A2 AFF

Access

Topshelf

1. **Uniqueness; Aitken ’18 of the IQVIA Institute for Human Data Science writes that because of a rise in generics, drug prices are falling by 17% right now. This means that the problem they’re talking about is solving itself as competition enters the market. Prefer this evidence over affirmative evidence saying prices are rising, as Aitken continues that evidence that says prices are rising are only looking at the list price, but the increased usage of discounts and rebates have lowered the final out-of-pocket costs for the consumer.**
2. **Turn; Moore ’18 of the Heritage Foundation writes that right now, follow-on drugs are developed even when drugs are still on patent, and these new drugs introduce competition into the market, thus lowering the cost of the entire therapeutical class for consumers. Indeed, he finds that these follow-on drugs are developed in less than 2 years on average. Unfortunately, he writes that price controls would slow the development of new drugs, lowering competition and raising prices for consumers.**
3. **Turn; Shepherd ’16 of New York University writes that because innovative drugs reduce medical spending on doctor visits, hospitalizations, and other medical procedures, every additional dollar spent on innovative drugs reduces total medical spending by seven dollars.**
4. **External DA: the drug-price balloon; Mello ’18 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 ’01 of the Journal of Tropical Medicine and International Health quantifies that prices of drugs are 1 to 5% of the price in America, giving access to medicine for millions in the developing world. Unfortunately, Mello ’18 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 has two implications:

   A. **Any access argument they win is simply a tradeoff with access in the developing world, which means they have no offense here.**

B. Developing world outweighs on scope because they're significantly more exposed to lethal diseases on a much wider scale than in America.

Moore, Stephen. "Foreign Price Controls Jeopardize Global Health and Raise Drug Costs for Americans." Chief Economist at The Heritage Foundation. July 2018. https://committeetounleashprosperity.com/wp-content/uploads/2018/07/CTUP_WhitePaper_Moore_Jul2018.pdf //RJ

Developing new drugs is a costly business, requiring an average $2.6 billion of R&D spending for each new treatment that receives approval. At the same time, the drugs developed by U.S. pharmaceutical companies are truly beneficial to all global citizens, as all people are susceptible to the ailments medicines are designed to treat. To equalize the costs of drug development, **the Trump administration has proposed a series of reforms to lower drug prices for Americans**. Here's where **innovation deserves another look, because pharmaceutical R&D isn't just the key to unlocking new cures: it's also one of the main ways of reducing prices for existing drugs, by encouraging competition in the marketplace**. Conversely, while some of the White House's proposed reforms make sense, **there is a danger that lowering prices and thus profits with artificial price controls here at home will chase investment outside the U.S. and slow the development of new drugs**. In fact, **this could paradoxically raise health care costs for several reasons**. First, research has shown that **the entry of a new drug into the marketplace, often with additional benefits in the form of increased efficacy or tolerability, forces down the prices of other drugs in the same therapeutic class—even before their patents have expired**. This is because, as physicians begin to sign prescriptions for the new entrant, insurers, pharmacy benefit managers and other intermediaries take advantage of this new competitor product to negotiate better deals for existing drugs. Similarly the introduction of several "me-too" or "followon" drugs with comparable efficacy diminishes differentiation for each, reducing the price premium drug makers can demand for them.13,14,15 One of the most spectacular examples of the impact of new entrants on drug prices in recent years came in the fast-growing field of Hepatitis C treatments. Following Gilead's introduction of the breakthrough Hepatitis C cure Sovaldi in 2013, competitors rushed a number of drugs exploiting the same underlying biological mechanism to market, resulting in dramatic price drops across the entire therapeutic class. This competition has resulted in rebates and discounts ranging from about 22 percent in 2014 to about 40-65 percent today.16,17 This analysis doesn't include the overall cost savings projected from curing 2.9 million Americans with chronic Hepatitis C, including hospital stays and transplant costs, estimated at $100.3 billion in the U.S.18 Hepatitis C drugs are just one of the more dramatic cases of new entrants bringing down prices by offering cheaper alternatives in the same therapeutic class. One study found that seven new "follow-on" drugs developed to treat conditions including nonHodgkin's lymphoma, ovarian cancer, psoriasis, and Huntington's disease offered discounts over the incumbent drug ranging from 21 percent to 61 percent.19 It should be emphasized that **these price reductions were achieved without resorting to artificial price controls and while all the competing drugs still enjoy patent protections, preserving marketplace incentives for continued innovation. These beneficial effects can be achieved relatively rapidly: the average time required to develop a "follow-on" drug has fallen from nine years in the 1970s to 1.7 years today**. In fact, **it's not uncommon for competitors to develop follow-on drugs and file to begin clinical testing before the original drug has even received final FDA approval**.20

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

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

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 //RJ

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.**

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.

A2 Nonadherence

1. **Delink; Oswald ’18 of the Pharmaceutical Journal writes that half of people skip their prescriptions in developed countries, and there hasn’t been any improvement in the past 50 years. This indicates that despite price controls in the developed world, external factors prevent adherence anyways.**

Oswald, Kirby. “Non-adherence: Medicine’s Weakest Link.” The Pharmaceutical Journal. Feb. 2018. https://www.pharmaceutical-journal.com/news-and-analysis/features/non-adherence-medicines-weakest-link/20204378.article?firstPass=false //RJ

Non-adherence to prescribed medicines is one of the biggest obstacles to effective healthcare, impacting on patients, healthcare professionals, pharmaceutical companies and healthcare systems. Pharmacists are ideally placed to improve adherence, but are effective interventions available and how can pharmacists match patients to an appropriate intervention? When a pharmacist hands over a medicine to a patient, they might assume the patient will take it as instructed, but a surprising number do not. In fact, it is thought that **only around half of medicines for long-term conditions are taken as prescribed in developed countries, and there is little evidence of any improvement in adherence rates over the past 50 years**[1].

A2 Generics Monopolies Uniqueness

1. **Turn; Sullivan ’18 of Policy and Medicine writes that price controls induce drug makers to exit various markets and to stop selling. That only encourages further monopolization. For example, Tate ’02 of the HealthCare Institute of New Jersey writes price controls reduced the number of developers of childhood vaccines from 20 to 4 companies in just a few years.**
2. **The IBIS, an industry research firm, writes that the number of businesses in the generic industry has risen by 2.9% in the past 5 years, indicating that the market is not consolidating itself. That’s why the Torreya Partners ’16 quantifies that the HHI index, a widely used index to measure industry consolidation, is only 0.021, far below the threshold of 0.25 that demarcates a highly concentrated industry. Holistically, Graham ’12 of the Mackinac Public Policy writes that in 2001, the top five generic manufacturers accounted for 90% of the market, but the concentration has only declined since then, with more manufacturers entering the market than those leaving it.**

Sullivan, Thomas. “Increasing Generic Drug Shortages Linked to Government Price Controls”, Policy & Medicine, 6 May 2018, http://hinj.org/government-pricecontrols-on-prescription-drugs-may-be-more-than-patients-bargain-for/

“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. **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.”

