Cinco RT PF NOV 2018 Blocks

Neg

OV: Developing Nations comes first

In today's round helping not just the US, but the entire world is the biggest impact in today's round on two scales:

First on scope, there are simply more people in the developing world than the US, and by keeping stable drug prices there you save more people.

Second on severity. **HPI in 2018** writes that drugs only make up 10% of US healthcare spending, because we have a ton more treatment options before using drugs, whereas in the developing world drugs make up 67% of healthcare spending, because the developing world lacks the infrastructure the US has. Here's the comparative: if you lose some access to drugs in the US you're fine as we have other treatment options. But if you lose access to drugs in developing countries, your literally facing death insofar as drugs are the only treatment option for most of the developing world.

A/2: Innovation

As an overview to their entire contention

The internal warrant to every link in this contention is that profits go down. However, according to Grande of the UIPS decreasing drug prices 20% would increase access by 23%, while only decreasing revenue by 1%. This is because most of the profit loss from decreased prices could be offset by more people being able to buy the drug. That's why he concludes that innovation won't be stifled with price controls.

Then 3 problems on the link

1) Delink, Most R&D doesn't even go to innovation. According to Light of U-New Jersey, companies only invest 1.3% of revenue into the actually innovative new drugs. They try to make it seem as if Innovation is a huge profit drain, when in reality its one to smallest parts of a corporate budget. Again, its just greed and corruption.

2) Huge de-link here. A majority of productive investment for R&D comes from the government rather than companies. Alternet in 2018 finds that all 210 drugs approved by the FDA between 2010 and 2016 were funded and spurred on by public sector investment. Alternet concludes that the private sector contributed little to no innovation and just monopolized the drugs. THE RESEARCH WILL CONTINUE; THE GOVERNMENT IS FINDING THE DRUGS, THEY ARE JUST MAKING IT.

3) Delink. Innovation decreasing in the status quo. Fleming of Forbes in 2018 finds that R&D returns on drug investment are currently at 3.2% and are projected to reach almost 0% by 2020. This means innovation has a short lifetime left until the point in which you barely receive any innovation for the investment you put in. If innovation is going down all the way to point of no return, then they can't link into their impact.

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4) We preq. All Neg impacts of R&D. This is because any innovation created would just be monopolized and made inaccessible to the large part of the population and would have little effect. A drug is only as effective as the amount of people it reaches. Even if they can create a breakthrough drug, if that Drug can only reach 5 people who can afford it then its more important to make drugs cheaper for millions. If the R&D is non unique, then aff pre-reqs bc we make that drug available to everyone.

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3) Heavily mitigate their impact. Most innovative drugs provide no unique value. Health Affairs in 2015 finds that instead of putting money towards the R&D for new medicines, pharma companies flood, destroy, and smash the market with slight variances of existing drugs in order to extend their patents. This is why they conclude that 80% of all new drugs in the US have no additional therapeutic value. Essentially, the "innovation" they talk about is legit changing one thing and calling it a new drug, that literally has no value.

a) This means we outweigh on probability because there is very low chance that any serious medical breakthroughs occur because of innovation, but there is a high probability of increasing accessibility insofar as price is the main barrier currently.

https://www.healthaffairs.org/do/10.1377/hblog20150706.049097/full/

Flooding the market with hundreds of minor variations on existing drugs and technically innovative but clinically inconsequential new drugs, appears to be the de facto hidden business model of drug companies. In spite of its primary charge to protect the public, the FDA criteria for approval encourage that business model. The main products of pharmaceutical research are scores of clinically minor drugs that win patent protection for high prices, with only a few clinically important advances like Sovaldi or Gleevec. This **business model works. Despite producing drugs with few clinical advantages and significant health risks, industry sales and profits have grown substantially, at public expense. Companies spend 2-3 times less on research than on marketing to convince physicians to prescribe these minor variations. Industry figures show the public pays companies about six times R&D costs through high prices on drugs. According to a study by Consumer Reports, high costs to patients lead them to postpone visits to physicians, avoid medical tests, and be able unable to afford other, effective drugs. For society as a whole, a leading health economist found that 80 percent of all new expenditures for drugs was spent on the minor variations, not the major advances.**

https://www.alternet.org/news-amp-politics/taxpayers-not-big-pharma-have-funded-research-behind-every-new-drug-2010

