**We affirm**

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

**First, with an observation.** The form of price controls put in place would be the plan outlined by Trump to restrict Pharmaceutical Benefit Managers as well as the initial pharmaceutical companies. Pharmaceutical Benefit Managers, or PBMS, are the people who sell medication to the local pharmacies. **Obrien writes in 2018[[1]](#endnote-1)** that Trump has detailed a plan to limit pharmaceutical prices charged by PBMs and reducing the middle man role.

**Second is the framework debate. Whichever team makes drugs most accessible should win the round as drug’s only have value if they can be consumed. There is no point in development of medicines that are not affordable to a majority of the population because that is where they gain inherent meaning. The negative has no solvency for rising drug prices and until they do so, they have no ground to win the round.**

**Contention One is Cutting Out the Middle Man**

Pharmacy Benefit Managers are functionally the middle man between insurance providers and pharmacies, negotiating the transactions between the two. **Loria[[2]](#endnote-2)** explains that PBMs achieve profit by offering discounts or rebates to pharmacies from manufacturers. Problematically, the higher the rebate, the higher their profit, which means the higher the original price, the more money PBMs make.This profit incentive makes PBMs highly resistant to lowering drug prices. **Shah[[3]](#endnote-3) explains in 2018** that due to their unique negotiating leverage, PBMs could functionally blacklist manufacturers opposing their profits, and prevent the sale of their drugs. This creates a system where PBMs have control over how much manufacturers can charge and how much pharmacies sell the drugs for, allowing for unbridled profiteering. Thus, **Medscape[[4]](#endnote-4) reports** that PBM’s are taking advantage of their profiteering power and vastly overcharging for generic pharmaceutical drugs. To contextualize the harms, **a Forbes[[5]](#endnote-5) analysis finds** that more than 200 generic drugs have doubled in prices within a year while 17 of which have seen a 1000% increase in the same time frame. Luckily, **Leaf[[6]](#endnote-6) of Forbes** findsthat under Trump’s proposal, PBMs are being heavily targeted to decrease pharmaceutical drug costs for American citizens through creating caps on original prices and rebates, allowing for increased affordability and competition between different medications. **Loria** continues that by restricting pharmaceutical benefit managers, the citizens of the United States would be able to have better access to medication by effectively cutting out the expensive middle man.

**The impact is increasing affordability**

**The FDA finds** that 9 out of 10 Americans fill prescriptions with generic brand drugs which help treat diseases without the huge price tags. The only solvency is provided by affirming and controlling PBMs who are the reason for generics increasing. Currently **Leaf** continues that ever-increasing drug prices, created by PBMs are decreasing prescription adherence, and American’s are not taking necessary medicine. In fact, **Bishop[[7]](#endnote-7)** finds that due to the US’ high drug prices, our prescription nonadherence is 7 times higher than that of comparable countries with price controls. Ultimately, **Brody[[8]](#endnote-8)** concludes that due to nonadherence, 125,000 people die each year.

**Contention Two is Innovation**

Currently, Pharmaceutical innovation is stagnant and unproductive**.** **Bolden explains[[9]](#endnote-9)** that research and development effectiveness has been decreased by 50% in the last 9 years. **Pryor[[10]](#footnote-1)** **explains**, Pharma companies focus on exploiting the market by creating new drugs that provide little new benefit but can still be charged at high prices. In fact, he finds that 84% of new drugs, are these “copy-cat” drugs meaning innovation is not yielding the needed results. Luckily, price controls change this in two ways

**First, is Market Expansion**

**Linn[[11]](#footnote-2)** **writes** that by increasing access and affordability to more consumers, the pharmaceutical market would expand which in turn generates greater incentive to innovate, thus every 1% increase in market size, increases the entry of brand-new innovative drugs by 6%.

**Second, Is Changing Priorities**

**Herper[[12]](#endnote-10)** **explains** that by allowing companies to charge high prices for low risk drugs, high risk innovation is an unattractive, so companies rarely target much needed areas of innovation. However, **Canoy[[13]](#footnote-3)** **of the** **Dutch Health Care Institute** **explains in 2018** that by enforcing lower drug prices through a price control, companies will no longer be able to rely on “copy-cat” drugs and will have to shift investments towards the projects with the greatest societal value.