Tate, Edward. “Government Price Controls On Prescription Drugs May be More Than Patients Bargain For”, HealthCare Institute of New Jersey, 7 Oct 2002, http://hinj.org/government-price-controls-on-prescription-drugs-may-be-morethan-patients-bargain-for/

Another even more important consideration is that **price controls stifle innovation and can lead to supply shortages in both the quality and quantity of medications**. Consider the recent flu vaccine shortage. **The largest purchaser of the vaccine is the federal Vaccines for Children Program. The program buys up nearly 70 percent of all childhood vaccines at government-set prices and then distributes them to states according to a federally-set formula.** 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. Thanks to these price controls, there now are only four developers of childhood vaccines. That's down from 20 companies just a few years ago."

Turk S. Generic Pharmaceutical Manufacturing in the US. IBIS World Industry Report, 2015 32541b. Accessed 15 Dec 2016. https://www.ibisworld.com/industry-trends/market-research-reports/manufacturing/chemical/generic-pharmaceutical-manufacturing.html //RJ

Over the past five years, the Generic Pharmaceutical Manufacturing in the US industry has grown by 1.1% to reach revenue of $60bn in 2018. In the same timeframe, the number of businesses has grown by 2.9% and the number of employees has grown by 1.0%.

Torreya Partners, "Generic Pharmaceutical Industry Yearbook." Feb. 2016. https://torreya.com/publications/generic-pharmaceutical-industry-yearbook-torreya-feb2016-gpha.pdf //RJ

It is readily apparent that the generic pharmaceutical segment is not highly concentrated. The value share of the top ten firms is less than 40% and **the largest company, Pfizer occupies only 9% of the value pie**. **A widely used measure of industry concentration and competitiveness is the Herfindahl Index** (HHI). **We compute that the global HHI Index as of February 2016 was 0.021, well below the U.S. DOJ threshold of 0.25 that demarcates a highly concentrated industry** – where caution would be exercised by antitrust authorities on horizontal mergers.

Graham, John. "The Shortage of Generic Sterile Injectable Drugs: Diagnosis and Solutions." Mackinac Center for Public Policy. June 2012. https://www.mackinac.org/archives/2012/s2012-04SterileInjectables.pdf //RJ

There is a widely held belief that there has been significant manufacturing consolidation recently. This is unfounded. Fewer than a dozen mergers occurred between 2005 and 2011, and these were small.14 Indeed, **in 2001 the top five manufacturers accounted for 90 percent of the market, and this market concentration has declined since then**.15 For generic injectable drugs overall, the number of manufacturer-drug combinations increased by 45 percent from 2006 through 2010. **In every year, the number of manufacturers entering the market with a new drug exceeded those leaving it, and manufacturers have stated plans to increase capacity.**16

A2 Insurance/Healthcare Costs Rising

1. **Uniqueness; Aitken ’18 of the IQVIA Institute for Human Data Science writes that because of a rise in generics, drug prices are falling by 17% right now. This means that the problem they’re talking about is solving itself as competition enters the market. Prefer this evidence over affirmative evidence saying prices are rising, as Aitken continues that evidence that says prices are rising are only looking at the list price, but the increased usage of discounts and rebates have lowered the final out-of-pocket costs for the consumer.**
2. **Mitigate; The Investor’s Business Daily ’18 writes that prescription drugs account for less than 10% of total health spending, and that share is identical to in 1960. Thus, Lakwadalla ’15 of the New York Times writes that imposing price controls would only shave off 2% of our total health care bill.**
3. **Uniqueness; The Investor’s Business Daily ’18 writes that recent FDA actions to accelerate the approval rates of generics is dramatically lowering drug prices for healthcare, which is why in 2016, the most recent year we have on record, the share of public spending on drugs went down.**
4. **Delink; Book ’18 of Forbes writes that government negotiations have historically failed to lower drug prices because companies simply take away discounts that they offer, thus not benefitting healthcare.**

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

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

Investor’s Business Daily. “Trump is, In fact, Taking on High Drug Prices.” Feb. 2018. https://www.investors.com/politics/editorials/drug-prices-trump-budget-medicare-price-controls/ //RJ

The Los Angeles Times, for example, reported last week that prescription drug prices are slated to climb 6.3% a year, on average, over the next decade, which is faster than overall health spending. It goes on to say that drug prices are one of the "biggest drivers" of health costs and this, in turn, has sparked "growing calls by Democrats for more government regulation of prices." But a look at

the data the Times used actually tells a much different story. **Despite all of the hue and cry about drug prices, prescription drugs account for slightly less than 10% of national health spending. That share is almost identical to where it was in 1960**, when the array of drugs available was far more limited. **And in 2016 — the last year for which the government has data — drug spending as a share of overall health spending actually dropped slightly.** Because drugs constitute a small share of the nation's health budget, holding down costs won't make much of a difference. For example, if drug spending were to climb at just 4% a year, instead of 6.3% a year, over the next decade, it would shave just 2% off the nation's health care bill in 2026. Meanwhile, the Trump administration is getting attacked because its budget plan, released last week, doesn't push to have the government set prices for Medicare drugs — something Trump himself once advocated — which would be tantamount to federal price controls on all drugs. But **Trump is tackling high drug prices. Trump's FDA** administrator, Scott Gottlieb, **is focused on increasing price-lowering market competition**. Gottlieb understands that **the more choices there are, the more price competition there will be. So he's pushed the agency to shorten approval times for generics, particularly when there's only one generic alternative on the market**. He's also working to streamline the FDA's approval process for new drugs, and lifting the FDA's prejudice against so-called me-too drugs. **This sort of competition is already working. A few years ago, price-control advocates pointed to Sovaldi, a breakthrough drug that can cure hepatitis C but cost $80,000 to administer, as the poster child for price controls.** Instead, the FDA last year fast-tracked approval of a second hepatitis C drug — Mavyret — which cost less than a third of Sovaldi. Suddenly, there was a price war for Hep C treatments. Competition, not price controls, cut costs overnight. **By boosting competition, Trump will be far more effective at lowering dug costs than any regime of federal price controls could ever hope to be.**