Trump's original spending proposal for fiscal year 2019, released last month, included major cuts to not just to the **NIH**, but the **National Science Foundation** as well. **It is those two publicly funded entities—not Big Pharma—that support the bulk of the country's basic research into diseases and pathways to new treatments.** According to a new study by a small, partly industry-funded think tank called the Center for Integration of Science and Industry (CISI), it is existentially important. **No NIH funds, no new drugs, no patents, no profits, no industry. The CISI study, underwritten by the National Biomedical Research Foundation, mapped the relationship between NIH-funded research and every new drug approved by the FDA between 2010 and 2016. The authors found that each of the 210 medicines approved for market came out of research supported by the NIH. Of the $100 billion it spent nationally during this period, more than half of it—$64 billion—ended up helping the development of 84 first-in-class drugs.** But the NIH doesn't get to use the profits from these drugs to fund more research, the way it might under a model based on developing needed drugs and curing the sick, as opposed to serving Wall Street. **Instead, publicly funded labs conduct years of basic research to get to a breakthrough, which is then snatched up, tweaked, and patented (privatized) by companies who turn around and reap billions with 1,000-times-cost markups on drugs developed with taxpayer money.**

Donald Light, U of New Jersey, 2012, http://www.pharmamyths.net/files/BMJ-Innova_ARTICLE_8-11-12.pdf

Although the pharmaceutical industry emphasises how much money it devotes to discovering new drugs, little of that money actually goes into basic research. Data from companies, the United States National Science Foundation, and government reports indicate that **companies have been spending only 1.3% of revenues on basic research to discover new molecules, net of taxpayer subsidies.23 More than four**

fifths of all funds for basic research to discover new drugs and vaccines come from public sources.24 Moreover, despite the industry's frequent claims that the cost of new drug discovery is now $1.3bn (£834m; €1bn),25 this figure, which comes from the industry supported Tufts Center,26 has been heavily criticised. Half that total comes from estimating how much profit would have been made if the money had been invested in an index fund of pharmaceutical companies that increased in value 11% a year, compounded over 15 years.26 While used by finance committees to estimate whether a new venture is worth investing in, these presumed profits (far greater than the rise in the value of pharmaceutical stocks) should not be counted as research and development costs on which profits are to be made. Half of the remaining $0.65bn is paid by taxpayers through company deductions and credits, bringing the estimate down to one quarter of $1.3bn or **$0.33bn.**27 The Tufts study authors report that their estimate was done on the most costly fifth of new drugs (those developed in-house), which the authors reported were 3.44 times more costly than the average, reducing the estimate to $90m. The median costs were a third less than the average, or $60m. **Deconstructing other inflators would lower the estimate of costs even further**

Toot van der Gronde. "Addressing the challenge of high-priced prescription drugs in the era of precision medicine: A systematic review of drug life cycles, therapeutic drug markets and regulatory frameworks." UIPS. 08-16-2017. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0182613
Schemes to reduce drug prices are used most often to reduce overall healthcare spending. For example, according to one calculation **setting prescription drug prices 20% lower than the current list price would increase the number of users who can afford the drug by 23%, while decreasing revenues for the drug company by only 1%.**[33] More examples with comparable outcomes exist.[4] Of course, the outcome is completely dependent on specific market conditions, prices and regulations. The general consensus is that **reducing prices increases the number of users, and this could at least partially offset losses due to lower pricing.** A popular argument against paying less for drugs is that innovation would not be financially worthwhile, and society would not enjoy the possible benefits of new innovator drugs.[77] This argument will be discussed later on.

A/2: Decrease Investment

1. Non-unqiue they don't even have uniqueness. Innovation decreasing in the status quo. Fleming of Forbes in 2018 finds that R&D returns on drug investment are currently at 3.2% and are projected to reach almost 0% by 2020 as he finds that the costs for the development of drugs are rapidly outpacing the returns from the industry. This means innovation has a short lifetime left until the point in which you barely receive any innovation for the investment you put in. If innovation is going down all the way to point of no return, then they can't link into their impact.
2. The internal warrant to every link in this contention is that profits go down. However, according to Grande of the UIPS decreasing drug prices 20% would increase access by 23%, while only decreasing revenue by 1%.This is because most of the profit loss from decreased prices could be offset by more people being able to buy the drug.

    a. Prefer this evidence over theirs because there's only looks at the profit loss from prices going down, ours actually looks at what happens as a result of accessibility caused by lower prices. Entire delink on the contention.

