**We negate**

**Resolved:** The United States federal government should impose price controls on the pharmaceutical industry

**Our First Contention is Nothing Comes Free (R&D)**

Restricting prices on pharmaceutical companies will undoubtedly hurt their bottom line which causes budget cuts in very important aspects of the business. **The National Bureau of Economic Research writes[[1]](#endnote-1)** that a cut in prices will lead to a 30 to 60 percent decrease in research in development projects and would hurt the patients in the long term. In fact, **Raj writes[[2]](#endnote-2)** that companies historically cut research and development spending whenever their revenues drop. **The IFPMA concluded[[3]](#endnote-3)** that this research investment goes to creating medical breakthroughs and medicines that save millions of lives and render previously life-threatening diseases to nothing but a simple cold. **The American Council on Science and Health explains[[4]](#endnote-4)** that patents and high prices are the main drivers in medical research and innovation incentives. If we remove the incentive for innovation, we are bound to see a decrease in R&D. However, continued and increased development of new treatment through innovation is key to combatting and decreasing the mortality rate of numerous diseases, specifically those without current effective treatment.

**The impact of decreasing R&D is 2-fold**

**First, is general innovation**

**Greenwood** finds that pharmaceutical development was the key factor in the 22% decrease in cancer mortality over the last 2 decades and each year innovative biomedicine saves over 40,000 lives. Unfortunately, **Filson[[5]](#endnote-5)** concludes that if the US were to adopt price controls, drug research would plummet and the flow of new drugs would decrease by 75% over the next decade. Critically, **Lichtenberg[[6]](#endnote-6)** finds that every $15 billion invested into R&D saves 1.6 million life-years, and hundreds of thousands of lives due to increased drug innovation which is decimated with price controls.

**Second, is developing countries**

**The IFPMA reports[[7]](#endnote-7)** that pharmaceutical companies are one of the top investors of curing neglected tropical diseases. **The FPMA furthers** that these projects have increased in frequency and they plan to release 18 different treatments by 2023. In fact, 6 of these treatments are available already. **Mello[[8]](#footnote-1) of the Stanford Law School** **writes** that because of the high prices in America, companies are willing to sell drugs at a lower cost in developing nations. Thus, **Ford[[9]](#footnote-2) quantifies** that prices of drugs are 5% of the price in America, giving access to medicine for millions in the developing world. Unfortunately, **Mello concludes** that price controls, by significantly cutting profits for companies in America, would force companies to hike prices elsewhere, preventing people from getting necessary treatment. This outweighs the entirety of their case on scope because even if you make drugs more affordable for Americans you make drugs inaccessible for the rest of the world, specifically those in developing countries already suffering from horrid living conditions. **The World Health Organization concludes[[10]](#endnote-8)** that these neglected tropical diseases have killed half a million people and over a billion people are at risk of catching one of the diseases.

**Our Second Contention is Drug Shortages**

**Winegarden[[11]](#endnote-9) explains in 2018** that generic companies operate in a competitive, low profit environment and they are very sensitive to price disruptions. Unfortunately, **Sood[[12]](#endnote-10) of the National Institute for Health** **explains** that price controls would significantly reduce profits for pharmaceutical companies. **Gottlieb[[13]](#endnote-11) of the Wallstreet Journal** **explains** that by capping a company’s ability to increase prices, price controls hamper generic manufacturers ability to maneuver through changes in the market, severely harming their financial viability. Problematically, these small profit companies, require higher prices to meet poor economic conditions, and if they cannot do so, companies will likely just exit the market and cut their losses. Dangerously, **PolicyMed[[14]](#endnote-12) finds** that company exits create shortages for the drugs they manufacture, as the number of drugs entering the market diminishes significantly. Empirically, **Milmo[[15]](#endnote-13) explains** that Europe has and is experiencing massive shortages in its markets, specifically in Romania and Portugal where over 2000 generic drugs have exited the market, due to the regions price controls.