Darius **Lakdawalla** is the Quintiles professor of pharmaceutical development and regulatory innovation in the School of Pharmacy at the University of Southern California, **2015**, New York Times, https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-end-up-costing-patients-their-health Drug Price Controls End Up Costing Patients Their Health

On the other side of the ledger, **drug price controls would not save that much money. According to federal government data, prescription drug spending makes up roughly one-tenth of America's total bill for health care. Lopping 20 percent off drug prices by negotiating prices would thus shave all of 2 percent off our total health care bill. What's more, we will enjoy only a one-time cost reduction, because drug spending has been growing no faster than overall health care spending over the past 10 years.**

Book, Robert. "Should the Federal Government Negotiate Drug Prices?" Forbes. 2018. https://www.forbes.com/sites/theapothecary/2018/01/24/should-the-federal-government-negotiate-drug-prices/#58de8e6e1bb9 //RJ

Anyone familiar with federal and state governments' track record in saving money through negotiations should immediately be skeptical of this sort of proposal. Cost over-runs in military procurement are legendary, and higher prices for government-negotiated prices for infrastructure projects go back at least two centuries, to the contract for the Erie Canal in the early 1800s. **In the case of pharmaceuticals, the record is no better**, and quite possibly worse. **In 1990, Congress pass a law requiring Medicaid programs to get the best prices for prescription drugs offered to any private payer**, or 15 percent off list price, whichever was lower – **and estimated that the federal and state governments would save $3.3 billion over five years** by getting the best discounts any private payers had been getting. **Faced with the options of giving deep discounts to the then-largest single buyer of prescription drives, or offending smaller entities payers by revoking their discounts, drug**

companies responded by reducing discounts overall. The Medicaid savings never really materialized, and private payer discounts dropped to – guess what, about 15 percent off list price

A2 Innovation

A2 Reference Pricing

1. **Tosini of the European School of Management and Technology writes that reference pricing also hurts innovation in a few ways:**
   A. **Reference pricing creates an incentive to avoid markets where there is high demand but also high competition, which means that they only focus on small markets with not many people being affected, neglecting large populations of people who need drugs.**
   B. **Pharmaceutical companies are more likely to cancel projects at later stages of the development process if they perceive that there is a high probability that another firm will launch a product to treat the same disease before them, resulting in sunk investment being wasted due to reference pricing.**
   C. **Reference pricing still lowers innovation because firms cannot predict that they will be the first to develop the new drug, so they expect a lower return on their investment.**

Tosini, Nicola. "An Economic Assessment of the Relationship between Price Regulation and Incentives to Innovate in Pharmaceutical Industry." European School of Management and Technology. N.d. http://static.esmt.org/publications/whitepapers/WP-109-03.pdf //RJ

Under the more lenient form of internal price referencing a similar situation will occur because the later-in-class drug is able to set its price freely as long as it is protected by patents. However, under the more stringent version of Internal Reference Pricing, **the price of the later-in-class drug will be constrained to the price of the generic as soon as the first-in-class drug goes off patent**. **This will substantially reduce the price that the owner of the later-in-class drug can charge, particularly in the case where it is able to convince medical practitioners that its drug has significant benefits relative to the firstin-class drug but it cannot convince the government health insurer that its drug is highly innovative.** This means that under the more stringent form of Internal Reference Pricing, the producer of a later-in-class drug will earn a significantly lower ROI over the product's life span than under market-based pricing.

Tosini, Nicola. "An Economic Assessment of the Relationship between Price Regulation and Incentives to Innovate in Pharmaceutical Industry." European School of Management and Technology. N.d. http://static.esmt.org/publications/whitepapers/WP-109-03.pdf //RJ

The incentive to avoid indications with a high degree of competition and to invest in indications that are not well served also exists under market-based pricing. However **the response to Internal Reference Pricing is likely to go beyond the level of product differentiation that would be usual with market-based pricing**. **It will instead lead firms to strategically avoid whole indications for which there is high aggregate demand but also high competition.** This means that, **rather than innovation leading to a range of differentiated products in a particular indication, each of which treats different patients with varying degrees of effectiveness, there is likely to be less innovation in drugs to treat indications with high**

expected demand and more innovation in drugs to treat areas with low expected demand. A related response to Internal Reference Pricing is that **pharmaceutical firms investing in indications with high expected demand are also more likely to cancel projects at later stages of the development process when they discover that there is a higher-than expected probability that another firm will launch a product to treat the same therapeutic indication before them**. This is because the realization that the firm will be later in class significantly lowers the expected return to further investment. Moreover, because **this realization typically does not happen until later in the R&D process** (for instance, at the time of entering Phase III trials) **it means that otherwise-worthwhile projects are more likely to be abandoned and the sunk investment wasted under Internal Reference Pricing.** This is an aspect of Internal Reference Pricing on which particular attention is drawn in our dynamic model of development and launch decisions—contained in Section 5 of this report.

Tosini, Nicola. "An Economic Assessment of the Relationship between Price Regulation and Incentives to Innovate in Pharmaceutical Industry." European School of Management and Technology. N.d. http://static.esmt.org/publications/whitepapers/WP-109-03.pdf //RJ

The effect of Internal Reference Pricing on the overall level of innovation depends on how the government health insurer implements the scheme. If the provider simply keeps the money that it saves on later-in-class drugs under internal price referencing, and does not compensate first-in-class innovations anymore, then **internal price referencing is likely to result in a lower level of innovation overall. Because pharmaceutical firms cannot predict whether they will be first or later-in-class in areas where there is likely to be competition, they will expect a lower return on investment in those areas.** They will respond to this by redirecting their investment to areas with less likely competition, but unless they completely redirect their investments to areas where they are guaranteed being first-in-class they will still expect to earn less across all their projects. **As a consequence, they are likely to reduce their investment in R&D and there is likely to be less innovation overall.**

A2 Smart Innovation

A2 NEG

A2 Innovation (General)