A/2: US does all the Innovation

There are three reasons why this entire argument isn't true.

The first is European Innovation.

Light in 2017 finds that idea of "freeloading" is a myth, and that in fact the rest of the world is still able to innovate at high rates even with price controls surpassing or equalling US levels. This why Health Affairs in 2009 concludes that from 1993-2003, Europe equalled or surpassed the United States in terms of pharmaceutical innovation even though they had heavy price controls.

The second is Patenting.

The US doesn't even lead the world anymore in new drugs patented. Bioworld finds that the US has already lost its position as global leader of patenting and is soon to lose their position in R&D as well, as the average return on investments is decreasing by 10% annually for US companies. Bioworld finds that due to this other countries will pass the US in the pharmaceutical industry such as China who is projected to pass the US by 2029.

The third is the historical analysis.

University of Rochester in 2015 finds that from 2004 to 2014 US contributions to global R&D decreased by 12% while other countries around the world have increased their innovations by 9.4%. Other countries are starting to carry us, not the other way around.

Askari in 2016 finds that from uptil 2013 the US only produced 22.79% of the world's new patents for drugs while Europe accounted for over 29.26% of innovation.

BUT THEN A HUGE CONTRADICTION: IF WE win bipartisanship any of the responses that the world is innovating more than that turns their innovation contention bc this innovation is happening under price controls.

A/2: Small Companies Harmed [Lobbying Link]

1) The evidence we read in case indicates big pharma companies heavily on small companies because that's where the vast majority of their R&D comes from. This means they would also lobby for small companies because they need them in order to continue innovating new drugs.
2) Lobbying is decreasing in the squo.

*A/2: Small Companies Harmed [General]

What biotrend finds that companies in the status quo are outsourcing their R&D to smaller companies in order to decrease in house costs. So, if profits are shrunk, then companies are going to look to use their money even more efficiently. This has two key implications:

1) At worst it serves as terminal defense because small companies aren't harmed. Companies know they have to keep getting drugs to sell, and so the last thing they're going to cut
2) At best it turns their case. Small pharma expands in growth because companies think that small pharma is the most efficient use of their profits.

A/2: Differential Pricing Weighing Overview

2 responses:

1. If we win any terminal defense on their case then even 1 American life saved will win us the round.
2. We can also turn or link into their own impact and we fully intend on doing so.

A/2: Differential Pricing for international shit

USE THE SEPERATE A/2 DOC

First, an overview. **The Guardian** writes that these large pharma companies are not charities, they do not donate drugs to the developing world to help them but rather establish a foothold in the market so when the country fully develops they have a monopoly over the country. This is why countries will never stop

donating drugs or selling them at deep discounts even if their revenue decreases; its crucial to their long term profit margins.

This is what has happened historically. The **WHO in 2**009 writes that during the 2008 recession which devastating the pharma industry, these same companies *increased* the amount of drugs going to the developing world while cutting prices for them even lower. This is because when companies see a market decrease as a revenue source, they fill in the gap by finding new revenue sources. In today's round that new revenue source is these developing nations.

This overview functions as terminal defense and a turn on their entire contention. Companies won't stop sending the drugs, and the amount of drugs going to the developing world only increases in an aff world.

Here's why you weigh our overview over their case.

It looks at the historical analysis, and history proves that the flow of drugs going to the developing world won't stop, but *increase* in an aff world.

But then, onto specifics:

Overall on their link

First, delink. Grande, 20% red. In prices, 23% inc. acceb. 1% dec. in rev, not enough of a brightline for their impacts to occur.

Second, Delink, companies aren't sending the right drugs. The PLOS in 2014 finds that pharmaceutical companies have little to no incentive to appeal to the developing world, instead they cater to diseases that affect the US market rather than tropical diseases that affect foreign market. For example, a lot of the developing nations need drugs for TB, but instead American companies are sending Cancer Drugs that cdcan't help.

Third, Non Unique. There are alternative reasons why people in these countries can't access drugs. Baker from the Journal of Ethics writes developing countries have broken health systems, insufficient health workers, weak regulation awnd distribution systems. Ths means even when you send drugs to these countries, they aren't able to distribute it to the people. NU their entire argument.

