Nihar and I negate Resolved: The United States federal government should impose price controls on the pharmaceutical industry.

~~Merriam Webster defines price controls as a government regulation establishing a maximum price to be charged for specified goods and services, specifically medicines in today’s debate.~~

### Contention 1 is Suppressing Innovation

**New medicines have revolutionized the treatment of numerous serious health conditions**

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]**.

**Medical development is dramatically accelerating.**

[Lori Ioannou CNBC, March 2018,](https://www.cnbc.com/2018/03/26/big-pharmas-scramble-to-invest-in-start-ups-to-fuel-innovation.html)  The worldwide prescription drug market is growing at 6.5% compounded annually and is expected to reach $1.06 trillion by 2022.**Small start-ups are driving pharma innovation, accounting for 63% of all new prescription drug approvals over the last five years, HBM Partners reports.** Drug companies have established venture capital funds and incubators to invest in promising start-ups working on new drug technologies. The allure is multifaceted. **Small biotech start-ups [since they] 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.

**However, Companies would be devastated by price controls that slash the profitability of developing new drugs**

[Matthew Herper of Forbes](https://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/#5c83f4c64a94) **- developing new drugs is incredibly difficult and expensive**

**The average drug developed by a major pharmaceutical company [on average costing] at least $4 billion [per drug], and [up to] $11 billion [because it takes so much research and testing to bring a drug to market].**

**Which is why** [**Easton of Stat News 2018**](https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/)

**If price controls pressure the U.S. [pharmaceutical] 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.

**Not only will companies spend less on innovation, they will undertake fewer projects as well.**

**Francis in 2005 quantifies that**

[**http://www.nber.org/digest/may05/w11114.html**](http://www.nber.org/digest/may05/w11114.html)

**cutting prices by 40 to 50 percent in the United States will lead to between 30 and [up to] 60 percent fewer R and D projects being undertaken** in the early stage of developing a new drug.

**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. **[cause research into] Complex diseases [like Alzheimer's] to be stopped [because]  would also be deselected**. While Alzheimer’s disease and diabetes have huge patient populations, **the extremely high cost of conducting the difficult research and the need for huge and complex clinical trials would dissuade all but the largest companies** from pursuing those illnesses if the potential pricing upside was to be significantly constrained. Moreover, for difficult diseases like schizophrenia, where today’s treatments are mostly inadequate, the flow of more effective new treatments would slow from a trickle to a rivulet, depriving those with these conditions from the possibility of relief.

~~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].~~**

[Scott Atlas Stanford University April 18](https://www.hoover.org/research/overlooked-key-lower-drug-prices)

In addressing legitimate public concern about drug prices, our politicians must avoid the temptation to impose top-heavy regulations. Price caps may seem intuitively attractive, yet price caps always restrict supply of the product, and drugs are no different. Iain Cockburn of Boston University showed that price regulation strongly delayed drug launches of 642 new drugs in 76 countries. The University of Connecticut’s Thomas Abbott showed that price controls significantly diminish early-stage research and development. In that study, cutting prices by 40 to 50 percent in the United States would lead to 30 to 60 percent fewer early-stage R&D projects. And Rexford Santerre of the University of Connecticut calculated that **drug price controls would have led to 198 fewer new drugs [over a 20 year period] 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 first impact is a devastating blow to our health

Critically, although individual rare diseases affect only a few people, rare diseases cumulatively affect a large proportion of the population.

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**.a

**As these innovative drugs spread across the world,**

https://**itif**.org/publications/2017/05/30/pharmaceutical-innovation-accounted-73-percent-increase-life-expectancy-30

Fact of the Week: **Pharmaceutical Innovation Accounted for 73 Percent of the Increase in Life Expectancy in 30 Developingand Developed Countries From 2000 to 2009**

**The second impact is decreasing healthcare costs**

[Paranicas HINJ 14](http://hinj.org/the-value-of-medical-innovation-saving-lives-saving-money/)
Impressively, **for every dollar spent on innovative medicines, total healthcare spending is reduced by $7.20 [by reducing the need for doctor visits, hospitalizations, and expensive surgeries down the road**] Certainly, these medicines, therapies, medical technologies, devices and diagnostic tools keep people healthier. They limit the need for frequent visits to the doctor. They help to avoid costly hospital stays. They help patients avoid expensive surgeries.

Making healthcare more affordable in the long run

###

### Contention 2 is creating shortages

Price controls would actually decrease the availability of drugs in three ways.