**The Impact is Combatting New Diseases**

Creating true innovation is crucial as **Balase[[14]](#endnote-11)**  **finds** that pharmaceutical companies have begun pulling out and decreasing innovation in the areas of greatest need, specifically in regard to anti-infective and anti-viral treatment, which is quickly becoming the health crisis of the 21st century. **O’Neill[[15]](#endnote-12) explains** that many bacterial infections are becoming increasingly resistant to medication, thus increasing the casualties of the diseases every year and unless sufficient action is taken, such diseases could kill 10 million people every year by 2050.

**Thus,**

**We you urge you to affirm**

1. Jack **O’Brien**, 5-11-**2018**, "'Eliminating the Middlemen': Trump Takes Aim at PBMs in Drug Pricing Speech," **Health Leaders**, <https://www.healthleadersmedia.com/finance/eliminating-middlemen-trump-takes-aim-pbms-drug-pricing-speech>

**The president outlined his plan to lower prescription drug costs and aid low-income Americans by reshaping Medicare and boosting competition.** President Donald Trump delivered his long-awaited speech Friday on prescription drug prices, promising to focus the administration's attention on four key strategies to make trips to the pharmacy less expensive for consumers**. Trump's plan seeks to eliminate what he described as the "dishonest double dealing" of healthcare middlemen, such as pharmacy benefit managers (PBMs), to receive rebates and discounts, instead aiming to have those savings redirected to consumers and patients.** "We're very much eliminating the middlemen," Trump said. "The middlemen became very rich. They won't be so rich anymore.". The president also directed the Department of Health and Human Services to allow more substitution through Part D for single-source generics, require health plans to share a minimum portion of drug rebates with patients, and limit Part B price increases above the inflation rate. [↑](#endnote-ref-1)
2. **On June 12, the Senate Health, Education, Labor, and Pensions Committee held a hearing to review the Trump administration’s plan to lower drug costs, with Alex Azar, secretary of the U.S. Department of Health and Human Services, testifying that pharmacy benefit managers (PBMs) are to blame for the high prices.** As part of his written testimony, **Azar said that since PBMs are paid based on the number of rebates they negotiate, the possibility exists for them to retaliate against manufacturers who cut prices by dropping them from formularies or placing them on a higher tier.** “We may need to move toward a system without rebates, where PBMs and drug companies just negotiate fixed-price contracts,” he said. “Such a system’s incentives, detached from artificial list prices, would likely serve patients far better, as would a system where PBMs receive no compensation from the very pharma companies they’re supposed to be negotiating against.” This, he said, would prevent PBMs from impacting prices, as a major criticism of the current system is that PBMs keep some of the rebates instead of passing them to consumers in the form of lower out-of-pocket costs. [↑](#endnote-ref-2)
3. SANDIP SHAH, 5/16/2018

Investor'S Business Daily, xx-xx-xxxx, "Pharmaceutical Middlemen, Not Patients, Profit Off New Treatments," Investor's Business Daily, https://www.investors.com/politics/commentary/pharmaceutical-middlemen-not-patients-profit-off-new-cancer-treatments/

The supply chain is complex. **Drug makers don't sell their drugs directly to patients. Instead, they sell to PBMs, which are hired by health plans to negotiate drug prices. PBMs process the majority of prescriptions in America and decide which drugs insurers will cover.**

**PBMs are the most influential actors in a chain of middlemen**. **Their role gives them a lot of negotiating leverage**. **If a pharmaceutical company wants patients to take its drug rather than a rival company's pills, the drug maker must offer the PBMs a good deal. Otherwise, the PBMs could blacklist the company and steer patients to a different firm's medications.**

**PBMs use this leverage to extract big discounts from manufacturers, who generally give PBMs a 30% rebate off the list price of brand-name drugs.** **When there are many similar drugs for the same illness, PBMs can play manufacturers off one another and achieve huge rebates of 60% or more.** [↑](#endnote-ref-3)
4. **Study findings that suggest PBMs are overcharging for generic drugs at the expense of retail pharmacies, consumers, and health plans have ignited a war of words between the Pharmaceutical Care Management Association (PCMA), representing PBMs, and the National Community Pharmacists Association (NCPA), representing independent pharmacies**. The study, "The Spread: Pilot Study of an Undocumented Source of Pharmacy Benefit Manager Revenue," describes how some **PBMs are making impressive, and largely hidden, profits on generic drugs.** Findings **of the study, conducted by Robert I. Garis, MBA, PhD, and Bartholomew E. Clark, PhD, of Creighton University Medical Center, were published in the January/February issue of the Journal of the American Pharmacists Association.** Garis and Clark describe how **some PBMs are increasing their clients' prescription drug expenditures by creating a significant price spread between what they charge employers and what they pay pharmacies.** The average generic spreads for the 2 PBMs studied were more than $10 per prescription for one, and nearly $32 for the other. One PBM billed an employer more than $200 for a single generic ranitidine prescription, for which it paid the dispensing pharmacy $15. In another instance, the PBM billed $80 for generic atenolol and paid the pharmacy $7. [↑](#endnote-ref-4)
5. **Forbes 15**