1. **Delink; Smith ’18 of Undark writes that the cost to bring a new drug to market increases at 9% each year, doubling every 8 years. This is because Stott ’17 of Endpoints News writes that since we’ve already cured all the easy diseases to cure, the remaining ones cost significantly more to cure to the point of unprofitability. Thus, Fleming ’18 of Forbes concludes that every single analyst agrees that R&D will be completely unprofitable by 2020 for private firms.**
2. **Turn; Frank ’17 of the Brookings Institute writes that the vast majority of new drugs being developed are going into markets that already have five or more products. Indeed, Young ’01 of Public Citizen quantifies that 78% of new drugs being developed are these copycat drugs that don’t have any tangible benefit to society. However, affirming would incentivize a diversification of investment into new drugs. Herper ’14 of Forbes writes that high prices incentivize companies to always prefer developing copycat drugs rather than new, innovative drugs because of higher risk for the novel drugs. Logically, price controls would solve this because it creates an incentive for companies to enter new markets where they are the only seller rather than compete in copycat drug markets where prices are capped.**
3. **Delink; Mazz ’13 of New Scientist writes that 75% of new, innovative drugs come from the public sector, despite a meager budget of $30 billion each year.**

Stott, Kelvin. “Pharma’s Broken Business Model: An Industry on the Brink of Terminal Decline.” Nov. 2017. Endpoints News. https://endpts.com/pharmas-broken-business-model-an-industry-on-the-brink-of-terminal-decline/?fbclid=IwAR1hKD7_dP-b6E60gZTUOtl2uP5dhvUT4cfd1ulbatpscJxyILaAFFv3cxQ //RJ

As each new drug improves the current standard of care, this only raises the bar for the next drug, making it more expensive, difficult and unlikely to achieve any incremental improvement, while also reducing the potential scope for improvement. **Thus, the more we improve the standard of care, the more difficult and costly it becomes to improve further, so we spend more and more to get diminishing incremental benefits and added value for patients which results in diminishing return on investment**, as illustrated here:

Smith, Drew. “We Have Reached Peak Pharma. There’s Nowhere to Go But Down.” Jan. 2018. https://undark.org/article/peak-pharma-drug-discovery/ //RJ

The number of protein molecules that are plausible drug targets is large, but far from infinite.
Each of these proteins is encoded by a gene; one of the surprises of human genomics is just how few protein-coding genes there are. Pre-genome

estimates assumed that creatures as complicated and exquisite as humans could not possibly be specified by less than a hundred thousand genes. The true number is closer to 19,000, a bit fewer than small worms that live in the soil. **The number of proteins encoded by these genes that have anything to do with disease is much smaller, amounting to perhaps a thousand in total. Of these, more than half have already been "mined" by pharma: a current estimate is that our pharmacopeia targets 555 proteins in total.** If we knew nothing else about drug discovery and development, we would know that the pace of new drug introduction is bound to decline. But we do know a good deal more. **We know that the rate of new drug approval (about 27 per year) has held steady for the past two decades, with no sign of a bump from genomics. And we know that the clinical value of these new drugs is shrinking, even as the search and exploitation of new targets intensifies. We know that the cost of bringing each of these new drugs to market increases at an exponential rate. Indeed this rate, 9 percent per year, is so steady, persisting unchanged through different regulatory regimes and new technological advances, that it has been given a name: "Eroom's Law"(Moore's law in reverse). Nine percent may not sound like much, but it means that costs double every 8 years.** In less than a decade, the cost of a new drug approval, now $2.6 billion, will be at $5 billion. In 16 years, it will be $10 billion. The dynamics of this decline are precisely those of a gold mine. The fist-sized nuggets have all been found, the gravel and sand is getting more expensive to recover, and soon there will be nothing but dust. Knowing this, you don't have to have a degree in economics to figure out that the day will come when the average new drug candidate is a money loser. That day has already arrived for some drugs. Britain's Office of Health Economics calculates that the value of new antibiotic candidates is negative $45 million. **Pharmaceutical companies figured this out several years ago and most have eliminated their antibiotic R&D programs. Other R&D programs are on the chopping block.**

Smith, Drew. "We Have Reached Peak Pharma. There's Nowhere to Go But Down." Jan. 2018. https://undark.org/article/peak-pharma-drug-discovery/ //RJ

Get used to this. **Moderately-priced mass-market drugs will disappear. Or rather, they will go off-patent and become generics. With no R&D expenses to recoup, they will become cheap commodities, costing a few dozen or hundred dollars per treatment.** New drugs, especially those protected from competition by the Orphan Drug Act, will cost hundreds of thousands of dollars per year. Don't be surprised when the first million-dollar treatment hits the market. These developments are no kind of tragedy — drugs cannot do much moreto lengthen human lifespan. Nor are these developments the result of a conspiracy or of unusual levels of greed. They are just the end-stage of the depletion of a resource.

Fleming, Standish. "Pharma's Innovation Crisis, Part 1: Why the Experts can't fix it." Forbes. 2018. https://www.forbes.com/sites/stanfleming/2018/09/06/why-experts-cant-fix-pharmas-innovation-crisis-part-1-and-what-to-do-about-it-part-2/#64b0cfe816fe //RJ

Dr. Stott bases his assessment on a number of charts on productivity, all pointing emphatically down and to the right. **R&D returns in drug development currently stand at 3.2% and could reach 0 in 2020, meaning that a dollar would return a dollar—i.e. no profit. And there is no reason to believe the decline should stop there. The data correlates with the observation of virtually every serious researcher who has looked at the industry.** The data are alarming—an industry that destroys investor value faces a dim future. Yet, when Dr. Stott proceeds from data to diagnosis and then to prescription, he fails to come up with a credible action plan. His study may be mathematically accurate, but his conclusions are based on faulty assumptions. As a result, they are misleading. He diagnoses the problem as a failure of technology and so looks for a science-based solution to the innovation crisis. What he finds provides no way out of the dilemma. **Failing productivity seems like a strange problem in an industry that generates more cash than it can deploy, enjoys unlimited demand and wields monopolistic pricing power. But pharma is not a "normal" business. Each new drug, each clinical trial is an experiment. Development is inherently unpredictable, as reflected in a success rate of 2%** (8% approval rate X 25% commercial success rate for small-molecule therapeutics), far worse than that offered by that notorious destroyer of value, Las Vegas. **As a result, biopharma companies cannot increase**

productivity by simply making more drugs. The current business model does not scale. Costs rise faster than expected returns. While most drug developers readily acknowledge the problem, they ignore it in running their businesses. The results are reflected in Dr. Stott's charts.