**The impact of drug shortages is harming drug accessibility**

**ISMP[[16]](#endnote-14) finds** that in time of drug shortages, 94% of healthcare providers ration and restrict medication. Thus **Jungman[[17]](#endnote-15) of PEW** **explains** that drug shortages can be fatal for those who need them most and that’s why, **Spiegel[[18]](#endnote-16)** finds that delays and shortages created by price controls, lead to 600,000 deaths in Europe each year.

**Thus,**

**We urge you to Negate**

1. Thomas A. **Abbott** John A **Vernon**, **2015** , "To Lower Drug Prices, Innovate, Don't Regulate," **National Bureau of Economic Research**, <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/to-lower-drug-prices-innovate-dont-regulate>

Previous empirical studies that have examined the links between pharmaceutical price controls, profits, cash flows, and investment in research and development **(R&D) have been largely based on retrospective statistical analyses of firm- and/or industry-level data**. These studies, which have contributed numerous insights and findings to the literature, relied upon ad hoc reduced-form model specifications. In the current paper we take a very different approach: a prospective micro-simulation approach. Using MonteCarlo techniques we model how future price controls in the U.S. will impact early-stage product development decisions in the pharmaceutical industry. This is done within the context of a net present value (NPV)framework that appropriately reflects the uncertainty associated with R&D project technical success, development costs, and future revenues. Using partial information estimators calibrated with the most contemporary clinical and economic data available, we demonstrate how pharmaceutical **price controls will significantly diminish the incentives to undertake early-stage R&D investment.** For example, we estimate that **cutting prices by 40 to 50 percent in the U.S. will lead to between 30 to 60 percent fewer R&D projects being undertaken (in early-stage development).** Given the recent legislative efforts to control prescription drug prices in the U.S., and the likelihood that price controls will prevail as a result, it is important to better understand the firm response to such a regulatory change. [↑](#endnote-ref-1)
2. **Raj of Multimedia University** <https://www.researchgate.net/publication/272477050_A_study_of_decrease_in_RD_spending_in_the_pharmaceutical_industry_during_post-recession>

The subprime crisis of 2007, which snowballed into a full blown recession in 2008, was the worst economic crisis since the Great depression (Richard 2009) in 1930. The so-called “Great Recession” has impacted almost every industry and those affected are still in recovery mode even after three years. Medicines are essential to humans and mankind will need healthcare regardless of how short of cash they are. Once regarded as a “recession-proof” industry (Wendy), pharmaceutical and biotech companies today are grappling with intense pressure to sustain the growth they had in pre-recession times. According to IMS Health, the global pharmaceutical market growth will be restricted to the mid-single digits (5-8%) by 2014 (Gary 2010). Lately, pharmaceutical companies have witnessed a variety of layoffs, cutbacks, and other restructuring efforts aimed at cost-cutting within the industry (Christe 2010). It is no secret that major pharmaceutical companies are no longer investing in internal drug discovery initiatives as much as they have in the past (Lisa 2010). With Pharma industry falling off, the associated clinical research and contract research organizations (CROs) are battling for their survival. Technical analysis data published in June 2011 (John 2011) indicate that the contract research organizations are far from recovered in terms of their finances. A sector which needs 10 to 15 years to bring a new product to market readiness should think, plan, and act in view of longer-term objectives. Traditionally, research-driven pharmaceuticals have been spending ~12-18% of their profits in research and development and the same was observed until 2007. However, the data released by Evaluate pharma in 2011 (Fig 2) on the R&D spending by pharmaceuticals is alarmingly low at 1-2% and there is no “feel good factor” in the forecast either. Does that mean “Global recession 2008” has impacted the $850-billion-a year pharmaceutical industry? What are the reasons that led the pharma giants to hand over tens of thousands of pink slips to their employees in the last three years? And will it recover once the recession is over? Or is it something else that is troubling the pharmaceutical industry and leading to the decline in pharmaceutical fortunes? The latter is the topic of the present study [↑](#endnote-ref-2)
3. <https://www.ifpma.org/wp-content/uploads/2017/02/IFPMA-Facts-And-Figures-2017.pdf>