#### First is by sacrificing manufacturing quality

[Marta Wosinska FDA 2012](http://sci-hub.tw/https%3A//doi.org/10.1038/clpt.2012.220)

Although such unanticipated events have the potential to cause major shortages, **very few actual shortages are linked to such unanticipated events. Instead, [most] drug shortages are first and foremost driven by** the inability of various firms to maintain production because of the **failures of quality management** in facilities that produce the finished dosage form of the drug (rather than the active ingredient). As Figure 1 indicates, **these failures which were directly responsible for 56% of sterile injectable drug shortages in 2011.**

**Decreasing prices through price controls would exacerbate this issue.**

 [~~Thomas Sullivan Potomac Center~~](https://www.policymed.com/2012/03/increasing-generic-drug-shortages-linked-to-government-price-controls.html) ~~May~~

**~~Low prices~~** ~~also~~**~~tend to 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 price controls on generic drugs limit the manufacturers’ margin~~** ~~to 6% in many cases.~~

[David Ridley Duke University 2016](https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0420)

**Low prices for products reduce the incentive for manufacturers to invest in quality and reliability.** Indeed, **[causing] manufacturing problems** were reported to be **[that 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**

#### The second is through Market Withdrawals

Price controls decrease the amount of manufacturers supplying a drug.

[James Lowe Newsmax September](https://www.newsmax.com/finance/markets/james-lowe-generic-drug-prices/2018/09/13/id/881656/)

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!

https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm#q4

**With fewer firms making** older sterile injectable **drugs**, **there are a limited number of production lines that can make these drugs**. The raw material suppliers the firms use are also limited in the amount they can make due to capacity issues at their facilities**. This small number of manufacturers and limited production capacity** for older sterile injectables, **combined with the** long lead times and **complexity of the manufacturing process** for injectable drugs, **results in these drugs being vulnerable to shortage**. **When one company has a problem or discontinues, it is difficult for the remaining firms to increase production quickly and a shortage occurs.**

This causes companies to stop producing medically vital drugs.

By Awi [**Federgruen**](https://www.wsj.com/articles/SB10001424052970203986604577253242913478400)  **WSJ** March 1, 2012

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 [medicare] price controls as the primary reason for the dramatic decline in the number of suppliers.**

[Healthcare Institute of New Jersey](http://hinj.org/government-price-controls-on-prescription-drugs-may-be-more-than-patients-bargain-for/)

The end result is that vaccines have been distributed to states where there is no epidemic often leaving a shortage where it is needed. Because the government controls the price, the vaccine makers are discouraged from producing more than what the government orders. Vaccine prices have remained stagnant since 1994.  **[because of] these price controls [in canada], [the number of childhood vaccine manufacturers decreased by 80%] there now are only four developers of childhood vaccines. That’s down from 20 companies just a few years ago.**

**The first impact is a rise in Mortality Rates**

In Canada, which imposes price controls

[Jennifer Lee CBC News 2018](https://www.cbc.ca/news/canada/calgary/pharmacist-drug-shortages-1.4590438)

"**Shortages** like this, I've never seen this bad, ever," said David Brewerton, pharmacy manager at Luke's Drug Mart in Calgary. "It's **[are] progressively getting worse and worse every year.**" The (CANADIAN) federal government started requiring that drug companies publicly report shortages in March 2017 According to Health Canada, about **4,400 actual and anticipated shortages have been reported since [2017] and are getting worse each year.** But it is unclear just how common the problem was prior to that because reporting wasn't mandatory. Dr. Jacalyn Duffin, Queen's University professor emerita, estimates **there are between 500 and [up to] 700 drugs in short supply** in Canada **at any given time.**"Since the majority of the shortages are generics — sometimes they are sold at such a low price that its almost impossible for the manufacturer to make a profit and there's zero interest in making a drug if they're not going to make a profit.

#####

These shortages are deadly as

[Lindsay Pickell, ASCO 2017](https://connection.asco.org/magazine/features/drug-shortages-enduring-effects-continued-challenges-2011-crisis) finds that

**Patients bear the brunt of shortage**s consequences.Some had their treatment delayed, some were required to pay exorbitant out-of-pocket costs for brand-name substitutes, and others risked unknown and potentially harmful effects from alternative treatments. Alternative treatments used during drug shortages are correlated with higher rates of medication errors, side effects, disease progression, and deaths. **[ Two year survival rates for children with lymphoma cancer decreased by 13 percent during a drug shortage.]** An analysis of a study of children with Hodgkin lymphoma treated with a regimen prescribing mechlorethamine revealed that patients treated with cyclophosphamide in place of mechlorethamine (during the period when mechlorethamine was unavailable) experienced significantly worse outcomes. **Two-year event-free survival was 88% for those treated with mechlorethamine compared with 75% for cyclophosphamide**.1 A recent study published in JAMA showed that the 2011 norepinephrine shortage was significantly associated with increased mortality among patients with septic shock (35.9% during normal use vs. 39.6% during shortage).2

#### The second impact is a rise in black market drugs, which price controls cannot affect

[John Goodman Health Affairs 2012](https://jamanetwork.com/journals/jama/fullarticle/2612912)

Economics teaches that when prices are kept artificially low, shortages develop. People cannot get all of the care they try to obtain at the existing rate. Also, regardless of the apparently multiple causes of the shortages, certain patterns tend to emerge. People **respond to** persistent **shortages** by doing things that invariably make the problem worse.