Fourth, Delink, status quo isn't even good. Drugs sold in the private market are still extremely expensive in the status quo as SMR in 2012 finds that 64% of drugs in the private market are still unaffordable, and even the ones that people account for consume 60 to 90% of people's incomes. This serves as terminal

defense on their case; most people still can't afford the drugs, and the ones that can are being bankrupted. They are not solving.

All four of these responses serve as terminal defense, if we win any of them then American accessibility to even one american wins the round.

With a handful of other drug makers, including the U.K.'sGlaxoSmithKline PLC, Switzerland's Novartis AG and France's Sanofi-Aventis SA, Pfizer is making a big push into the developing world. In addition to Venezuela, the company is expanding in China, India, Brazil, Russia and Turkey. Pfizer brought in $1.4 billion in sales from emerging markets in the first quarter of this year. That's a fraction of its $10.8 billion in overall sales in the same quarter, but a slice Pfizer says it's determined to expand.

PLOS evidence.

To see it evidently, from over 1500 drugs which have been approved during 1975–2004, only about 1 % of them were related to the diseases which are known as neglected [11], while over 10 % of global burden of disease is caused by these diseases [12]. This is also reflected in 10/90 phenomena: only 10 % of R&D expenditures is related to problems of 90 % of world population [13]. These facts clearly show an insufficient attention from pharmaceutical companies to this field of health needs. According to WHO, already over one billion people are affected by neglected tropical diseases [14], which may considerably decrease both the life expectancy and quality of life. By considering the higher rate of these diseases in low income countries, it is to say that this situation can cause a huge discrimination between high and low income societies, not only in terms of health, but also economically as a consequence of low health level.

All these modern structures, from patents and TRIPS-plus agreements to bias in pharma industry, cause a decrease or imbalance in access to medicine, and hence an inequity in health between and within the communities, which can be considered as a breach of human rights as will be explained further.

*A/2: Drug Shortages

PICK BETWEEN 1 AND 2. DO NOT READ BOTH.

1) The FDA solves. **The NCBI** explains that the FDA actively detects and works to solve shortages with manufacturers. Empirically in 2010, the FDA averted 24 impending drug shortages with this

assistance. **Statnews in 18'** furthers that the FDA is planning for a new task force to even better solve the issue of shortages.

2) Non-unique. **The NCBI** finds that shortages are already on a rampant increase in the status quo, with 211 drug shortages in 2010 and 210 in 2012, record breaking numbers.
3) Shortages only occur when the market is at equilibrium for prices. In the case of the specialized drugs that most people have trouble affording, there's a huge surplus, meaning you only move the price to equilibrium.
4) Never occured empirically in other countries.

The evidence also has a bunch of shit about the reasons for shortages so u can look at that if u want (NCBI) like 87% of all shortages are caused by reasons OUTSIDE of supply and demand

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/

Once a shortage of a medically necessary drug has been verified, the FDA works with the manufacturer toward resolving the identified problem. The FDA doesn't have the authority to mandate manufacturers to resume or ramp up production to correct drug shortages.12 However, **the FDA can provide assistance,** even if the shortage is due to business decisions, voluntary recalls, cGMP noncompliance, or other factors.2 **In 2010, the FDA was able to avert 24 impending drug shortages through assistance provided to pharmaceutical manufacturers.**

https://www.statnews.com/2018/07/12/fda-tackle-drug-shortages/

The Food and Drug Administration said Thursday it wants to more aggressively fight medication shortages that have led to rationing of some drugs and disrupted patient care. The agency announced plans for a task force to find ways to improve the supply of crucial drugs. It's a new approach for the drug regulator, which has very little control over drug makers' operations. It generally can't act until drug makers tell the agency that shortages are imminent or that it will stop making a drug.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/