**Pharmaceutical R&D has dramatically improved the lives of patients.** **Medical discoveries, big and small, have increased life expectancy and resulted in a better quality of life for many. Vaccines have proven to be one of the most effective preventative technologies in the fight against infectious diseases** with an almost unparalleled impact on public health, including, but by no means limited to, ridding the world of smallpox, driving polio to the brink of eradication, and virtually eliminated measles, diphtheria and rubella in many parts of the world. **Currently, vaccines save the lives of over 2.5 million children each year. Between 2000 and 2014, immunization campaigns cut the number of deaths caused by measles by 79%**  [↑](#endnote-ref-3)
4. <https://www.acsh.org/news/2018/06/23/government-big-reason-epipen-and-other-generics-are-so-expensive-13114>

**High prices for medications are nothing new. They are often expected, given the role of the patent system in fostering innovation in the pharmaceutical industry. Thomas Edison knew the value of patents. He held more than 1,000 in his name. From www.shutterstock.com Patents create incentives for persons to innovate by giving them a limited period of exclusivity, currently from the date the patent issues until 20 years after its application date.** During the patent’s term, the owner can stop others from making, using or selling the patented invention. Without this period of exclusivity, companies would have little incentive to engage in research and development. Pharmaceutical research and regulatory approval is a costly endeavor. The average cost to bring a drug to market is $2.6 billion, according to the Tufts Center for the Study of Drug Development. [↑](#endnote-ref-4)
5. Darren Filson, Feb 27 2007. Claremont Graduate University. “The Impact of Price Controls on the Performance of the Pharmaceutical Industry” http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.377.7990&rep=rep1&type=pdf

**What happens if the U.S. adopts price controls like those in the rest of the world? Firms reduce research substantially, and in the long run, the flow of new drugs falls by approximately 75%. Industry firm value falls approximately 80%**. The full impact takes over a decade to occur, because most late-stage candidates in the pipeline remain profitable under the policy change. The option to pursue a late-stage candidate is usually well “in the money” because many hurdles have been overcome, many R&D costs are sunk, and the prospect of obtaining profits is more near**. Consumer welfare in the U.S. rises for the first twelve years and falls thereafter. Lower prices yield short run benefits, but the harmful effect of the reduced flow of new drugs outweighs the price effect in the long run.** The net present value (NPV) of consumer welfare falls in the U.S. and in the rest of the world by over $13 trillion year 2000 dollars. In the current environment, the prospect of high U.S. profits encourages innovation that consumers everywhere benefit from. [↑](#endnote-ref-5)
6. Frank R. Lichtenberg, Fda), xx-xx-xxxx, "Pharmaceutical Innovation, Mortality Reduction, and Economic Growth," NBER, http://www.nber.org/papers/w6569

We 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 $15 billion subsequently saves 1.6 million life-years per 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. [↑](#endnote-ref-6)
7. <https://www.ifpma.org/wp-content/uploads/2017/02/IFPMA-Facts-And-Figures-2017.pdf>

**The World Health Organization (WHO) has identified 17 neglected tropical diseases (NTDs), which form a significant part of the global disease burden and affect the lives of more than 1 billion people**47. Some **NTDs can have lifelong consequences for individuals.** Others lead to acute infections that can be fatal. These diseases – whose names are not commonly known – include Buruli ulcer disease, dengue, cholera, trachoma, and guinea worm disease, and primarily affect poor people in tropical and subtropical areas. **NTDs demand a distinct business/innovation model because the potential market does not adequately support R&D investments on a commercial basis.** **In this context, various pharmaceutical companies have collaborated with different stakeholders to form product development partnerships (PDPs)**, **which bring together the expertise and resources of different players including academia, industry, private foundations, and governments.** These partnerships are often funded by public or philanthropic organizations, as well as by the research-based pharmaceutical industry. In 2014, the industry contributed about 22% of the total research funding for malaria, 8.8% for dengue, and 19% for tuberculosis48. **Overall, industry was the third largest funder for NTDs research, investing over USD 534 million.** Small Pharmaceutical Companies & Biotech MNCs = Multinational Pharmaceutical Companies LMICs = Low and Middle-income Countries HICs = High-income Countries These partnerships have proven fruitful and most PDPs currently have a healthy pipeline. For example, the portfolio of the TB Alliance consists of six drugs between phase 1 and 4 of clinical trials51. **The Drugs for Neglected Diseases initiative (DNDi) aims to deliver 16 to 18 new treatments by 2023 for Chagas disease, malaria, leishmaniasis, helminths, pediatric HIV, and sleeping sickness, of which six are already available** – unprecedented progress in the fight against these diseases52. WIPO Re:Search has facilitated 105 collaborations since its first year to (October 2011) to August 201653…