Frank, Richard. "Pharmaceutical Industry Profits and Research & Development." Brookings Institute. Nov. 2017. https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2017/11/17/pharmaceutical-industry-profits-and-research-and-development/ //RJ

A third conclusion has recently emerged but it reflects only one research effort. Using changes in market size stemming from insurance expansion, Dranove and colleagues examined both the number of new drugs brought to market and the degree to which new drugs are "truly innovative," as measured by being aimed at an under treated illness or being rated by the U.S. Food and Drug Administration (FDA) as high priority. Like prior **researchers**, they **found that** as markets grow the number of new products increases; **the vast majority of increases occur in markets where there are already five or more products being sold.** Dranove and colleagues **found no meaningful increases in the number of drugs rated by the FDA as high priority as market size grew.**

Young, Bob. "Rx R&D Myths: The Case Against the Drug Industry's R&D Scare Card." Public Citizen. 2001. https://www.citizen.org/sites/default/files/rdmyths.pdf //RJ

Drug industry R&D does not appear to be as risky as companies claim. In every year since 1982, the drug industry has been the most profitable in the United States, according to Fortune magazine's rankings. **During this time, the drug industry's returns on revenue (profit as a percent of sales) have averaged about three times the average for all other industries represented in the Fortune 500. It defies logic that R&D investments are highly risky if the industry is consistently so profitable and returns on investments are so high. Drug industry R&D is made less risky by the fact that only about 22 percent of the new drugs brought to market in the last two decades were innovative drugs that represented important therapeutic gains over existing drugs. Most were "me- too" drugs, which often replicate existing successful drugs.** (See Section VI)

Science Daily, "Potential Solutions to Drug Shortages and the Lack of Competition in Generic Medicines." Aug. 2018. https://www.sciencedaily.com/releases/2018/08/180809112443.htm //RJ

Increasing incentives and modifying regulations to improve competition. Financial incentives should be considered in order to entice new companies to enter a small market, as should reduced regulatory barriers to avoid deterring new competitors. Increasing competition in this way spreads out drug manufacturing, which adds redundancy and protects against price hikes. **Reasonable drug price controls may also act as a safety net for when normal market mechanisms fail and may help curb the out-of-control rate increases in health care costs.** It also aligns the United States with other industrialized countries successfully using price control strategies. Redirect overinvestment in new drug development to the generic drug market to foster competition. **The race to develop new, but rarely superior, drugs ultimately draws resources away from the high-value generic drug market**. **Three general strategies to address this problem include: dis-incentivizing overuse of high-cost, low-value brand drugs**; incentivizing the use of low-cost, high-value generic drugs (reducing co-payments); and/or ensuring access to rare high-cost, high-value breakthrough drugs that do not have a generic peer.

Matthew Herper, Forbes, 10-23-2014 Could High Drug Prices Be Bad For Innovation?, https://www.forbes.com/sites/matthewherper/2014/10/23/could-high-drug-prices-be-bad-for-innovation/, 10-30-2018

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.

Mariana Mazz, "State of innovation: Busting the private-sector myth", N.S. News, August 21, 2013, https://www.newscientist.com/article/mg21929310-200-state-of-innovation-busting-the-private-sector-myth/, SP, October 14, 2018

The examples don't just come from the military arena, either. **The US National Institutes of Health spends around $30 billion every year on pharmaceutical and biotechnology research and is responsible for 75 per cent of the most innovative new drugs annually**. Even the algorithm behind Google benefited from US National Science Foundation(NSF) funding.

A2 Innovation (Biotech / Venture Capital)

1. **Delink; Smith ’18 of Undark writes that the cost to bring a new drug to market increases at 9% each year, doubling every 8 years. This is because Stott ’17 of Endpoints News writes that since we’ve already cured all the easy diseases to cure, the remaining ones cost significantly more to cure to the point of unprofitability. Thus, Fleming ’18 of Forbes concludes that every single analyst agrees that R&D will be completely unprofitable by 2020 for private firms.**
2. **Delink; Lutz ’17 of Medical Express writes that venture capitalists have already fled the biotech industry because it’s simply more profitable to invest in other industries that are much lower risk. Indeed, Mukherjee ’15 of Biopharma Drive corroborates that there were 40% fewer venture investors for biotech in 2013 than in 2007.**
3. **Delink; Mukherjee ’15 of Biopharma Drive writes that the majority of VC funding goes to small diseases that hardly affect anybody, ignoring the large population diseases that kill the majority of the people.**

Stott, Kelvin. “Pharma’s Broken Business Model: An Industry on the Brink of Terminal Decline.” Nov. 2017. Endpoints News. https://endpts.com/pharmas-broken-business-model-an-industry-on-the-brink-of-terminal-decline/?fbclid=IwAR1hKD7_dP-b6E60gZTUOtl2uP5dhvUT4cfd1ulbatpscJxyILaAFFv3cxQ //RJ

As each new drug improves the current standard of care, this only raises the bar for the next drug, making it more expensive, difficult and unlikely to achieve any incremental improvement, while also reducing the potential scope for improvement. **Thus, the more we improve the standard of care, the more difficult and costly it becomes to improve further, so we spend more and more to get diminishing incremental benefits and added value for patients which results in diminishing return on investment**, as illustrated here:

Smith, Drew. “We Have Reached Peak Pharma. There’s Nowhere to Go But Down.” Jan. 2018. https://undark.org/article/peak-pharma-drug-discovery/ //RJ

The number of protein molecules that are plausible drug targets is large, but far from infinite. Each of these proteins is encoded by a gene; one of the surprises of human genomics is just how few protein-coding genes there are. Pre-genome estimates assumed that creatures as complicated and exquisite as humans could not possibly be specified by less than a hundred thousand genes. The true number is closer to 19,000, a bit fewer than small worms that live in the soil. **The number of proteins encoded by these genes that have anything to do with disease is much smaller, amounting to perhaps a thousand in total. Of these, more than half have already been “mined” by pharma: a current estimate is that our pharmacopeia targets 555 proteins in total.** If we knew nothing else about drug discovery and development, we would know that the pace of new drug introduction is bound to decline. But we do know a good deal more. **We know that the rate of new drug approval (about 27 per year) has held steady for the past two decades, with no sign of a bump from genomics. And we know that the clinical value of these**

new drugs is shrinking, even as the search and exploitation of new targets intensifies. We know that the cost of bringing each of these new drugs to market increases at an exponential rate. Indeed this rate, 9 percent per year, is so steady, persisting unchanged through different regulatory regimes and new technological advances, that it has been given a name: "Eroom's Law"(Moore's law in reverse). Nine percent may not sound like much, but it means that costs double every 8 years. In less than a decade, the cost of a new drug approval, now $2.6 billion, will be at $5 billion. In 16 years, it will be $10 billion. The dynamics of this decline are precisely those of a gold mine. The fist-sized nuggets have all been found, the gravel and sand is getting more expensive to recover, and soon there will be nothing but dust. Knowing this, you don't have to have a degree in economics to figure out that the day will come when the average new drug candidate is a money loser. That day has already arrived for some drugs. Britain's Office of Health Economics calculates that the value of new antibiotic candidates is negative $45 million. **Pharmaceutical companies figured this out several years ago and most have eliminated their antibiotic R&D programs. Other R&D programs are on the chopping block.**