There have been increasingly frequent drug shortages in the U.S. during at least the past decade.3,4 These have been tracked by both the American Society of Health-System Pharmacists (ASHP) and the FDA.3,4 However, these two organizations define the term drug shortage differently. The ASHP defines a drug shortage as "a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent," whereas the FDA focuses only on "products used to prevent or treat a serious or life-threatening disease or medical condition for which there is no other available source with sufficient supply of that product or alternative drug available."2–5 The Drug Information Service at University of Utah Health Care (UUHC), which partners with the ASHP to manage its drug shortage program, tracked **a total of 211 drug shortages in 2010—the highest number recorded to date in a single year** (Figure 1).3,6,7 By comparison, **the ASHP identified 224 drug shortages during the entire six-year period between January 1996 and June 2002.**3 An analysis by the Premier Healthcare Alliance in March 2011 also found that **more than 240 drugs were in short**

supply or completely unavailable in 2010, and more than 400 generic medications had been back-ordered for five days or more.8 **The number of drug shortages has been rapidly escalating in recent years;** ASHP/UUHC reported 70 in 2006, 129 in 2007, 149 in 2008, and 166 in 2009.4,9 For 2011, there have been 210 shortages reported as of September 15. At the time of this writing, 203 drugs were listed on the ASHP/UUHC drug shortage Web site and 73 medically necessary drugs were listed on the FDA Web site.10,11

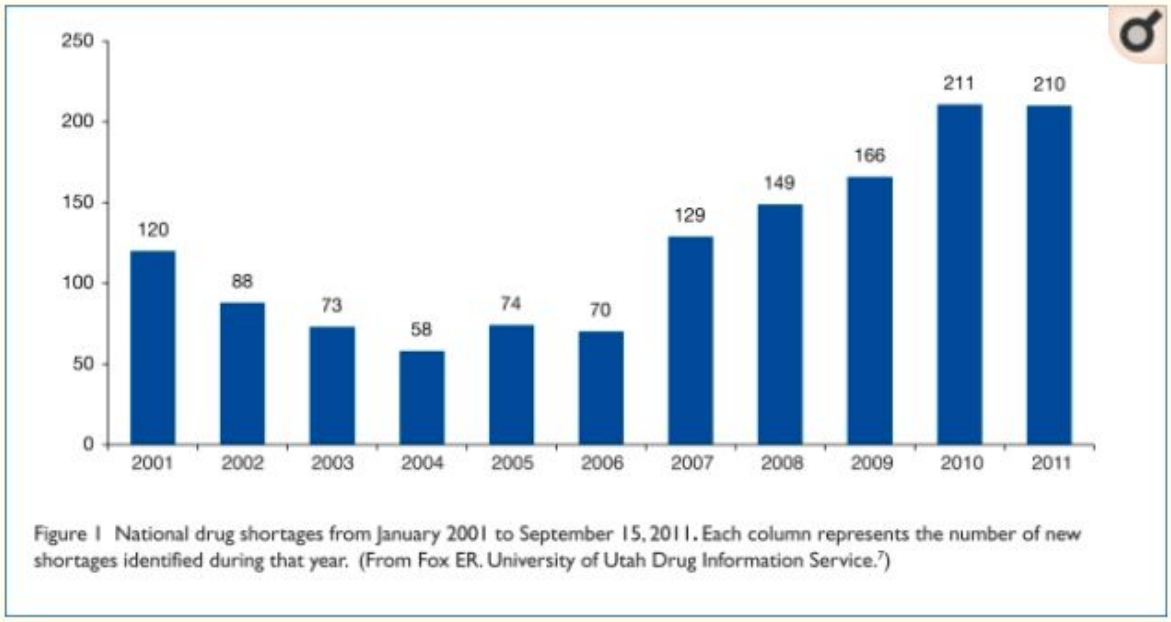

Figure 1 National drug shortages from January 2001 to September 15, 2011. Each column represents the number of new shortages identified during that year. (From Fox ER. University of Utah Drug Information Service.[7])

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National drug shortages from January 2001 to September 15, 2011. Each column represents the number of new shortages identified during that year. (From Fox ER. University of Utah Drug Information Service.[7])

*A/2: AMR shortages

First, The Guardian writes that the AMR shortage problem is getting really bad right now in the status quo, they have to prove a significant brightline as to how much it increase with Price Controls. At the end of the day, no matter who you vote for the shortages will continue on their own logic.

Second, you can turn it. The overarching problem with this argument comes from the University of Minnesota in 2018 who writes that the only way to address this shortage in the long term is through more market competition, because right now the few companies that do make the antibiotics are just skyrocketing prices and aren't making enough. So, if we prove competition increases when you affirm we win the round, and there are two ways that happens:

1. We decrease the capacity to do an Merger and acquisition by decreasing revenues. When revenues are low people are less incentivized to merge with you.

2. We decrease the incentive to do an M&A by taking away the main incentive to merge, which is jacking up the price by controlling a huge monopoly.