**Currently, IFPMA members have 119 ongoing R&D projects related to NTDs**54. **The number of projects, undertaken in-house or in PDPs, has steadily increased over the years. Through its many partnerships, the research-based pharmaceutical industry is helping to construct innovative models to develop and deliver essential healthcare for patients living in the poorest areas of the world.** [↑](#endnote-ref-7)
8. **Mello**, Michelle. “What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?” **2018**. **(She is a Professor of Law, Stanford Law School, and Professor of Health Research and Policy, Department of Health Research and Policy, Stanford University School of Medicine; Ph.D., University of North Carolina** **at Chapel Hill; J.D., Yale Law School; M.Phil., University of Oxford; A.B., Stanford University.** She has no financial relationships with pharmaceutical or biotechnology companies, but have served as a consultant to CVS/Caremark, whose business includes pharmacy benefit management, on a topic unrelated to prescription drugs.). Minnesota Law Review. <http://www.minnesotalawreview.org/wp-content/uploads/2018/07/Mello_MLR.pdf>

Another perplexing moral problem is that **tradeoffs may exist between improving the affordability of prescription drugs for Americans and maintaining their affordability to patients in other countries**.53 Branded drug prices in the United States are generally higher than in other countries because most foreign governments have adopted stronger mechanisms than the United States for controlling prices—for example, more consolidated price negotiations or direct price controls.54 **Because we pay so much, pharmaceutical companies may be more willing or able to grant price concessions elsewhere, including outright donation of critical medications to low-income countries.** **Actions we take to restrict price, therefore, could have unintended, but real, effects on drug affordability in less wealthy countries.** This prospect raises the question of what obligations, if any, Americans have to patients in the rest of the world. Some conceptions of global justice hold that members of relatively wealthy societies have a moral obligation to consider the welfare of individuals in poorer countries in making policy decisions.55 Other views challenge the notion that such duties exist.56 Some even assert that the status quo is unfair: Americans not only pay more for marketed drugs, they shoulder a disproportionate share of the cost of developing those drugs.57 **Pharmaceutical R&D is underwritten both by the high prices Americans pay for medicines and the tax dollars we spend on basic-science research to identify promising new molecules.**58 Americans have not openly confronted these clashing viewpoints as a polity, but strong measures to reduce the cost of prescription drugs here would make the global-justice dilemma hard to ignore. Further, as with the other moral dilemmas discussed above, the problem has greater salience in the context of prescription drugs than in other areas of health policy. It is true that other health policy decisions we make, such as how much of federal agencies’ budgets to devote to health system capacity building in low-income countries, also affect the healthcare costs that poor countries must bear. However, **because the market for prescription drugs is global but is propped up by high prices in the United States, tamping down drug prices has a zero-sumgame quality that is unique**. **Squeezing one part of the drug-price balloon may cause it to bulge out in other areas.** [↑](#footnote-ref-1)
9. Ford, Nathan. “Pricing of Drugs and Donations: Options for Sustainable Equity Pricing.” Journal of Tropical Medicine and International Health. Nov. 2001. <https://www.ncbi.nlm.nih.gov/pubmed/11703854> //RJ