Black Markets. Another thing that happens **is the [shortages lead to the] development of black** (or gray) **markets, where price gougers buy up [all the remaining] quantity of a drug in short supply and sell it for a much higher price — even higher than would have been charged if the government had simply left the market alone**. For example, in their 2005 letter to Secretary Leavitt, hospitals complained that shortages were exacerbated by drug distributors who filled their more lucrative commercial orders instead. (The federal government, incidentally, claims this is illegal.)

And because people have no choice but to buy from these black market suppliers,

Members of the Premier healthcare alliance **[people] report paying “[black] market” prices as much as 335 percent [higher]** above the approved rate. A recent Kaiser Daily Health Policy Report highlighted how “the chain of custody in the gray market may pass from one distributor to another, creating a string of transactions that lead to higher prices and drug integrity concerns.”

**The impact of shortages is long term, since**

##### [Professor Ridley](https://sci-hub.tw/10.1377/hlthaff.2015.0420) continues

##### Vaccine shortages peaked at seven in 2007, and only two were reported in 2013 (Exhibit 1). For the twenty-four vaccine-year shortages during the study period, the distribution of reasons for them was as follows: manufacturing, 13; raw materials, 2; supply or demand, 2; and unknown, 7. We saw little evidence of the number of doses rising during shortages, which indicates supply rather than demand shocks. Often the number of doses fell much more for vaccines that had shortages than for those that did not. The average length of a shortage was 510 days, with a minimum length of 88 days. In any given year in the study period, the average vaccine in our sample had a 10 percent probability of a shortage, a price per dose of $50, and two manufacturers (Exhibit 2).

**Don’t let patients die from a lack of medicine, negate.**

####

### Innovation Cards

**Problematically, Americans would suffer in a world with higher prices.**

[Beasley](https://www.insurancejournal.com/news/national/2018/06/22/493065.htm) 18

Dr. Atul Gawande, a surgeon who was named this week to head the company being formed by Amazon, Berkshire Hathaway and JPMorgan Chase to trim employee healthcare costs, on Thursday cited **surgery, [not drug costs], is the single biggest U.S. healthcare cost** and said there are ways to both cut costs and improve patient care.

**Which too many patients cannot afford.**

#### The Second Impact is a global cure

[Ryan Huber Arc Digital 17](https://arcdigital.media/u-s-health-care-reality-check-1-pharmaceutical-innovation-574241fb80ba)

o **the United States produces the most novel****and** **cutting edge [medicines]** therapeutic compounds despite the most expensive and stringent approval process **and sells them to other countries at much lower [subsidized] prices than we do at home**. In doing this, we are indeed subsidizing research and development of drugs and medical devices for the rest of the world. This subsidized medical innovation is a major contributing factor to the out-of-control health care costs in the United States, and losing this innovation will be one of the sacrifices we make if we move toward a more cost-controlled or government.

**Because innovative American drugs diffuse across the world,**

#### The global poor will be hit the hardest by the loss of our low-cost drug exports

[Anna Rees citing the World Health Organization 15](https://en.reset.org/knowledge/diseases-and-links-poverty)

**[That the 1.2 billion people that live in extreme poverty will suffer the most from infectious disease because they don’t have proper medical care.]**

**Poverty and disease are** stuck **in a**n ongoing, vicious relationship**. One goes a long way towards intensifying the other with studies demonstrating that infection rates of certain diseases are highest** in regions **where poverty is rife**.

According to the World Bank, an estimated **1.2 billion live in extreme poverty** (defined as those who live on less than 1,25 USD per day) **worldwide. Running parallel to statistics about global poverty are statistics about infectious diseases**. Terms such as “neglected tropical diseases” and “infectious diseases of poverty” are employed to define a number of infectious diseases more commonly found in areas where poverty is high. This list includes widely recognised diseases such as HIV/AIDS, malaria and tuberculosis as well as lesser-known ailments such as dengue, chagas disease and foodborne trematode infections. **The relationship between poverty and diseases is** emphatically intertwined however we paint with too broad a brush when we generalise that infection rates go down as poverty declines. This trend is not a given and spikes in infection rates do occur when disastrous events take place such as natural disasters or the outbreak of conflict.

The Chicken and the Egg A common train of thought is that poverty is a driving force behind poor health and disease. While certainly not disputable, that fact reflects only one side of the argument and does not take into account the nuanced links between poverty and health. The fact of the matter is that the relationship between poverty and health is inextricably linked, presenting a chicken-an-egg situation **where one seemingly exists**, in part, **because of the other**.The Global Report for Research on Infectious Diseases of Poverty (put together by the European Commission, the World Health Organization and TDR) offers a clear rationale of this relationship “**Poverty creates conditions that favour** the **spread of** infectious **diseases and prevents affected populations from obtaining adequate access to prevention and care.** Ultimately**, these diseases...disproportionately affect people** living **in** poor or marginalised communities. Social, economic and biological factors interact to drive a vicious cycle of poverty and disease from which, for many people, there is no escape.”

https://**itif**.org/publications/2017/05/30/pharmaceutical-innovation-accounted-73-percent-increase-life-expectancy-30

