMR caused by overprescription

Blue Health Intelligence in 2017

Since 2010, antibiotic prescription rates in the U.S. have been declining among the commercially insured population, falling **9 percent** during this period. **This decline indicates that considerable progress is being made in public health campaigns to limit** the use of antibiotics and prevent the **development of antibiotic-resistant bacteria**

AMF 18

Supply chain collapse leads to antibiotic shortages, which are linked to disease outbreaks and antimicrobial resistance

This is the more probable cause of resistances in the squo because overprescription is going down in the squo

FL: US doesn't provide global antibiotics

Grand View Research 2016

For instance, In August 2016, Pfizer entered into an agreement with AstraZeneca to acquire the development and commercialization rights to its late-stage small molecule anti-infective business, mainly outside the U.S.

FL: Superbugs develop anyways

~~FL: Companies will innovate more antibiotics~~

According to a recent Tufts University estimate, it costs more than $1.3 billion to bring a new drug to market (Kaitin, 2010). **Antibiotics** in particular **offer pharmaceutical companies a low return on investment; patients take them for only a week or two, in contrast to lifetime regimes of maintenance drugs. There would be even less monetary incentive to develop antibiotic** for only the poorest parts of the world. Preserving antibiotics is imperative and depends on maintaining drug quality as much as on encouraging rational use.

FL: Antibiotics are super cheap and won't be severely impacted by PC

Reinberg of Health Day 2015

"The rising cost of new drug development -- about $2.6 billion per drug -- is making drug companies make a rational decision to emphasize products where they are likely to make their money back, and that's not going to be in antibiotics," Kinch said. "Drug companies may also be saying, 'We are not making much money on antibiotics, so why bother to stock that product.'"
Therefore, when revenue goes down, they will deselect production on antibiotics

FL: Will cut other places than RnD
IHP says that companies prioritize short term profits to appeal to investors. This means they will cut RnD instead of marketing because investors see marketing as imperative to revenue.

Stone from Forbes in June writes
Antibiotic shortages also **contribute to antibiotic resistance, when physicians substitute** unnecessarily **broad-spectrum antibiotics.** Growing resistance is a double whammy, occurring **at the same time as there are fewer antibiotics in the development pipeline to treat these superbugs.**

The impact is creating antibiotic resistance
Hirschler from Reuters in 2017 writes

But **antibiotic shortages** can **have** especially **dire consequences, since doctors have to resort to sub-optimal treatments that are less efficient at killing specific pathogens, leading to the rise of resistant bacteria or so-called superbugs**. An estimated 70 percent of bacteria are already resistant to at least one antibiotic that is commonly used to treat them, making the evolution of such superbugs one of the biggest threats facing medicine today.

Resistances are devastating, as
Holpach in 2016
antimicrobial resistance will make providing high-quality universal **healthcare coverage more difficult if not impossible**," said Ban. "It will undermine sustainable food production. And it will put the sustainable development goals in jeopardy.

O' Neill 14 from the anti microbial review warns **if [drug] resistance is left unchecked, 300 million people are expected to die prematurely because of drug resistance over the next 35 years** and the world's GDP will be 2 to 3.5% lower than it otherwise would be in 2050. This means that between now and 2050 the world can expect to lose between 60 and 100 trillion USD worth of economic output if antimicrobial drug resistance is not tackled. This is equivalent to the loss of around one year's

total global output over the period, and will create [creating] significant and widespread human suffering. Furthermore, in the nearer term we expect the world's GDP to be 0.5% smaller by 2020 and 1.4% smaller by 2030 with more than 100 million people having died prematurely.

FL Public Sector investment

https://www.policymed.com/2011/02/nejm-the-private-sector-discoveries-account-for-79-90-of-pharmaceutical-products.html?fbclid=IwAR2idq2iCHA9ixOR4n4PbCa-mzzmGgw9b57WIP2fbSnhTXZ5-fNgfenhxKw

Sullivan

The Private Sector Discoveries Account for 79–90% of Pharmaceutical Products

Johnson from the London School of Medicine in 2013

The inadvertent **use of suboptimal doses of drugs is likely to be one of the key factors contributing to antimicrobial resistance and thereby leading to the wider spread of disease**. This has been most widely discussed with regard to malaria [106–108]; the repeated administration of subtherapeutic doses of antimalarials will promote the selection and spread of resistant parasites [95,106]. Indeed, artemisinin-resistant malaria has been reported in Cambodia and Thailand [109,110], although the extent to which this can be attributed to the use of substandard drugs is unknown. Likewise, poor-quality antibiotics may contribute to the resistance and spread of diseases such as tuberculosis [23,111,112]. **The use and subsequent failure of substandard narrow-spectrum antibiotics may lead to the unnecessary administration of broad-spectrum antibiotics, thus potentially creating further resistance** [113]. **Substandard**

antihelminthics have been implicated in the development of drug-resistant human helminths [114]**, and substandard antiviral drugs are likely to contribute to the evolution of drug-resistant viruses, including** human immunodeficiency virus **(HIV)**

The first impact is lowering costs

Howard of the New York Times in 2015

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.**

The second impact is saving lives.