Concerted international procurement efforts for vaccines and **contraceptives** have been able to significantly reduce prices for these products**,** through a combination of strategies. **Prices of 1-5% of western market prices have been achieved, with millions gaining access to these products while pharmaceutical companies increased their sales and re-importation to wealthier markets was prevented**. AIDS and other life-threatening diseases require similar longer-lasting, more engaging solutions than the current trend of discounts and drug donations with their associated problems of sustainability, geographical and quantitative restrictions, indication restrictions, time restrictions and delays in implementation (Guilloux & Moon 2000). No single strategy will be sufficient to achieve and sustain a real impact on access to vital drugs in developing countries. Rather, a comprehensive system of mutually supportive strategies is required. [↑](#footnote-ref-2)
10. <https://www.who.int/bulletin/volumes/94/2/15-152363/en/>

Neglected tropical diseases (NTDs) can result in disabilities, disfigurement, impaired childhood growth and cognitive development, death and increasing poverty in affected communities.1 **Worldwide, about 2 billion people are at risk of one or more NTDs and more than 1 billion people are affected by these diseases.1–3 Up to half a million deaths and up to 57 million disability-adjusted life years lost have been attributed annually to NTDs**.1,2,4,5 Brazil accounts for a large proportion of NTDs occurring in Latin America, including leprosy (86%), dengue fever (40%), schistosomiasis (96%), Chagas disease (25%), cutaneous leishmaniasis (39%) and visceral leishmaniasis (93%).6–8 Most NTDs occur in populations with low-socioeconomic status, mainly in the north and north-east of the country.6 Knowledge of the magnitude of NTD-related deaths in endemic countries is essential for monitoring and evaluation of the impact of interventions and the effectiveness of specific control measures.9–11 However, there are only a few systematic and large-scale studies investigating NTD-related mortality.9,10,12–16 Here, we describe the epidemiological characteristics of deaths due to NTDs in Brazil over a period of 12 years. [↑](#endnote-ref-8)
11. Wayne Winegarden, 5-17-2018, "Pharmaceutical Price Controls Will Not Improve Health Care Outcomes in Illinois," Forbes, https://www.forbes.com/sites/econostats/2018/05/17/pharmaceutical-price-controls-will-not-improve-health-care-outcomes-in-illinois/#2e265be370d5

Further, **pharmaceutical expenditures are not growing faster than overall health care expenditures**. According to the latest national health expenditure data, **retail prescription drug expenditures rose 1.3 percent in 2016, less than one-half the growth in overall health care expenditures of 4.3 percent.**

**Generic medicines play an invaluable role creating these positive outcomes. The purpose of generic medicines is to enable a competitive market that drives down prices and creates significant budgetary savings**. According to the Association for Accessible Medicines, **generic medicines** in 2016 (the latest data available) **have enabled $9.6 billion in savings for Medicare, Medicaid, commercially insured, and uninsured patients in Illinois alone.**

**The competitive environment that generic medicines enable also means that these firms will typically operate with very small profit margins**. Due to these thin profit margins, HB 4900’s price controls are particularly damaging for these manufacturers. Consequently, HB 4900 could have the perverse impact of driving out manufacturers. **This would worsen the competitive environment and (ironically) lead to higher cost pressures**.

More fundamentally, HB 4900 does not solve the problems that are driving the health care affordability problem. Illinois cannot fix the systemic un-affordability problem by imposing price controls on any individual part of the health care system. Instead, systemic reforms are necessary. There are many potential reforms that would help.

For instance, **the health care system unnecessary obstructs competition in the practice of medicine and has failed to effectively embrace the information technology revolution**. Other policies, such as the inefficiencies inherent in our current health care payment model or the excessive costs created by the tort liability system, are currently dis-incenting innovations and best practices. Fundamental reforms in these areas will meaningfully reduce health care costs while improving overall health care quality.

Coupling price controls with the threat of large regulatory fines will impose heavy costs on Illinois. Perhaps most importantly, **this policy** combination **will discourage generic competition** **in the state that is essential for improving access to more affordable medicines. The result will be higher health care costs, and lower health care quality**, in Illinois.