Fact of the Week: **Pharmaceutical Innovation Accounted for 73 Percent of the Increase in Life Expectancy in 30 Developing and Developed Countries From 2000 to 2009**

### Shortages

##### [Ridley Continues that](https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0420)

##### 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

[~~Mackenzie Bean 2018 Becker’s Hospital Review~~](https://www.beckershospitalreview.com/supply-chain/5-factors-driving-drug-shortages.html)

~~1. Market withdrawals. Drug companies said market~~**~~withdrawals~~~~, which~~ ~~reduce the amount of manufacturers supplying a drug, [and] play a role in shortages~~**~~.~~ ~~They listed a number of reasons manufacturers exit a market, including quality issues, introduction of placement drugs on the market and company decisions to realign a portfolio or focus on other products.~~

#### Third is by removing buffers

Manufacturers usually keep a stockpile of excess supply to protect against sudden changes in demand - leading to a

[Morton, 2015](http://faculty.som.yale.edu/sangkim/DrugShortage.pdf) (PG)

This Önding points to a possible explanation for the sudden rise of the current drug shortages. Prior to the onset of shortages, high drug availability may have been supported by the investments in production capacities rather than investments in improving reliability of their manufacturing facilities. That is, large disruption risks may have been hidden under the capacity bu§ers that prevented shortages. Our model predicts that, in such situations, **a substantial reduction in price** (or an increase in 23 capacity holding cost) **can trigger a precipitous drop in availability as the firms react to this change by quickly removing the inflated capacity buffers that concealed large disruption risks.** Reports indicate that the generic sterile injectable drug industry had experienced signiÖcant price pressure and product proliferations in a short period of time leading up to the onset of current shortages, while the aging facilities had received few upgrades. According to our model, these are the ingredients for a ìperfect stormî of sudden shortages

[Morton Yale](https://www.ftc.gov/system/files/documents/public_comments/2017/12/00508-142616.pdf)

Price declines, e.g. due to the expiration of patent protection, may cause firms to remove capacity buffers, making shortages more widespread

#### ~~Fourth is increasing lobbying efforts~~

[~~Kohler 2016~~](https://www.transparency.org.uk/wp-content/plugins/download-attachments/includes/download.php?id=5375)

**~~Pharmaceutical companies can unduly influence national political systems through their large spending power~~**~~.~~ ~~Pharmaceutical companies often fund candidates that support their position on key issues. Outside of elections, the~~ **~~pharmaceutical industry spends vast sums of money lobbying.~~**~~Estimates suggest that in 2009 the industry association Pharmaceutical Research and Manufacturers of America (PhRMA), as well as one of the member companies Pfizer, each spent over US$25 million.137~~ **~~Such funding can shape policy debates to favour a pharmaceutical company’s profit maximisation priorities and negatively impact public health objectives~~**

Higher drug prices prevent these shortages

[Eli Liebman Duke University](https://sci-hub.tw/10.1377/hlthaff.2015.0420)

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 [decrease]increase in prices was associated with a nearly 1 percent [increase]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.

[~~Kathryn Nix, 2011~~](https://www.heritage.org/health-care-reform/report/how-medicare-price-controls-have-contributed-drug-shortages) ~~(PG)~~

**The current “cost-plus” Medicare drug pricing scheme has controlled costs, but due to the system’s conflicting incentives, many manufacturers have stopped making low-cost, generic injectable drugs rather than increase their prices. Treatments are delayed as patients are put on waiting lists, and physicians must pursue alternative treatment options with which they are less familiar, increasing the risk of mistakes. Health care spending increases when doctors have to substitute more expensive drugs or patients’ illnesses worsen due to delayed care. Another consequence of drug shortages is the emergence of a gray market, defined as “a supply channel that is unofficial, unauthorized, or unintended by the original manufacturer.”[7] When providers cannot purchase a scarce drug from standard suppliers, they look elsewhere.** According to the Department of Health and Human Services (HHS), the problem occurs when secondary distributors purchase drugs from end users and then re-sell them to other end users.[8] **Drugs supplied on the gray market may be stolen or counterfeit, and their cost is exorbitantly higher. The Premier Healthcare Alliance, which includes more than 2,500 hospitals, reported an average markup of 650 percent, but the most significant markups were as high as 4,533 percent. The disruption to the normal distribution process has increased concerns that patients will receive drugs that have been improperly stored and handled. This can cause treatments to lose their efficacy, threatening patient safety in addition to raising costs.**

#### ~~The third impact is drug discontinuities~~

####

~~Janet~~ [~~Woodcock Center for Drug Evaluation~~](http://sci-hub.tw/https%3A//doi.org/10.1038/clpt.2012.220)

**~~[9% of shortages in 2011 resulted in product discontinuation since companies try to optimize profitability. Firms have even discontinued medically necessary products]~~**