Smith, Drew. "We Have Reached Peak Pharma. There's Nowhere to Go But Down." Jan. 2018. https://undark.org/article/peak-pharma-drug-discovery/ //RJ

Get used to this. **Moderately-priced mass-market drugs will disappear. Or rather, they will go off-patent and become generics. With no R&D expenses to recoup, they will become cheap commodities, costing a few dozen or hundred dollars per treatment.** New drugs, especially those protected from competition by the Orphan Drug Act, will cost hundreds of thousands of dollars per year. Don't be surprised when the first million-dollar treatment hits the market. These developments are no kind of tragedy — drugs cannot do much moreto lengthen human lifespan. Nor are these developments the result of a conspiracy or of unusual levels of greed. They are just the end-stage of the depletion of a resource.

Fleming, Standish. "Pharma's Innovation Crisis, Part 1: Why the Experts can't fix it." Forbes. 2018. https://www.forbes.com/sites/stanfleming/2018/09/06/why-experts-cant-fix-pharmas-innovation-crisis-part-1-and-what-to-do-about-it-part-2/#64b0cfe816fe //RJ

Dr. Stott bases his assessment on a number of charts on productivity, all pointing emphatically down and to the right. **R&D returns in drug development currently stand at 3.2% and could reach 0 in 2020, meaning that a dollar would return a dollar—i.e. no profit. And there is no reason to believe the decline should stop there. The data correlates with the observation of virtually every serious researcher who has looked at the industry.** The data are alarming—an industry that destroys investor value faces a dim future. Yet, when Dr. Stott proceeds from data to diagnosis and then to prescription, he fails to come up with a credible action plan. His study may be mathematically accurate, but his conclusions are based on faulty assumptions. As a result, they are misleading. He diagnoses the problem as a failure of technology and so looks for a science-based solution to the innovation crisis. What he finds provides no way out of the dilemma. **Failing productivity seems like a strange problem in an industry that generates more cash than it can deploy, enjoys unlimited demand and wields monopolistic pricing power. But pharma is not a "normal" business. Each new drug, each clinical trial is an experiment. Development is inherently unpredictable, as reflected in a success rate of 2%** (8% approval rate X 25% commercial success rate for small-molecule therapeutics), far worse than that offered by that notorious destroyer of value, Las Vegas. **As a result, biopharma companies cannot increase productivity by simply making more drugs. The current business model does not scale. Costs rise faster than expected returns.** While most drug developers readily acknowledge the problem, they ignore it in running their businesses. The results are reflected in Dr. Stott's charts.

Lutz, Diana. "Researcher Says pharma industry's ability to deliver new drugs may be coming to an end." Medical Express. January 12, 2017. https://medicalxpress.com/news/2017-01-pharma-industry-ability-drugs.html // RH

Kinch repeatedly emphasizes that decisions like these are rational and not based on "dark motivations." And the point of the book is really that the high cost of bringing a new drug to market ($2.6 billion) is largely the unintended consequence of the desire to make

sure drugs are safe. By chapter 10, the author is describing how such **high costs led pharmaceutical companies to cut costs, dismantled their own research and development wings but were forced to replenish their drug pipelines by buying one another and then biotechnology start-ups.** Altogether, Kinch says, the biotechnology sector was responsible for more than two-thirds of all new medicines in the past decade. But Kinch says this finesse is already failing. **The number of successful biotech companies peaked at 141 in 2000 and had fallen to 60 by the end of 2014. It is simply easier and less risky for venture capitalists to invest in two guys in a garage writing code, says Kinch, than in a large, complex biotech lab. As a result, the entire industry, Kinch says, may be "fading to black."** To make sure the reader understands the stakes, Kinch mentions three looming crises in drug therapy. One is antibiotic resistance, which, some experts say, will break the surface and come to widespread public notice. in 2017. A similar problem, but one that has received less attention, is the emergence of resistance to AIDS drugs. One in five AIDS patients had a virus that was resistant to at least one component of the current drug cocktail, Kinch says. Seven of the 10 companies that successfully developed AIDS drugs have dropped research in this area. And then there is Alzheimer's. **Fully 99.6 percent of experimental drugs designed to treat Alzheimer's failed in clinical trials, according to a 2015 report that Kinch cites. Many pharmaceutical companies, not surprisingly, have reduced or completely eliminated programs that had been focused on Alzheimer's disease and other neuroscience indications.**

Mukherjee, Sy. “How VC funding for biotech has fundamentally changed—and what it means for the industry.” Biopharma Dive. June 2015. https://www.biopharmadive.com/news/how-vc-funding-for-biotech-has-fundamentally-changedand-what-it-means-for/399988/ //RJ

Between 2004 and 2008, VC firms invested $21.5 billion in biotech drug R&D. Over the next five-year period, that figure fell 21% to $16.7 billion, according to a report by the Biotechnology Industry Organization (BIO). **Perhaps the most striking shift between 2008 and 2013**, other than the considerably lower level of overall funding, **has been the therapeutic areas that are no longer receiving as much funding.** "**The big takeaway for me, which we didn't expect going in to this [study], was the drastic drop in the large population diseases**," said David Thomas, CFA and one of the two co-authors of the BIO analysis in a telephone interview with BioPharma Dive. "So, the diabetes, endocrinology, gastrointestinal, respiratory, and cardiovascular areas. "**When we looked at before the financial crisis and after, for those numbers to be down 50% or more for a lot of them, was very surprising**. We instinctively knew there was a lot more interest in rare disease companies and platform companies, etc. But the degree to which there's been a decrease [for those major therapeutic areas] was pretty staggering."