Team Trefis. "Why Are Generic Drug Prices Shooting Up?." *www.forbes.com*, 27 Feb. 2015, https://www.forbes.com/sites/greatspeculations/2015/02/27/why-are-generic-drug-prices-shooting-up/. Accessed 22 Oct. 2018.

However, **generic prices have been moving up** for some time now, which is leading to some serious concerns for the pharmacy retail industry in the form of reimbursement rate pressure (Here’s a detailed analysis of this issue**). The Rise Of Generic Prices According to a report by Elsevier, a drug product and pricing information provider, out of a research sample of 4421 drug groups, 222 drug groups increased in price by 100% or more (between Nov’13 and Nov’14). There are also some extreme cases (17 drug groups) where price increases of more than 1000% were seen. One such product is tetracycline, which is commonly prescribed for bacterial infections. During the same period (between Nov’13 and Nov’14), it’s per tablet price increased from $0.0345 to $2.3632. That is a 67-fold increase in one year**! But, why are generic drug prices increasing at such high rates? YOU MAY ALSO LIKE Factors That Contributed To The Price Rise Industry Consolidation In 2009, generic drug markets were saturated and projections looked dull. To avoid falling into losses, generic drug makers began to consolidate through mergers and acquisitions to achieve the scale needed to maintain profitability. Typically, when a branded drug loses patent protection, multiple generic manufacturers produce the drug and compete on price. But post-industry consolidation, fewer generic manufacturers are applying to the FDA for permission to produce those drugs. With substantially fewer manufacturers producing a particular generic drug (in some cases only 2 or 3 makers), generic prices have crept up with time. However, there are more influential factors than this. [↑](#endnote-ref-5)
6. Clifton **Leaf**, MAY 21, **2018**, "Canada Is Considering Cancer Warning Labels Printed on Individual Cigarettes”, **Fortune**, <http://fortune.com/go/health/drug-prices-pharmacy-benefit-managers/>

**At issue, says the Trump Administration in its 44-page blueprint for lowering drug prices, “American Patients First,” isn’t quite that the PBMs are getting rich. (In point of fact, Mr. Trump tends to like that quality.) Rather, the “hidden negotiation and wealth transfer between drug manufacturers and PBMs,” which is now leading to “a direct increase on consumer out-of-pocket spending that likely decreases drug adherence and health outcomes.” FDA Commissioner Scott Gottlieb was even blunter in a speech the week before the president—suggesting that these hidden negotiations might even be “kickbacks”: “To take one example, one of the dynamics I’ve talked about before that’s driving higher and higher list prices, is the system of rebates between payers and manufacturers. And so what if we took on this system directly, by having the federal government reexamine the current safe harbor for drug rebates under the Anti-Kickback Statute? Such a step could help restore some semblance of reality to the relationship between list and negotiated prices, and thereby boost affordability and competition.”** I won’t get into the nitty gritty of what exactly PBMs do. You can read my previous Brainstorm Health essay here and—definitely—read Katherine Eban’s 2013 feature in Fortune, “Painful Prescription,” here. But in any case, I agree with the President and with Commissioner Gottlieb, the PBM business at large deserves extra scrutiny right now. Notably, however, this may come from various states before it comes from Uncle Sam. Earlier this month, the Connecticut legislature easily passed its own bill to control prescription drug costs, Public Act No. 18-41, which is awaiting the signature of Governor Dannel Malloy. That bill, among other things, requires PBMs, beginning in 2021, to report to the state’s insurance commissioner any rebates they receive, including drug formulary rebates collected from pharmaceutical companies—and disclose what share goes to consumers. [↑](#endnote-ref-6)
7. High prices harm patients – people in the US can’t afford necessary drugs, whereas those in other countries can because of measures to limit out-of-pocket costs Sarnak, Dana, Squires, David, and Bishop, Shawn. [Researchers at the Commonwealth Fund]. “Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?”. Commonwealth Fund, 2017. hĴps://www.commonwealthfund.org/publications/issuebriefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier.