~~Some~~ **~~firms have discontinued~~** ~~older,~~ **~~medically necessary products. Product discontinuations, which accounted for 9% of sterile-injectable shortages in 2011, are often triggered by capacity constraints, many of them brought about by quality-related production line disruptions.~~** ~~Economic theory suggests that companies would generally consider a product to be worth producing if the revenue it generates can cover the costs of production. This production rule no longer holds true when the~~ **~~firm~~**~~reaches production capacity and managers are forced to make trade-offs among products, exposing products~~ **~~with low–average revenue for potential cuts as companies try to optimize profitability of their production lineup~~**~~.~~ ~~Such pressures could be contributing to the discontinuations we observe~~

[Mclaughin](https://www.ncbi.nlm.nih.gov/pubmed/24156647)

The survey was sent to 1,516 directors of pharmacy. There were 193 respondents (response rate 13%) who participated in the survey. Approximately 40% of respondents reported between 1 and 5 adverse events probably or possibly associated with drug shortages at their institution. The majority of respondents reported between 1 and 10 medication errors. The most common types of medication errors reported were omission (n = 86, 55.5%), wrong dose dispensed/administered (n = 85, 54.8%), and wrong drug dispensed/administered (n = 54, 34.8%). T**he most common outcomes reported by respondents were alternative medication used (n=146, 85.3%), delay of therapy (n = 121, 70.8%), and increased patient monitoring necessary (n = 84, 49.1%).** Patient complaints were reported by 38% of respondents. The majority of respondents reported an estimated quarterly institutional cost from shortages of less than $100,000, and approximately one quarter of respondents reported adding at least 1 full-time equivalent to manage drug shortages. The majority of participant comments mentioned the increasing institutional costs attributed to drug shortages.Medication errors and adverse events continue to occur from drug shortages, often resulting in inadequate patient care, high institutional costs, and patient complaints. Delayed care and cancelled care have been reported from shortages. Further research is necessary to better classify medication errors and adverse events during a drug shortage.

## Extra Evidence

### Cards Removed from case

[Frank Lichtenberg Columbia University](https://www0.gsb.columbia.edu/faculty/flichtenberg/schump.pdf)

We then perform an econometric investigation of the contribution of pharmaceutical innovation to mortality reduction and growth in lifetime per capita income. In both of the periods studied (1970-80 and 1980-91), there is a highly significant positive relationship across diseases between the increase in mean age at death (which is closely related to life expectancy) and rates of introduction of new, “priority” (as defined by the FDA) drugs. The estimates imply that in the absence of pharmaceutical innovation, there would have been no increase and perhaps even a small decrease in mean age at death, and that new drugs have increased life expectancy, and lifetime income, by about 0.75-1.0% per annum. The drug innovation measures are also strongly positively related to the reduction in life-years lost in both periods. **Some of the more conservative estimates imply that a one-time R&D expenditure of about [just] $15 billion [in R&D funding] subsequently saves 1.6 million [combined years of life] each year,** whose annual value is about $27 billion. All age groups benefited from the arrival of new drugs in at least one of the two periods. Controlling for growth in inpatient and ambulatory care utilization either has no effect on the drug coefficient or significantly increases it.

### Innovation

<https://www.ncbi.nlm.nih.gov/pubmed/18634121> [Lichtenberg FR](https://www.ncbi.nlm.nih.gov/pubmed/?term=Lichtenberg%20FR%5BAuthor%5D&cauthor=true&cauthor_uid=18634121)1. 2009

Every $24 spent on new medicines for cardiovascular diseases in OECD countries saves $89 in hospitalization costs.22

This study examines the effect of changes in the vintage distribution of cardiovascular system drugs on hospitalization and mortality due to cardiovascular disease using longitudinal country-level data. The vintage of a drug is the first year in which it was marketed anywhere in the world. We use annual data on the utilization of over 1100 cardiovascular drugs (active ingredients) in 20 OECD countries during the period 1995-2003. Countries with larger increases in the share of cardiovascular drug doses that contained post-1995 ingredients had smaller increases in the cardiovascular disease hospital discharge rate, controlling for the quantity of cardiovascular medications consumed per person, the use of other medical innovations (computed tomography scanners and magnetic resonance imaging units), potential risk factors (average consumption of calories, tobacco, and alcohol), and demographic variables (population size and age structure, income, and educational attainment). The estimates also indicate that the use of newer cardiovascular drugs has reduced the average length of stay and the age-adjusted cardiovascular mortality rate, but not the number of potential years of life lost due to cardiovascular disease before age 70 per 100,000 population. The estimates indicate that if drug vintage had not increased during 1995-2004, hospitalization and mortality would have been higher in 2004. We estimate that per capita expenditure on cardiovascular hospital stays would have been 70% ($89) higher in 2004 had drug vintage not increased during 1995-2004. Per capita expenditure on cardiovascular drugs would have been lower in 2004 had drug vintage not increased during 1995-2004. However, our estimate of the increase in expenditure on cardiovascular hospital stays is about 3.7 times as large as our estimate of the reduction in per capita expenditure for cardiovascular drugs that would have occurred ($24).