If the goal is to bend the health care cost curve, then **it is important to recognize that reforms that target one part of the health care system, such as the ill-conceived price controls on pharmaceuticals, will not succeed**. The better approach is to implement holistic reforms that directly address the problems that plague the health care system. [↑](#endnote-ref-9)
12. Neeraj Sood, “The effect of regulation on pharmaceutical revenues: experience in nineteen countries”, National Institute for Health, Dec 16 2008, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3829766/

 “Several important patterns emerge from our analysis. **First, we find that a majority of regulations reduce pharmaceutical revenues significantly.** Second, we find that most countries that adopted new regulations since 1994 already had some regulations in place for controlling costs. We find that such additional regulation had smaller impact on further controlling costs, though this is an average effect across all regulations introduced since 1994, including both enforced and poorly or un-enforced policies. **However, we find that introducing new regulations in a largely unregulated market, for example the US, could reduce pharmaceutical revenues significantly.** Finally, we show that **the effects of price controls increase over time – price controls not only reduce the level of pharmaceutical revenues** but also reduce the rate of growth of pharmaceutical revenues.” [↑](#endnote-ref-10)
13. Scott Gottlieb, 11-5-2018, "Solving the Growing Drug Shortages," WSJ, https://www.wsj.com/articles/SB10001424052970203716204577015702644712634

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.** [↑](#endnote-ref-11)
14. Policy &amp; Medicine, 5-6-2018, "Increasing Generic Drug Shortages Linked to Government Price Controls," https://www.policymed.com/2012/03/increasing-generic-drug-shortages-linked-to-government-price-controls.html

First, the number of suppliers of generic drugs has dwindled. There were 26 U.S. vaccine makers in 1967; today there are only six. Supply disruptions are common, including the possibility that a facility completely shuts down for a protracted time because of quality or safety problems.

Second, unlike in most consumer-goods industries, many pharmaceutical manufacturers have failed to invest in the technology and quality-control improvements that would reduce the risks of partial or complete facility shutdowns—and this despite the FDA’s regularly issued current guidelines for good manufacturing practices (cGMPs).

**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 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.**

In the case of vaccines, for example, the Centers for Disease Control and Prevention (CDC) 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.**  [↑](#endnote-ref-12)
15. Sean Milmo, 3-2-2018, "Tackling Medicine Shortages in Europe," No Publication, http://www.pharmtech.com/tackling-medicine-shortages-europe

**The European pharmaceutical industry and regulators are worried about an imminent worsening of the persistent problem of shortages of medicines in the region.** **Although both agree that regulations are partly to be blamed for a likely rise in the number of incidents of drug scarcities, they have different views on the issue of how regulations are reducing the availability of medicines.**

The industry contends that regulations, particularly those relating to pricing policies, are being applied too strictly so that it has become uneconomic to retain low-priced drugs on the market. The regulators reckon that shortages are occurring when regulations are not being used effectively enough to ensure that medicines remain available.

**The Falsified Medicines Directive and Brexit**

**The first half of 2019 could be a crunch time for medicines supplies in Europe as a result of a new packaging regulation coming into effect, which is aimed at combating counterfeit drugs**, and the United Kingdom’s official departure from the European Union triggering legal changes that will have a big impact on pharmaceutical supply chains. The implementation of rules on the identification of individual medicine packs under the EU’s Falsified Medicines Directive (FMD) will be followed by Brexit, where the UK will no longer be a member of the EU’s single market. Supply bottlenecks could start to form before the two events through to their aftermath.

“Both FMD and Brexit will come into operation within a couple of months,” Adrian van den Hoven, director general of Medicines for Europe, representing generic medicines and biosimilars producers, said at the 17th Regulatory and Scientific Affairs Conference, which took place in London on 25–26 Jan. 2018. “Are we going to risk a total regulatory overload within a six-month period from the end of this year to the spring of 2019 during which the supplies system could become clogged up?” he asked.