PATIENTS’ EXPOSURE TO PHARMACEUTICAL COSTS **Just as pharmaceutical spending differs across countries, the degree to which patients are exposed to out-ofpocket costs varies**. Cost exposure is determined by the extent of insurance coverage among the country’s population and by national standards (or a lack thereof) for insurance benefit design and protections against high out-of-pocket costs for poor or sick patients (Appendix). **In Norway, for example, copayments for pharmaceuticals can be more than $50 per prescription, though these charges are capped at approximately $260 annually**. In contrast, the U.K.’s National Health Service requires little or no patient cost-sharing. Despite the differences among them, all countries do more than the U.S. does to limit patients’ exposure to high out-of-pocket costs. While insured U.S. patients often pay little or nothing for generic prescriptions, they can be billed tens of thousands of dollars for certain high-priced medicines. Even Medicare’s Part D prescription drug benefit has no out-of-pocket cap for beneficiaries. Only a handful of U.S. states have passed legislation to limit out-of-pocket spending for insurance sold within their borders; for example, Maryland has a $150 monthly cap for specialty-tier drugs.**11 In a 2016 international survey of adults, 14 percent of insured Americans reported that, in the past year, they did not fill a prescription or skipped doses of medicine because of the cost, compared with 2 percent in the U.K.** and 10 percent in Canada, the nation with the highest rate after the U.S. (Exhibit 6).12 Among Americans without continuous insurance coverage over the past year, the rate was twice as high: one-third reported they did not fill a prescription for medicine, or skipped doses of medicine, because of the cost. Add to ChartCart For patients with chronic conditions, cost barriers are particularly detrimental, as they can undermine adherence to highly effective medication regimens.13 **The 2016 survey found that, in most countries, patients with two or more chronic conditions were significantly more likely to skip medications because of costs than were healthier patients, with one-fourth of chronically ill adults in the U.S. reporting such a problem** (Exhibit 7). **Notably, the only countries where such patients were not significantly more likely to report cost barriers to prescription drugs were France, Germany, and the U.K. — countries that have instituted protections to reduce out-of-pocket charges for their chronically ill populations.** [↑](#endnote-ref-7)
8. Jane E. **Brody**, 4-17-2017, "The Cost of Not Taking Your Medicine," **New York Times**, <https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html>

**There is an out-of-control epidemic in the United States that costs more and affects more people than any disease Americans currently worry about. It’s called nonadherence to prescribed medications, and it is — potentially, at least — 100 percent preventable by the very individuals it afflicts.** The numbers are staggering. “Studies have consistently shown that 20 percent to 30 percent of medication prescriptions are never filled, and that approximately **50 percent of medications for chronic disease are not taken as prescribed**,” according to a review in Annals of Internal Medicine. People who do take prescription medications — whether it’s for a simple infection or a life-threatening condition — typically take only about half the prescribed doses.**This lack of adherence, the Annals authors wrote, is estimated to cause approximately 125,000 deaths and at least 10 percent of hospitalizations, and to cost the American health care system between $100 billion and $289 billion a year.** [↑](#endnote-ref-8)
9. Jack W. **Scannell**, Alex **Blanckley**, Helen **Boldon** and Brian **Warrington**, No Date, "To Lower Drug Prices, Innovate, Don't Regulate," **Semantic Scholar (Peer Reviewed Studies)**, https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/to-lower-drug-prices-innovate-dont-regulate

Abstract | The past 60 years have seen huge advances in many of the scientific, technological and managerial factors that should tend to raise the efficiency of commercial drug research and development (R&D). Yet **the number of new drugs approved per billion US dollars spent on R&D has halved roughly every 9 years since 1950, falling around 80‑fold in inflation-adjusted terms. There have been many proposed solutions to the problem of declining R&D efficiency. However, their apparent lack of impact so far and the contrast between improving inputs and declining output in terms of the number of new drugs make it sensible to ask whether the underlying problems have been correctly diagnosed**. Here, we discuss four factors that we consider to be primary causes, which we call the ‘better than the Beatles’ problem; the ‘cautious regulator’ problem; the ‘throw money at it’ tendency; and the ‘basic research–brute force’ bias. Our aim is to provoke a more systematic analysis of the causes of the decline in R&D efficiency. [↑](#endnote-ref-9)
10. **David Pryor (U.S. Senate Hearing) “PRESCRIPTION DRUG PRICES: ARE WE GETTING OUR MONEY'S WORTH?”**