https://www.brookings.edu/research/the-global-burden-of-medical-innovation/

Increasing European prices by 20 percent— just part of the total gap — would result in substantially more drug discovery worldwide, assuming that the marginal impact of additional investments is constant. These new drugs lead to higher quality and longer lives that benefit everyone. After accounting for the value of these health gains — and netting out the extra spending — such a European price increase would lead to $10 trillion in welfare gains for Americans over the next 50 years. But Europeans would also be better off in the long run, by $7.5 trillion, weighted towards future generations.[14 ]This is because European populations are rapidly aging, and they need new drugs too. For example, if the burden of dementia in Europe is as high as it is in the U.S., its social costs could be $1 trillion annually. If higher prices in Europe spurred just a few innovators to develop effective dementia treatments, the added costs could easily be justified. In other words, low prices in Europe not only hurt Americans, they hurt Europeans.[18,19]

https://www.nber.org/papers/w18235.pdf

#### The estimates indicate that the increase in life expectancy at birth due to the increase in the fraction of drugs consumed that were launched after 1990 was 1.27 years—73% of the actual increase in life expectancy at birth.

[Lori Ioannou, March 2018,](https://www.cnbc.com/2018/03/26/big-pharmas-scramble-to-invest-in-start-ups-to-fuel-innovation.html)

New approaches to combat antimicrobial resistance urgently need to be developed. Already, more than 700,000 people die each year from infections resistant to most or all antibiotics, and the number is increasing by the day. Antimicrobial resistance is projected to kill more people than cancer by 2050, which would reduce global economic output by between 2 percent and 3.5 percent and severely cripple modern medical and surgical advances.

A 2009 study in Health Affairs calculated that as a result of fewer innovative pharmaceuticals being developed, average American life expectancy in 2060 would be around 2 years lower than it would otherwise have been.

#### Pharma R&D key to medical nanotech breakthroughs

**White et al ’17** (Mark White, Tom Nassim, Jeff Carbeck, Asif Dhar, Delloite University Press, “Exponentials watch list: Science and technology innovations on the horizon”, <https://dupress.deloitte.com/dup-us-en/focus/tech-trends/2017/exponential-technology-digital-innovation.html>, February 7, 2017)

**How long before you need to consider how to incorporate nanotechnologies, energy systems, biotechnology, and quantum technologies into the business? Not long: Though these emerging forces may be distant on the horizon, they’ll disrupt industries, strategies, and business models soon enough. Though business applications for nanotechnologies, energy systems, biotechnology, and quantum technologies may seem light-years away, in reality they are approaching rapidly**. **In the next three to five years, expect to see business use cases emerge and pioneering deployments accelerate around these once-futuristic technologies. With this in mind, increasing numbers of CIOs, CTOs, and business strategists are already taking exploratory steps with these and other exponential technologies. They are sensing and scanning disruptive forces and putting in place deliberate, disciplined innovation responses. These leaders understand that waiting for exponentials to manifest as mature technology trends before taking action may be waiting too long**.Show more Unlike other trends examined in this report that demonstrate clear business impact in the next 18 to 24 months, the exponentials we are discussing appear a bit smaller on the horizon. **These are emerging technology forces that will likely manifest in a horizon 3 to 5 timeframe—between 24 and 60 months. But when they manifest, the speed with which they impact markets will likely grow exponentially.**

#### Nanotech research key to prevent superbugs- prevents extinction- absent nanotech innovation the aff *magnifies* the risk of antimicrobial resistance diseases- turns solvency

**Lo ’14** (Chris Lo, NRI Digital, “Nanotech takes on antimicrobial resistance”, <http://www.pharmaceutical-technology.com/features/featurenanotech-takes-on-antimicrobial-resistance-4447494/>, November 24, 2014)