Mukherjee, Sy. “How VC funding for biotech has fundamentally changed—and what it means for the industry.” Biopharma Dive. June 2015. https://www.biopharmadive.com/news/how-vc-funding-for-biotech-has-fundamentally-changedand-what-it-means-for/399988/ //RJ

There's also a significantly lower number of VC firms specializing in biotech in general now compared to a decade ago. "**Venture capital really started to leave the life sciences in 2008**," said Thomas. "**There were 40% fewer venture investors in the field in 2013 versus 2007. Basically, what happened was a lot of investors that aren't necessarily hardcore life sciences investors, that weren't fully committed to biotech funds, said in 2008 and 2009, 'We're not going to take on the risk of funding drug developers, we're going to focus our efforts elsewhere.'"**

A2 Shortages

1: Graham ’12 – if it were true that price controls resulted in shortages, shortages would be permanent, not episodic. However, the fact that suppliers clean up manufacturing and re-enter indicates that price controls aren’t causing the shortages.

Graham, John. “The Shortage of Generic Sterile Injectable Drugs: Diagnosis and Solutions.” Mackinac Center for Public Policy. June 2012. https://www.mackinac.org/archives/2012/s2012-04SterileInjectables.pdf //RJ

Government intervention in setting prices might have some impact on drugmakers’ willingness to produce generic injectable **drugs. The evidence is not convincing, however, especially considering the episodic nature of the shortages**. **If government intervention in pricing were the dominant cause, we would expect to see suppliers quit the market for good, not just clean up their manufacturing and re-enter.**

A2 Developing Nations

1. **Gehrke ’12 – less pricey medicine would not improve medical care in developing nations because there are external factors such as a lack of health infrastructure, doctors, and supply.**
2. **Ford ’01 of the Journal of Tropical Medicine and International Health writes that the pricing policy of pharmaceutical companies is not set according to the purchasing power of different countries, but based on a strategy to maximize profit, thus resulting in a widened health gap between the rich and poor.**
3. **Ford ’01 of the Journal of Tropical Medicine and International Health writes that voluntary price reductions have not been systemic, but appear to be a public relations response to political pressure.**
4. **Cox ’13 of Vice writes that America’s pharmaceutical companies use evergreening to stop companies in the developing world from producing the same drugs.**
5. **Pinheiro ’08 of the NIH writes that drugs that are donated are often expired and don’t meet the recipients’ real needs. That actually results in the developing countries needing to spend more to dispose of the drugs as waste, which ultimately harms the developing world.**

Gehrke, Mirjam. “Pharmaceutical Industry Neglects Developing Nations.” DW News. Oct. 2012. https://www.dw.com/en/pharmaceutical-industry-neglects-developing-countries/a-16331939 //RJ

Prices for new drugs, in particular, are "totally exorbitant," says Christian Wagner-Ahlfs of the BUKO pharmaceutical campaign: "It is a major problem that the companies do not reveal their actual research costs, so the prices are difficult to control." The Federal Coordination of Internationalism, or BUKO, unites 130 German action and solidarity groups that work for the benefit of developing nations. The campaign was started with the aim of examining the activities of the German pharmaceutical industry in Third World countries. **Less pricey medicine alone would not improve medical care in developing countries**, however, says Norbert Gerbsch, deputy managing director of the Federation of German Industry (BPI). Gerbsch told Deutsche Welle he considers it their responsibility, too: "**That is a challenge that can only be solved by development. There is not only a lack of inexpensive medicine in these countries; they also lack health infrastructure, such as doctors, logistics, supply, drugstores and diagnoses**," he says. "It is a challenge that addresses all of society. Such deficits cannot be corrected ad hoc." Hunger and malnourishment also promote diseases, such as diarrhea, pneumonia and malaria, the BPI expert adds.

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

The pricing policy of pharmaceutical companies is not set according to the purchasing power of the different countries, but follows a general strategy of maximizing profit. Originator's drug prices are often equal, or more expensive, in developing countries than in rich countries. Such a profit-driven pricing policy further widens the health gap between the rich and the

poor. In many cases, more affordable drugs are produced by the generic industry, even for the most recent drugs. However, decisionmakers often do not have the information they need to identify manufacturers who can supply these drugs. They require easier access to comparative, updated prices.

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

Voluntary lowering of prices by the pharmaceutical companies for low-income countries is a promising strategy. Some aspects and regulations, such as preventing lower-priced drugs from flowing back into high-income markets, the scope of these reductions in terms of populations covered, diseases, and rate of discount applied, require further elaboration. But **thus far voluntary price reductions for HIV/AIDS drugs have not been systematic; rather, they appear to have largely been a public relations response to political and international public pressure.**

Cox, Joseph, "Surprise! Big Pharma Don't Want Developing Countries Having Access to Cheap Medicine", October 2013, Vice. https://www.vice.com/da/article/8g344x/american-lobbyists-are-fighting-to-halt-the-availability-of-affordable-medicine-to-the-3rd-world //KV

However, aggressive lobbying from US pharmaceutical companies is set to change all that. **America's pharmaceutical plutocrats are attempting to revise intellectual property laws in India, meaning that many people seeking treatment will be forced to buy expensive US imports instead of domestically produced replicas**. Which obviously isn't great news for the 96.9 percent of citizens living with less than $5 (£3) a day. **In most drug-producing countries that aren't India, once a drug has been developed and a first patent filed and granted, pharmaceutical companies then engage in a practice called "evergreening". That practice basically involves undermining access to affordable medicines by using a variety of tactics to extend the company's monopoly on the drug past its initial 20-year patent period. By obtaining multiple secondary patents, often for trivial modifications to the original, companies are able to protect their product for decades, preventing production of cheaper generic replicas.** Because Indian patent law forbids evergreening, the country's generic pharmaceutical companies have been able to produce affordable versions of foreign medicines to suit their nation's income. But it's that law that's coming under pressure from the US government and international drug companies, with both institutions wanting India to allow evergreening, therefore further tightening the companies' grasp on drug monopolies. That, of course, means that low-cost generic medicines will simply disappear, leaving India's sick the choice of whether to submit to severe poverty in order to raise the cash for US imports, or forego treatment altogether. Either way, India loses.