[**https://www.aging.senate.gov/imo/media/doc/publications/7181989.pdf**](https://www.aging.senate.gov/imo/media/doc/publications/7181989.pdf)

The drug companies want us to believe that it takes $125 million to invent the next penicillin, or a cure for AIDS, or treatment for Alzheimer's' disease. All of us would consider a cure for these diseases a bargain at $125 million. And, I would like to take this opportunity to personally recognize and praise the long hours and hard work put in by researchers, scientists, and technicians who daily fight the battle against such dreaded diseases. But, let's be honest here. **These drugs are not "breakthrough" drugs. In fact, for every breakthrough product they invent, American drug companies bring 24 drugs to market that provide little or no therapeutic gain as rated by the Food and Drug Administration. Some people call these me-too, drugs because they represent a company's attempt to jump into a profitable market for an existing drug therapy. If we look at the next chart [REFER TO APPENDIX A OF AGING COMMITTEE STAFF BRIEFING PAPER], you will see that of the 348 new drugs brought to market by the top 25 American drug companies between 1981 and 1988, 292 were "me-too" drugs. These companies produced a total of only 12 "Important" new drugs and 44 other products that make what FDA calls a 'Modest" contribution to existing therapies. This means 84% of new drugs fall into FDA's "C" category, making "little or no" contribution to anything but the bottom line of a profit and loss statement.** The story is the same if you consider the value of the new drugs referred to by the PMA in their ad: about 60% are rated by FDA as "me-too" drugs with questionable benefits no matter how you slice it. [↑](#footnote-ref-1)
11. **Joshua Linn (Massachusetts Institute of Technology) “MARKET SIZE IN INNOVATION: THEORY AND EVIDENCE FROM THE PHARMACEUTICAL INDUSTRY” 2004**

[**https://economics.mit.edu/files/4464**](https://economics.mit.edu/files/4464)

**More important, there is a statistically significant response of the entry of nongeneric drugs, which more closely correspond to new products and “innovation”: a 1 percent increase in potential market size leads to approximately a 4 percent increase in the entry of new nongeneric drugs. We also look at the relationship between market size and entry of new molecular entities. These drugs, which contain active ingredients that have not been previously marketed in the United States, provide a measure of more radical innovations** (there are 442 new molecular entities compared with 2203 new nongenerics during our sample period). We find that a **1 percent increase in potential market size is associated with a 4–6 percent increase in the entry of new molecular entities.** These results together show an important effect of potential market size on pharmaceutical innovation. [↑](#footnote-ref-2)
12. Matthew **Herper**, 10-23-**2014**, "Could High Drug Prices Be Bad For Innovation?," **Forbes**, <https://www.forbes.com/sites/matthewherper/2014/10/23/could-high-drug-prices-be-bad-for-innovation/#190c74325a80>