**Antibiotic resistance is one of the greatest global health threats of the 21st century, but nanotechnology is offering new solutions to the problem. From detection and diagnosis to alternative antimicrobial treatments, nanotech-driven innovations are tapping the world of the tiny to prepare for the possibility of a post-antibiotic era. There are few threats to global health more serious than antimicrobial resistance (AMR). Given that antibiotics represent one of the core pillars of modern medicine, at present there is no easy answer to the threat of dangerous microorganisms developing resistance to antibiotic treatment. Antibiotics, through their long-term over-prescription and the ease with which multi-drug resistant (MDR) pathogens are spreading through our interconnected world, have shifted from the revolutionary cure of the 20th century to the looming health crisis of the 21st. World Health Organization (WHO) director-general Dr Margaret Chan left none in doubt as to the gravity of the situation in a 2012 speech at an AMR conference in Denmark. "Hospitals have become hotbeds for highly-resistant pathogens, like MRSA, ESBL and CPE, increasing the risk that hospitalisation kills instead of cures," Chan said. "These are end-of-the-road pathogens that are resistant to last-line antimicrobials...A post-antibiotic era means, in effect, an end to modern medicine as we know it. Things as common as strep throat or a child's scratched knee could once again kill." Chan's vision borders on the apocalyptic, but the growing list of disease-causing microbes that are antibiotic-resistant does raise the worrying prospect of potentially deadly conditions like tuberculosis, E. coli infections and superbugs like MRSA running rampant with little medical recourse**. Already, the conventional tackling of drug-resistant bugs requires costly and time-consuming treatment, often with a combination of drugs, causing many more side effects for a clinical outcome that remains uncertain. Pharma companies, meanwhile, have few incentives to invest in developing new antibiotics as over-use could render them ineffective before their R&D costs have been recouped, meaning the pipeline for new antibiotics has dwindled to a mere trickle. As the medical world drifts ever closer to Chan's 'post-antibiotic' vision, university labs and other research organisations are responding to the problem by thinking outside the box, and it is becoming clear that nanotechnology - already a highly promising research area in fields such as drug delivery and medical imaging - has much value to add to the fight against AMR. A new weapon: nanotech vs. AMR In the UK nanotechnology features prominently in a new 'war cabinet' formed in July 2014 to help tackle AMR. The initiative, which brings together all seven of the UK's research councils for the first time, echoes other proactive projects in the EU and around the world by seeking to attack the problem from multiple fronts. "This is about tackling the problem at every level and in every environment," said Medical Research Council chief executive Sir John Savill. Can honey help in the fight against antibiotic resistance? New research indicates that honey may have a role in the fight against bacterial resistance to antibiotics. The Engineering and Physical Sciences Research Council's contribution to the programme is being run by Professor Rachel McKendry of the London Centre for Nanotechnology (LCN). McKendry's research is leveraging nanotechnology, big data and other elements of maths, physics and engineering to gain new insights into AMR, including the antibiotic vancomycin and the effectiveness of drug binding to weaken and kill bacterial cells. More widely, three of the 15 AMR research projects being funded under the EU's Seventh Framework Programme aim to bring nanotech to bear against drug-resistant bacteria. The projects include FORMAMP, which is investigating nanoformulation of antimicrobial peptides (AMPs) - molecules that are part of the natural host immune system and could become potent antibiotic agents - to maximise stability and efficacy. Detection and diagnostics While many nanotech research strands are dedicated to finding alternatives or complements to antibiotic treatments, other projects are contributing to the fight against AMR by developing new methods to detect and track antibiotic resistance in bacteria. Faster and more effective detection and diagnosis of drug-resistant infections is important because giving a patient access to the correct treatment earlier can have a major influence on the clinical outcome, not to mention continued transmission of the infection. At the Methodist Hospital Research Institute in Houston, Texas, researchers have developed a nanotech-driven approach to detecting multi-drug resistant tuberculosis (MDR-TB). MDR-TB is one of the most dangerous drug-resistant infections, with treatments fraught with side effects and lasting up to two years, but with a shockingly low success rate of just over 50%. By using wafers of elastic silicone polymers dotted with thousands of microscopic wells that isolate Mycobacterium tuberculosis cells, the researchers have been able to streamline the TB diagnosis process, and the ability to simultaneously detect the bacterial antibodies means TB and drug resistance can be assessed in the same test, rather than the separate test required to detect resistance using culture methods, which can take weeks. "Polymer molecules attack the bacterial cells physically rather than chemically." In Lausanne, a team led by Giovanni Longo have made use of atomic force microscopy cantilevers - tiny silicon beams with tips measuring in the nanometres - to assess bacterial susceptibility or resistance to antibiotics by measuring microscopic fluctuations in cantilevers coated with bacteria in response to various stimuli. "The work of Longo and colleagues provides renewed hope for the development of rapid diagnostics to improve the use of antibiotics and preserve their effectiveness for future generations," wrote LCN's Rachel McKendry in an article about the research. **Nanotech-enabled treatment As important as nanotechnology's role in the detection of antibiotic-resistant infections undoubtedly is, the new treatment options it's bringing to the table are generating more excitement as a host of new possible treatments for drug-resistant pathogens begin to emerge.** Nanotechnology is not only being envisioned as a replacement for antibiotic treatments, however. As McKendry noted, nanotechnology also holds the potential to preserve and extend the effectiveness of existing antibiotics, primarily by acting as an enhanced drug delivery system to unleash a large and sustained payload of antibiotics to harmful bacteria in a more selective way. Nanotech advancements have been indicated for use in targeted cancer treatments for a while now, but their application as vehicles for antibiotic delivery is relatively new. **Researchers at the Massachusetts Institute of Technology (MIT) and nearby Brigham and Women's Hospital have developed nanoparticles made of polymer capped with polyethylene glycol, which can evade the body's immune system before delivering antibiotics - vancomycin, in this case - directly to the infection site, activated by the slightly acidic environment surrounding bacteria. Like targeted cancer therapies, the dose delivered is high and extended to ensure maximum damage.** "You don't want just a short burst of drug, because bacteria can recover once the drug is gone," said MIT researcher Aleks Radovic-Moreno. "You want an extended release of drug so that bacteria are constantly being hit with high quantities of drug until they've been eradicated." HuTrial - human surrogates for clinical trials becomes a reality Crown Bioscience have unveiled a new human surrogate trial platform, HuTrial, which functions as a low-cost substitute for a phase-II trial. **Beyond boosting existing antibiotics, nanotech innovations have revealed a number of possible replacement therapies. These include the use of metal and metallic oxide nanoparticles, especially silver nanoparticles, which have been shown in several studies to be effective against antibiotic-resistant bacteria like MRSA, ampicillin-resistant E. coli and MRSE. Knocking down walls IBM Research and its nanotechnology partner, Singapore's Institute of Bioengineering and Nanotechnology, have been making great strides in creating novel nanostructures that are effective at targeting and destroying disease-causing bacteria.** But unlike antibiotics, the team's polymer molecules attack the bacterial cells physically rather than chemically, ripping open the cell wall and membrane so the cell breaks down. This offers no chance for the bacteria to formulate a resistance. The nanostructures could be injected into the body to target conditions like MDR-TB, or - thanks to a breakthrough announced in 2013 - applied directly to the skin as a hydrogel to disinfect wounds and treat skin infections. "We're not going in like antibiotics and trying to do a chemistry function; we're just going in and destabilising," IBM Research advanced organic materials scientist told Co.Exist in 2012. "Even some of the microbes that have more robust cell walls, we're starting to be able to knock down." **It's this kind of nanotech-driven innovation that brings hope for the future of antimicrobial treatment. Nanotechnology has demonstrated the potential to help detect AMR faster, enhance and extend the effectiveness of existing antibiotics and offer alternative treatments when antibiotics fail. Nanotech researchers might be operating in the world of the miniscule, but it appears the possibilities stemming from their work are anything but.**