This is why **Vitzez in 2016** concludes that in 2015, with record high stock levels, there was a 90% increase in the amount of mergers. Cut their excess profit, and companies will be forced to compete with each other rather than just buying each other out.

Here's why you weigh our turns over any frontline they try to bring: It's try or die for the aff – there are tons of monopolies right now, and the trend is towards more monopolization which means you vote aff on the risk of solving.

Laura J. Vitez , BioPharma Dealmakers, 12-8-2016, ["Trends in pharmaceutical mergers and acquisitions," https://biopharmadealmakers.nature.com/users/9880-biopharma-dealmakers/posts/13880-trends-in-pharmaceutical-mergers-and-acquisitions, DOA: 11-3-2018] // ZWS

2015 was another big year for mergers and acquisitions (M&A) in the pharmaceutical industry. There were 468 announced deals involving therapeutic drug assets, devices, diagnostics and insurance companies, according to data from Thomson Reuters, representing a 10% increase over 2014 and a 90% increase over 2012, when dealmaking hit a 10-year low (Fig. 1). This extends a trend of an increasing number of deals, beginning in 2013 after a sustained decrease during the economic downturn around 2008.

ut in the long run, the report cautions, to get more companies commit to producing antibiotics and maintain a sufficient supply of affordable antibiotics, steps to improve the market for antibiotics are needed. These could include market entry rewards or other economic incentives to encourage new antibiotic development. "Without a competitive market, there will not only be more frequent shortages and quality issues, but the last few companies left in the market will have greater power to dictate prices," the authors write.

This effort, they say, will require collaboration between the pharmaceutical companies, regulators, governments, public health officials, and other stakeholders.

*AT Mergers and Acquisitions

1) The rate of mergers in pharma today is already super high, meaning any increase they have is pretty marginal. In fact, according to the Kurmann Partners, pharma has the highest rates of mergers of any industry. They have to prove that an increase is more than the status quo trend, and even then their impact is heavily mitigated. They have no impact.

Then turn the argument:inn

We decrease mergers and acquisitions in two ways:

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A/2: Delays from negotiations

Their Spiegel Evidence has two key problems:

1) It concedes the problem is NU because it says quality is also a huge problem, they don't prove the quality changes in their world, they can't link in
2) The author of the article is literally a lead lobbyist for the largest pharmaceutical lobbying firm in the US, complete BS article. That's why he provides no sources, no warrant, and no logic.

Delink. Sure, in other countries because the market is small they can afford to take the L and stall out for a better price. But because these companies main market is the US, they can't afford to lose the revenue for 3 months on their new drugs, that's just simple economics. Companies aren't going to burn their biggest revenue market source.

Delink. Motley in 2018 writes that the drug verification is A) completely different in europe compared to the US and B) not delayed because of Price Controls but rather bureaucracy.

He explains that once a drug gets approved in the US, you can start selling it right away. That doesn't change with Price Controls. In Europe however, because all these countries have universal healthcare, drug companies have to negotiate a different price with every country individually. Obviously negotiating prices with 30 different countries will take 3 months, but negotiating with one will literally take a couple days. They are extrapolating an extreme example to a different country that isn't even applicable.

But then, some weighing. Even if you buy their entire argument that drugs will be delayed for 6 months, we always outweigh in the long term for two reasons.

1) This argument only applies to drugs after they come out on the market. The Millions of people that can be saved tomorrow by drugs that exist right now will still benefit.
2) Their time frame is only 3 months, but after the drug gets put on the market, because the price will now be affordable, in the long term millions will still benefit, outweighing any marginal impact they bring.

Cut out turn for Plano LW round:

Turn: Delays are crucial for maintaining quality. Northwestern University writes that the FDA forces these companies to wait 10-12 years before releasing their product to ensure that clinical trials are in place and prove the drug is safe. This has two key implications:

1) Adding 3 months onto 12 years isn't that dramatic of a change. They have to prove that this small increase will lead to all their deaths.
2) This extra time is crucial for maintaining quality. There's a chance something is found out in those 3 months that would make the drug unusable. For example, Northwestern continues that there was a drug that was quickly approved in the rest of the world, but the FDA rejected it and

wanted longer testing, and it turns out the drug was super deadly and killed thousands across the world. Thus, Norman of the BMJ writes that if anything, we need to delay drug entries more, to ensure the FDA can do more verification. He concludes that every attempt to increase the quality of drugs has been stopped by people like their spiegel guy.