Policymakers are scrutinizing high prices for specialty drugs like never before. Gilead’s Sovaldi at $84,000 for a treatment course is in part to blame -- or credit -- for this, but so are Vertex’ Kalydeco, Merck’s Keytruda , and a series of other six figure drugs. The pharmaceutical industry has responded in a predictable way. High prices are needed to fuel the fire of innovation they explain. True. Absent a potential return, investors would certainly stay far away. But what about the follow on question? Just how high do prices need to be? When does the potential to profit exceed that which is needed to drive innovation and pervert the market? I think we’re already there. Case in point: there are seven drugs in human trials that target lung or and/or other cancers caused by an acquired genetic abnormality called the ALK rearrangement (Figure). Roche’s Alectinib is in Phase 3. Ariad, Tesaro, Pfizer and Ignyta all have agents in Phase 2. There are four more compounds soon to enter human testing. That’s a lot of drugs that all target the same cancer causing mechanism. Maybe this would make sense if ALK rearranged lung cancer constituted a vast market. But it doesn’t. The key first and second line indications in lung cancer are already occupied by Pfizer’s Xalkori and Novartis’ Zykadia, respectively. And only three to eight percent of metastatic lung cancers are driven by the ALK alteration, which amounts to only a few thousand patients per year in the US. If it’s not a huge market, then why the ALK drug mosh pit? I think its high drug prices. The Federal Medicare program, and most private insurers, must include new cancer drugs on formulary regardless of their price or the existence of cheaper alternatives. And as the industry has continued to test the waters with higher and higher prices, its gone swimmingly but for a few pointed editorials and stories of patients driven into bankruptcy. **With high prices available to every new drug for cancer, companies are stumbling over one another in a race down a well trodden molecular road to profits. That makes pursuing high risk innovation a less attractive option, even though that will be how we get novel drugs that tackle unmet needs**. Drugs that will rely on mechanisms that today still seem hypothetical. You might say that it’s not one or the other, but if so, then the whole argument about why we need high prices to fuel innovation falls apart. **There are apparently only so many investment dollars to go around, so dollars going to generate yet another drug for ALK are dollars away from a new idea that hasn’t yet been proven. Same goes for the research infrastructure, and for the patients enrolling on these studies.** Some macro events show the distorting effects of high prices. Gilead paid an 89 premium for Pharmasset because they knew that they could affix an unheard of price to any Hepatitis C drug that actually worked. The purchase bridged them to a jaw dropping stream of profits. That’s the return to investors we keep hearing about. But wait, this is not actually a story of how stratospheric potential prices for Sovaldi fueled innovation in the treatment of Hepatitis C. It’s a story of a company, Gilead, that realized drug prices are immune to gravity, something the other bidders for Pharmasset and Wall Street missed. We know that Pharmasset forecast charging $36,000 for a treatment course – 42 of what Gilead is charging. So that was the price -- that much lower price -- that was needed to drive the innovation. Not Gilead’s number. Mind boggling prices for new specialty drugs are now an expectation and those who missed Sovaldi won’t miss next time. They’ll bake crazy prices into their models and that will mean higher valuations. Roche just paid a handsome 40 premium for Intermune in a deal totaling more than $8B. Intermune has one drug – Esbriet. It’s a great drug, and may benefit up to 100,000 people with Idiopathic Pulmonary Fibrosis. When the FDA approved the drug this month Roche announced a $94K per year pricetag, more than twice what the drug costs in Europe. Simple math – if they ever could achieve full market penetration Roche would make back their entire investment in a single year. Once again, the potential to affix this huge pricetag to Esbriet didn’t spur the innovation, it spurred Roche to pay up for the company. Today’s shareholders are super happy (and I’m glad for them), but how many of them were even around and invested in the company back when the high risk decision to develop Esbriet was made? **High prices may be needed to fuel the fire of innovation, but while the drug industry keeps saying that they enable the pursuit of rare prizes, the market is telling us the opposite: that prices have become the prize.** [↑](#endnote-ref-10)
13. Marcel Canoy, “Lower drug prices can improve innovation”, Dutch Health Care Institute, 2018, <https://editorialexpress.com/cgi-bin/conference/download.cgi?db_name=EARIE45&paper_id=550>, SP, October 15, 2018

While the news is packed with articles on high drug prices2 , governments are often reluctant to counteract high prices with the innovation argument in the back of their mind. The innovation argument tells us that actions by governments, regulators or competition authorities against high drug prices are detrimental to pharmaceutical companies’ incentives to innovate. This innovation argument needs to be qualified. Sure enough, pharmaceutical companies’ incentives to invest in drug development are affected by the revenues they expect to realise in case of success: the higher the revenue in case of success, the more attractive it is to invest in the project.3 It is equally well-known that many drug development projects are ultimately unsuccessful (roughly nine out of ten research projects never receive market authorisation4 ). Hence, high drug prices may be necessary to make development projects attractive ex ante. Although true, this notion can easily lead to the misunderstanding that more revenue is always better for innovation. We develop a simple analytical framework showing that this is not necessarily the case. We also identify under which conditions drug revenues generate socially optimal investment incentives.