A large part of the conference focused on the issue of shortages of medicines and the impact of the FMD packaging legislation and Brexit on their availability.

“**The evidence that the root causes of medicines shortages are economic, including unsustainable pricing and reference pricing policies, is overwhelming**,” Marc-Alexander Mahl, head of the generic-drug business of Fresenius Kabi and president of Medicines for Europe, told the meeting. He noted that claw- and pay-back measures used by governments to limit public sector overspending on pharmaceuticals were also partly to blame. A claw- or pay-back is a tax imposed when there is overspending within a budget so that the total net expenditure is kept within the budget’s limit.

**Challenges faced by generic-drug companies**

**In Romania, 2000 medicines had been withdrawn because of reference pricing and a claw-back tax, while in Portugal, there had been a “drastic reduction” in the number of hospital drug suppliers due to the impact of a pay-back scheme**, according to Mahl. He cited the conclusion of a 2016 report (1) by the European Commission on the fiscal sustainability of funding healthcare. “**While overspending is recovered via the claw-back tax, it has led to withdrawals of generic medicines from the market**,” the report said (1).

**Not only have generic-drug companies struggled to cope with the downward pressures on their profits and sales revenues, but they also have to cope with the expense of running complex supply chains in a high-volume, low-margin business**, Mahl highlighted at the meeting. He pointed out that a large generic-drug company in Europe may have as many as 25,000 marketing authorizations, with more than 800 supply-chain employees working with more than 2000 partners and shipping products to up to 50,000 locations. **At the same time, generic-drug companies have to invest in R&D to launch new products, formularies, and biosimilars to ensure competition and wider pharmaceutical access in the market**, he said. [↑](#endnote-ref-13)
16. **Institute For Safe Medication Practices, 1-11-2018, "Drug Shortages Continue to Compromise Patient Care," https://www.ismp.org/resources/drug-shortages-continue-compromise-patient-care**

Limit or extend drug use. **Ninety-four percent of respondents reported rationing or restricting drugs in short supply**. Examples included establishing criteria for using products, restricting access to drugs via override in automated dispensing cabinets (ADCs), and providing kits for emergency drugs. Thirty percent of all respondents said they have used a drug in short supply outside its specific labeling to help extend its use, such as keeping expired products (without FDA-extended dating) in code carts. [↑](#endnote-ref-14)
17. Authors, 1-10-2017, "How Market Forces Contribute to Drug Shortages," No Publication, https://www.pewtrusts.org/en/research-and-analysis/articles/2017/01/10/how-market-forces-contribute-to-drug-shortages

**When lifesaving medications go into shortage, the results can be fatal. Ensuring the continuity of the drug supply chain is therefore critical to public health**. Quality issues, which can cause manufacturing lines to shut down or lose productivity, are cited as a primary contributor to shortages, but they are not the only forces at play. The market dimensions and investments that influence shortages have not been as thoroughly explored. To better understand these contributing factors, The Pew Charitable Trusts joined with the International Society for Pharmaceutical Engineering to develop a report, Drug Shortages: An Exploration of the Relationship Between U.S. Market Forces and Sterile Injectable Pharmaceutical Products—Interviews With 10 Pharmaceutical Companies.

The report includes data collected through interviews with 51 executives from 10 sterile pharmaceutical manufacturers of various types and sizes that have experienced shortages. Researchers asked them to cite factors in addition to quality that drove shortages at their companies. The following themes emerged:

**Market withdrawals. A company may take a drug product off the market for many reasons, including quality issues, replacement drugs introduced into the market, and decisions to realign a portfolio to focus on products with greater margins**. These market withdrawals can play a role in causing shortages.

Supply chain design. Lack of coordination among processes involving sales, demand planning, inventory management, and production makes it challenging to plan for and meet estimated demand for a drug product. Although many companies build additional capacity into their supply chains, not all products receive the same level of manufacturing redundancy. Instead, companies establish levels of redundancy based on manufacturing complexity, return on investment, and impact on patients if a shortage occurs.