Drug resistant infections will kill 10 million people every year- that’s one person every three seconds

O’Neill 16 (Jim, former Principal Associate Deputy Secretary of the U.S. Department of Health and Human Services, “Tackling Drug-Resistant Infections Globally: Final Report and Recommendations,” Review on Antimicrobial Resistance, May 2016, [https://amr-review.org/sites/default/files/160525\_Final%20paper\_with%20cover.pdf)](https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf%29)

Based on scenarios of rising drug resistance for six pathogens to 2050, we estimated that unless action is taken, **the burden of deaths from AMR could balloon to 10 million lives each year by 2050, at a cumulative cost to global economic output of 100 trillion USD.** On this basis, by 2050, **the death toll could be a staggering one person every three seconds** and each person in the world today will be more than 10,000 USD worse off8. It is impossible to predict the path of emerging drug resistance, but it is a trend that has largely run only in one direction so far. What we can be certain of is that, in the absence of interventions to slow the emergence of resistance, and increase the supply of new antibiotics, the impacts will be felt not just in isolated areas but at a far more fundamental level, across our societies and healthcare systems. **As the antibiotics available to us become less effective, so the risks of many treatments which rely upon antibiotics becomes higher.** This will progressively undermine the viability of interventions that many may not directly associate with antibiotics. Cancer chemotherapy or organ transplantation are just two examples of medical treatments that leave the patient highly vulnerable to bacterial infections. Most invasive surgery (particularly ‘dirty’ procedures, such as those involving the gut) is today routinely and dependably ‘de-risked’ by effective antibiotic prophylaxis and by the availability of reliable therapy for infections that do occur despite best practices. Intubated patients in intensive care facilities already experience very high rates of infection, including drug-resistant ones, as a result of the ventilation that they receive – and the mortality risk associated with this will rise further if treatment options for such infections deplete. These secondary impacts are difficult to quantify but they threaten to dramatically change healthcare as we know it today

Innovation is key to developing treatment for antibiotic resistant diseases

Shore 17 (Carolyn, Director of the Forum on Drug Discovery, Development, and Translation at the National Academies of Sciences, Engineering, and Medicine, “Deadly Superbug Resistant to All Antibiotics in U.S. Highlights Need for Innovation,” Pew Charitable Trusts, February 2, 2017, [http://www.pewtrusts.org/en/research-and-analysis/analysis/2017/02/02/superbug-resistant-to-all-drugs-causes-death-highlighting-need-for-antibiotic-innovation)](http://www.pewtrusts.org/en/research-and-analysis/analysis/2017/02/02/superbug-resistant-to-all-drugs-causes-death-highlighting-need-for-antibiotic-innovation%29)

The recent death of a patient in Nevada is a stark reminder of what a post-antibiotic era could look like, and why there is no time to waste in finding new drugs. An elderly woman who first contracted a bone infection while in India later died from the disease, which was caused by carbapenem-resistant Enterobacteriaceae (CRE)—bacteria that are resistant to a type of antibiotic that is used when other drugs fail. Indeed, the Centers for Disease Control and Prevention subsequently confirmed that the bacteria which caused this deadly infection were resistant to all 26 antibiotics available in the United States.

Globally, there is an urgent need for new antibiotics. The more these drugs are used, the less effective they become as bacteria develop resistance to them. Yet despite the urgency, far too few antibiotics are currently in the drug development pipeline. Of these, only a handful of products have the potential to treat infections caused by CRE.