The framework shows that – purely from an innovation perspective - incentives are socially optimal if the pharmaceutical company can appropriate the entire benefit of a new drug to society. In this case the pharmaceutical company internalizes all the public benefits and costs of the drug. If a company extracts less than the entire benefit of a new drug to society, innovation incentives can be too low from a social point of view. Apart from investing too little money in the project, it may result in the company’s decision not to develop the drug at all even though this would be in the public interest. However, if companies gain more than the benefit of the drug to society, we show that this creates two inefficiencies in innovation. **First, companies invest too many resources in projects where they expect to be able to gain more than the drug is worth to society. Second, pharmaceutical companies invest too few resources in other valuable drug development projects. As a result, high drug prices lead to crowding out of valuable drug development projects. In these instances, enforcing lower prices does not harm innovation but improves it, because as a result of lowering those prices future investments will be geared towards projects that are more desirable for society.** The fact that pharmaceutical companies can obtain higher prices than the true value, is by no means a hypothetical case. In his recent New York Times column Nobel laureate Paul Krugman is worried about this too. Krugman refers to Frank and Zeckhauser (2017)5 who claim that the current system produces outcomes where “pricing gets almost unmoored from the value of the drugs produced.” [↑](#footnote-ref-3)
14. Manica **Balasegaram**, MéDecins Sans FrontièRes, Speaking of Medicine, 02-14-**2014** Drugs for the Poor, Drugs for the Rich: Why the Current RandD Model Doesn't Deliver, <https://blogs.plos.org/speakingofmedicine/2014/02/14/drugs-poor-drugs-rich-current-rd-model-doesnt-deliver/>