Purchaser-manufacturer incentives. Companies said they need incentives, such as guaranteed-volume contracts or the ability to retain contracts, to mitigate the risks of making investments to prevent shortages. Lack of such incentives can keep companies from entering a market to resolve a shortage issue or build the systems needed to avoid shortages.

Limited market insights into future demands. Without accurate information about the expected demand for a product, especially low-volume, low-margin products, companies are reluctant to invest in setting up additional manufacturing capabilities to protect against future shortages.

Managing regulatory expectations. Companies said regulatory challenges contribute to shortages because of the time scales and costs incurred in obtaining approval to expand manufacturing capacity or upgrade a piece of equipment. **The risks of a shortage increase when these perceived regulatory challenges dissuade companies from making changes, especially to products developed 10 to 20 years ago, that might help meet an anticipated increase in demand.** [↑](#endnote-ref-15)
18. Andrew **Spiegel** , 5-5-**2017**, "The tragic toll of drug price controls," **The Hill**, <https://thehill.com/blogs/pundits-blog/healthcare/332145-the-tragic-toll-of-drug-price-controls>

One of the most popular forms of drug price controls is "reference pricing." Officials group drugs into therapeutic classes, based on how the drugs attack disease. They then set a single price for each class. In fact, several forms of reference pricing do not distinguish between innovative new medications and older generic alternatives.

So, for instance, a new**, breakthrough medication gets priced exactly the same as an older, less effective drug that's been off-patent for years. By doing this, reference pricing fails to value the innovative nature of the next generation of treatments and cures. The Canadian province of British Columbia has incorporated reference pricing into its public health system. So have Italy, Spain, and Germany.** Less developed economies have resorted to even more nefarious means. By issuing so-called "compulsory licenses," they have broken patent protections on innovative medicines. Compulsory licenses were designed to be used only in the event of a public health disaster, but some countries are now using them to drum up discounts for drugs without any plausible connection to an emergency. In Indonesia, compulsory licensing is an industrial policy tool. If a new treatment isn't manufactured locally, anyone can petition the government to break the patent on that product. And, of course, several major economies have installed straight-up caps on drug prices. South Korea's public insurance system imposes some of the most stringent caps in the world, tightly controlling even generics.Newly introduced generics can't be sold for more than 60 percent of the price of the brand name upon which they're based. And that cap drops to 53 percent after a year. Likewise, India's National Pharmaceutical Price Authority aggressively controls product prices, dictating down the cost of diabetes drugs by 40 percent over the last year and cancer drugs by nearly 90 percent. And these controls are only going to get tighter. Just this February, the World Health Organization released a draft report criticizing industry pricing practices and sketching out a spreadsheet for governments to calculate a "fair price" for medicines.

That's a barely disguised call for lower caps. The justification for these controls rests on a simple story: drug prices as a whole are spiraling skyward, preventing sick patients from affording needed medications.That's pure fiction.

Drugs actually represent a relatively small slice of global medical spending. Just consider: over the next decade, spending on prescriptions will account for less than 10 percent of total healthcare spending growth in the OECD, the economic association encompassing the United States, Canada, and much of Europe. And the price control process significantly degrades patient well-being. Pharmaceutical firms have to undergo a long, drawn-out negotiating process every time they want to sell a new medication in a controlled market. All the while, sick people aren't getting the medicines they need. In America, which has a relatively free drug market, the average medicine is approved 90 days quicker than in Europe and about a year quicker than in Canada.

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.

This fatal foot-dragging, and the accompanying wave of price controls, must end. That's why my organization, the Global Colon Cancer Association, and over 70 other groups have sent a letter to President Trump and other government officials asking them to pressure foreign allies to expand access to lifesaving medicines.

Everyone wants lower healthcare costs. But it's counterproductive to blame companies that create life saving therapies.

Foreign leaders would better serve their citizens by expanding access to treatments that improve health and lower long-term costs. [↑](#endnote-ref-16)