A. Heres why you weigh our turn over their entire contention. Its on historical precedent. Northwestern provides the backward looking analysis that in the past and squo drugs are being rushed to market and we need to slow it down. Drugs are good, but only if they work.

https://www.fool.com/investing/2018/05/19/how-drug-approvals-in-europe-are-different-than-in.aspx
Motley 2018
Exactly. In many ways, there are parallels between the FDA and the EMA, the European Medicines Agency. But where the system really starts to differentiate itself is what happens after that central agency says, "Yes, this drug can be approved." **In the United States, after that, you're pretty much good to go. You can get on the market and start selling it.**

But in Europe, the key difference to note is that the drug makers must then go nation by nation to get reimbursement approval. And that's because, in these countries, since there is a centralized universal health insurance program, it's the government itself that's going to wind up paying for these drugs, so they want to be able to negotiate a price. And if the price isn't deemed worth it, or if, for whatever reason, they don't want to cover this drug, they don't have to. And that's a conversation that the drug maker must have country by country.

Norman of BMJ
https://www.sciencedirect.com/science/article/pii/S2452302X16300638

A frequently held assertion is that slower FDA approval processes deprive American citizens of effective DADs that are available to Europeans (2), and critics have characterized FDA processes as “slow, risk averse, and expensive” (3). However, **the Institute of Medicine determined that current FDA pre-marketing procedures for medical devices are insufficient to assure device safety, particularly those approved largely on their similarity to previously cleared “predicate” devices, rather than on prospective, randomized clinical trials (4). In the EU, concerns abound that DADs may be approved too quickly, to the detriment of patient safety. In recent years, there have been calls to tighten approval processes and to establish regulatory consistency between the FDA and the EU.** Efforts include recent legislation in the U.S. Congress to facilitate release in the United States of drugs that have already achieved European approval (5). Proposed changes to regulations of the European Commission (EC) regarding device approval are under discussion (6), **but are vigorously opposed by both**

industry and patient groups insisting that it will impede availability of innovative therapies to the public.

A/2:The real a2 Drug Shortages

As an overarching response to this entire contention, the FDA in the status quo is solving:

The NCBI in 2018 writes that the FDA has been increasing its assistance to stop shortages and as a result was able to avert 24 drug shortages in just one year. Even moreso, Statnews in 2018 writes that the FDA is ramping up its anti-shortage policies, creating a new federal task force to work even harder to stop shortages. The problem is being solved back in the status quo.

But then, on specifics.

First, it's important to realize that there are two types of drugs, ones that are not profitable, and ones that are.

Starting with the ones that are unprofitable, Health Affairs in 2012 writes that they are increasing in shortages right now. This means they have no risk of solving for any shortages of generics, the problem is really bad right now; it's non-unique.

Then on the drugs that are profitable, price controls wouldn't cause shortages here. **Wagner in 2004** writes that shortages in generic markets would never happen because the margin on most single source drugs is so high that a decrease in prices to levels in other countries with price controls wouldn't do anything to affect shortages. Corrupt companies make too much in the status quo to the point where decreasing it literally won't affect them.

These responses have two key implications:

a) First, it serves as hard terminal defense because Price Controls won't cause any shortages to happen.
b) Second, even if their link is still there at the end of the round the impact is severely mitigated because they never prove how much it gets worse compared to the status quo trend of shortages increasing right now.

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https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/
Once a shortage of a medically necessary drug has been verified, the FDA works with the manufacturer toward resolving the identified problem. The FDA doesn't have the authority to mandate manufacturers to resume or ramp up production to correct drug shortages.12 However, **the FDA**

can provide assistance, even if the shortage is due to business decisions, voluntary recalls, cGMP noncompliance, or other factors.2 **In 2010, the FDA was able to avert 24 impending drug shortages through assistance provided to pharmaceutical manufacturers.**

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https://www.denialism.com/2012/02/17/drug-shortages-reveal-the-free/

Three of every four drugs on the US government's shortage list were sterile injectable drugs, according to a report by HHS. ***For the most part, these are relatively low-cost generics. Simply put, most of those drugs are not very profitable to produce and sell, or supplies of them would not have dried up.***