Pinheiro, Cristina. "Drug Donations: What Lies Beneath." National Institutes of Health. 2008. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2649461/ //RJ

Recent accounts of emergency relief operations throughout the world reveal that **all major donations of pharmaceuticals fail to meet the recipients' real needs**.[3] **The inappropriateness of drug donations comes primarily from their origin** (industry surpluses, free medical samples, drugs collected by independent organizations or returned to pharmacies for disposal). Some **drugs arrive unsorted and labelled in languages unknown to the professionals in the field. Expired drugs (at the time of their arrival) and drugs close to expiry still comprise a large proportion of donations from** nongovernmental organizations, **corporations**, pharmaceutical industries and associations.[4] This practice is defended by a sad assertion that making use of expired, partially degraded drugs is better than having none at all. It obviously raises an ethical issue about the existence of first-hand/first-class drugs and second-hand/lower-class drugs and a disturbing division between the rights and worth of different populations. **Drug donations provide benefits such as tax deductions and are a very convenient way for industries to get rid of stagnant stocks without having to pay for their controlled and expensive destruction in their country of origin**.[5] **Some entities seem to find it**

legitimate to send unusable drugs to nations which are not prepared to dispose of them safely and properly. The recipients receive the drugs as donations and instead are obliged to manage them as waste. Lamentably, there is no international convention to regulate the transfer of non-requested pharmaceutical products and surpluses across borders. Once received into a country, the donations cannot be returned to donors, as recommended by the guidelines, because they are considered hazardous cargo and their shipment must respect the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal.[6] This legal demand involves the existence of consented protocols between exporters and importers, and time-consuming procedures that severely compromise its feasibility. Therefore, we can clearly say that **drug donations are not for free and most of the time their costs to the recipient countries surpass the very fair value of the donations**. If the recipients have to pay more (for something they do not need and did not ask for) than they would by just purchasing the medicines and equipment needed, then what good are the donations?

Till, Brian. “How Drug Companies Keep Medicine Out of Reach.” The Atlantic. May 2013. https://www.theatlantic.com/health/archive/2013/05/how-drug-companies-keep-medicine-out-of-reach/275853/ //RJ

Bill Gates, speaking to the Royal Academy of Engineers in London last March, managed to capture the problem that Love's idea would be leveled against: "**Our priorities are tilted by marketplace imperatives**," Gates said. "**The malaria vaccine, in humanist terms, is the biggest need, but it gets virtually no funding**. If you are working on male baldness or the other things you get an order of magnitude more researching funding because of the voice in the marketplace." **This fact -- that research-based pharmaceutical companies focus on the most lucrative products, rather than the most needed -- is particularly damning for the global poor, whose diseases will never be profitable enough to attract the industry.** The WHO has recognized 17 such diseases, known as either type III or neglected tropical diseases (NTDs). Almost all of them edge on biblical in both scope and horror. "**The needs are pervasive because these diseases have been so understudied**," said Peter Hotez, the founding dean of the National School of Tropical Medicine at Baylor University. "Look at a disease like hook worm infection. Well we now know that single dose mebemindizole doesn't work against Nacator americanus, which is the major hookworm. Why is that? We really don't know," Hotez said. "The WHO I think did us a disservice a few years back when they coined the term 'tool ready' versus 'tool deficient' diseases. All neglected tropical diseases are tool ready, and those same diseases are tool deficient," Hotez said, meaning **drugs exist to fight all of the conditions, but many are met by severe resistance and others are poorly adapted for low-resource settings.**

Anderson, Angela. “Global Pharmaceutical Patent Law in Developing Countries- Amending TRIPS to Promote Access for All.” University of Tulsa. 2006. https://sites.hks.harvard.edu/m-rcbg/fellows/T_Christian_Study_Group/Overview/Global_Pharmaceutical_Patent_Law_in_Developing_Countries.pdf //RJ

The major complaint concerning current international patent law is the imbalance between rights of the pharmaceutical companies and the lack of obligation to provide access to essential medicines.9 **Despite the assurance from the developed countries that the global patent system is a stimulant for pharmaceutical innovation, research, and development; in reality, this innovation, research, and development is almost exclusively confined to the private sector and areas of profitable return.10 Therefore, in developing countries with relatively small commercial markets and low levels of disposable income, there is very little incentive for pharmaceutical companies to conduct extensive research and development in creating drugs for life-threatening diseases limited mostly to the developing world.11 Only 1% of the 1,400 new medicines created in the last 25 years were developed for the treatment of tropical diseases (AIDS, malaria, tuberculosis, etc.), despite tropical diseases killing tens of thousands of people each year**.12 Tropical diseases are almost entirely confined to the developing world and again, do not represent a profitable market for the pharmaceutical industry.13 The developed country argument that patent protection facilitates innovation and thereby improves overall world health is rebutted with data showing that although patent protection has increased over the last 20 years, the drug innovation rate has fallen and the number of drugs with little or no

therapeutic gain has increased.14 “Essential medicines are not a luxury whose availability can be left to private market forces only, but an essential component of the fulfillment of the right to health.”15

Robert, Adam. “Drug donations are great, but should Big Pharma be setting the agenda?” Apr. 2013. The Guardian. https://www.theguardian.com/world/2013/apr/29/drug-company-donations-bigpharma //RJ

Take drug donations. **While giving people free medicine might seem a sure-fire winner for corporate PR and the world's poor, some practitioners have reservations.** Firstly, **donations may focus the public health community on interventions for which companies have cures – albeit donated ones – without sufficient consideration of cost effectiveness, opportunity cost or prioritisation. Such factors are relevant, as free donations can lock governments and donors into particular programmes which they later have to fund themselves.**

Levy, Moshe. “The Pricing of Breakthrough Drugs: Theory and Policy Implications.” 2014. National Institute of Health. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4244177/

Figure 2 implies that a small change in price relative to the monopolistic price has a first-order effect on consumer surplus and the number of patients using the drug, but only a second-order effect on revenues. From this perspective it is clear that some amount of price regulation is socially desirable. Of course, the practical question is how much regulation is not too much? If a price cap is set too low, this may have a drastic influence on revenues, stifling all R&D incentives for the pharmaceutical companies. Tables 1 and and22 present some quantitative results regarding this issue. Table 1 reports **the effects of imposing a price cap which is 20% lower than the monopolistic price** (An external file that holds a picture, illustration, etc. Object name is pone.0113894.e074.jpg), for various different drugs (different values of h). **This amount of regulation leads to a decrease in revenues of only about 1%, but to an increase in surplus of about 10%.** The magnitude of An external file that holds a picture, illustration, etc. Object name is pone.0113894.e075.jpg is about 25 times the magnitude of An external file that holds a picture, illustration, etc. Object name is pone.0113894.e076.jpg. **The regulation leads to an increase of about 23% in the number of patients using the drug**.