The past month has seen the reputation of Big Pharma dented more than usual. The CEO of German pharmaceutical company Bayer, Marijn Dekkers, was reported as saying that the company didn’t develop a cancer drug for the Indian market, but rather “for Western patients who can afford it”. The comment summed up the attitude of the pharmaceutical companies towards the poor and succinctly described what is wrong with today’s research and development (RandD) system. In a similar vein, last month British/Swedish pharma company AstraZeneca announced it was pulling out of all early-stage Current RandD for malaria, tuberculosis (TB) and neglected tropical diseases – all diseases of the developing world. Instead, the company stated they will focus efforts on drugs for cancer, diabetes and high blood pressure, all diseases that affect rich countries, with potentially plenty of people to pay the high prices on new drugs. This system of RandD – which increasingly relies on patents, market monopolies and high prices of drugs to recoup costs – is broken. We are seeing a complete lack of RandD into areas of real need, especially in diseases that affect the poor. The effects of this system on patients in developing countries is something that I – as someone who has worked as a doctor in some of the most remote areas in the world with Médecins Sans Frontières (MSF) – have witnessed for years. The pharmaceutical industry touts the need for strong intellectual property (IP) protections and patents as a means to secure funding for RandD needs. **They say that without 20-year-plus patent terms and the ability to have patents granted on even minor modifications on existing drugs – known as ‘evergreening’ – we simply wouldn’t have innovation. And yet, incredibly, the industry is pulling out and stopping innovation in the areas of the greatest need. This trend is not new. Pfizer stopped RandD into all anti-infective drugs in 2012; in the same year, barely a third of the estimated funding needed for TB drug development was met. The need for new TB drugs and new regimens to treat TB – especially drug-resistant forms of TB – is increasing worldwide, including in some parts of Europe and countries such as South Africa and India.** The lack of RandD for new drugs doesn’t only affect developing countries; wealthy countries are also faced with a huge gap in medical innovation. With the numbers of cases of antibiotic resistance on the rise in many parts of the world – including in western hospitals – there are, worryingly, few new antibiotics being developed. We are fast approaching the point, if we’re not there already, where people will develop infections that are resistant to all existing antibiotics, and we’ll have nothing effective with which to treat them. The problem is simply this: pharmaceutical companies like Pfizer, AstraZeneca and Bayer lack the incentives to develop drugs like antibiotics that are only taken for a short period of time, or against diseases that primarily affect the poor. With an obligation to shareholders, pharma companies develop those drugs that will most enable them to achieve high sales in targeted lucrative markets. **Typically, these drugs are for diseases that affect mostly people in wealthy countries who can afford – for the most part – to pay the high prices that come with a RandD system which relies on patent monopolies to recoup costs. Increasingly, we’re seeing not only the unavailability of drugs for medical needs, but also unaffordability when drugs are priced out of the reach of most people.** The drugs that are developed today are priced so highly that even people in the USA, UK and the EU – the very markets that Big Pharma are targeting – are unable to afford price tags such as US$84,000 for the new hepatitis C drug sofosbuvir, or cancer drugs priced at over $100,000. **We have to ask ourselves – if the drugs being developed are priced so highly that no-one can afford them, is society actually benefiting? The pharmaceutical industry’s response to criticism over high prices is that it costs a lot to develop these drugs. While this is undoubtedly true, there are two important points of clarification: first, a lot of the RandD behind successful new drugs is heavily subsidised by the tax payer – globally, about half of all RandD is paid for from the public purse and by philanthropic organisations**. In effect, we’re paying twice for new drugs. Secondly, there is a lack of transparency from the pharmaceutical industry- so we don’t really know how much it costs, and how much this can vary. The industry often throws around the figure of $1 billion as the cost. Yet this figure is often questioned, even by one of their own; last year, GSK’s Sir Andrew Witty called the $1 billion figure “a myth”. Other organisations have proved that it’s possible to develop new drugs for significantly less than $1 billion, and have no patents or high prices attached. For example, a non-profit public-private partnership used up-front funding to develop an artemisinin-based combination therapy for malaria, which has no patent, is priced at less than US$1 and has seen over 250 million treatments used in 31 African countries. Private-public partnership Drugs for Neglected Diseases initiative has estimated that development of a new chemical entity can cost as little as $50 million per successfully developed drug; with attrition and failure rates taken into account, it’s still as little as $200 million. Pharma has a vision for RandD – tough intellectual property rights and patents on new medicines, and high prices. But clearly, this approach doesn’t entirely work to deliver public health benefits. Our vision for RandD involves an overhaul of the current system. New drugs should be developed according to actual medical needs in a system that does not exclusively rely on patents and high prices to recoup costs. There are other ways to pay for RandD and alternative business models that can be used. It is essential these are further developed to ensure that innovators are sufficiently and transparently rewarded for developing useful products. It is possible to develop drugs for neglected diseases and diseases that affect the developing world. It is possible to develop new antibiotics and drugs where we aren’t forced to pay more than $100,000 for each patient treated. [↑](#endnote-ref-11)
15. The system is broken; it’s time we fixed it – for the benefit of everyone, including the pharmaceutical industry.
ABR Diseases will kill 10 million people a year. O’Neill 16:
Jim O’Neill, Review on Antimicrobial Resistance, Tackling Drug-Resistant Infections Globally: Final Report and Recommendations, May 2016, Accessed 11-01-2018, [http://life-worldwide.org/assets/uploads/files/Jim20O'Neill20Review20on20AMR-20Final20paper-20EMBARGOED2000\_0120BST2019th20MAY.PDF//DW](http://life-worldwide.org/assets/uploads/files/Jim20O%27Neill20Review20on20AMR-20Final20paper-20EMBARGOED2000_0120BST2019th20MAY.PDF/DW)
**We estimated in our first report, published in December 2014, that in total about 700,000 people die every year from drugresistant strains of common bacterial infections, HIV, TB and malaria. This number is likely to be an underestimate due to poor reporting and surveillance. Nearly 200,000 people die every year from multidrug-resistant and extremely drugresistant tuberculosis (TB) alone2**. In India, antibiotic-resistant neonatal infections cause the deaths of nearly 60,000 new-borns each year3. A current death toll on this scale means that more than one million people have lost their lives to drug-resistant infections in the 19 months since we published our first report. Our ability to cure infections that were once considered benign is already damaged. For instance, the rapid development of drug-resistant strains of gonorrhoea combined with the fact that we do not have a rapid diagnostic test to guide doctors’ choice of prescription, means we are down to using our ‘last line’ antibiotic to treat gonorrhoea4. After this antibiotic fails, there are no more treatment options on the shelf. For other infections, doctors running out of better options are using antibiotics that were once avoided due to their bad side effects. This is the case with colistin, for example, which can cause kidney failure and so was never given to patients for many years. Over the past decade however, it has re-entered use as a last resort treatment for patients with particularly hard-to-treat Gram-negative bacterial infections5, and already colistin resistance is emerging. The economic impact is also already material. In the US alone, more than two million infections a year are caused by bacteria that are resistant to at least first-line antibiotic treatments6, costing the US health system 20 billion USD in excess costs each year7. **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.  [↑](#endnote-ref-12)