At an online presentation for journalists in November, Valerie Jensen, associate director of the FDA's Drug Shortage Program, provided a casebook example. She mentioned the price of the tried-and-true sedative propofol, a lethal dose of which was found to have caused the death of singer Michael Jackson: The cost is forty-eight cents for a twenty-milliliter vial. ***"The older, sterile injectables are not economically attractive" for manufacturers to produce and market, Jensen said. Other generic drugs can have higher profit margins.***

https://www.annualreviews.org/doi/pdf/10.1146/annurev.publhealth.25.101802.123042

WAGNER 2004

Lower revenues would not keep pharmaceutical companies from producing drugs already on the market because manufacturer prices of most single-source drugs far exceed the marginal costs of producing them. This is true even in countries that obtain relatively low prices for single-source drugs. Table 1 gives a rough estimate of the premium that single-source drugs command over the cost of production in the United States. Average manufacturer prices of generic drugs were only 20% as high as the equivalent price of brand-name multisource drugs purchased by Medicare beneficiaries in 1995, and only 8% as high as the equivalent price of brand-name single-source drugs. For the most part, generic manufacturers face vigorous price competition; therefore, generic prices can be considered reasonable proxies for the cost of production.10 **If the GAO finding is correct that U.K. prices are just 60% as high as U.S. prices (38), a reduction in U.S. prices to the level prevailing in the United Kingdom would still leave substantial net revenues available to the sellers of such drugs.**

A/2:The real a2 Innovation

1. Delink. They tell you companies would cut R&D if revenue fell, but the problem here comes from **Avorn of Harvard in 2016** who finds that in the status quo, companies price their drugs not off of the R&D cost but just the maximum the US market can bear.

    a. As such, even with price controls, as more people buy a drug at a rate that is still profitable **Grande of the UIPS** decreasing drug prices 20% would increase access by 23%, while only decreasing profits by 1%.

2. Non-Unique. Bala of MSF in 2014 writes that the pharma industry is pulling out and stopping innovation in the areas of greatest need, because a) drugs have a short profit timeline and b) the new drugs only help diseases that a few people. As such, **Stott of London Business School in 2017** finds that R&D will no longer be profitable in 2 to 3 years.

3. Delink, companies would just cut marketing budgets instead of R&D. **Mohammed of the Harvard Business Review in 2015** finds that in response to price controls, companies would opt to cut marketing budgets rather than R&D, because the incentive to R&D will still exist. According to **Hopkins of FGC in 2012** writes that US pharmaceutical companies receive a 50% tax deduction for their R&D expenses. The benefit to R&D will always exist.

4. Non-Unique, Government subsidization solves. **Kesselheim of Harvard in 2016** finds that more than half of new products are the result of publicly-funded research. No matter who you vote for innovation will continue.

5. Turn. **Light of Health Affairs in 2015** finds that instead of putting money towards the R&D for new medicines, pharma companies flood the market with slight variances of existing drugs in order to extend their patents. This is why they conclude that 80% of all new drugs in the US have no additional therapeutic value.

    a. **Canoy of the Dutch Institute in 2008** finds that lower drug prices incentivize better innovation, because companies will focus on products that are more desirable to society to gain the most from them. The average benefit to society of each drug is higher in our world.

Avorn of Harvard in 2016

Thus, there is **little evidence of an association between research and development costs and drug prices 93; rather, prescription drugs are priced in the United States primarily on the basis of what the market will bear.** This **explanation** also helps to account for several high-profile case studies, **including high-priced new branded products and exorbitantly priced generic drugs described above.**

Bala of MSF in 2014

The lack of R&D 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 R&D system which relies on patent monopolies to recoup costs.**

Stott of London Business School in 2017

Now the scariest thing about this analysis, is just how robust, consistent and rapid is **the downward trend in return on investment over a period of over 20 years. But moreover, these results confirm that return on investment in pharma R&D is already below the cost of capital, and projected to hit *zero* within just 2 or 3 years. And this despite all efforts by the industry to fix R&D and reverse the trend.**

Mohammed of the Harvard Business Review in 2015

A common reaction to any whiff of price regulation is concern that pharma R&D will be reduced. This is a fair concern, but it's not a given that R&D will decrease. Pharma companies may opt to cut sales and marketing costs (which 9 out the top 10 pharma companies spend more on than R&D), executive compensation, or dividends instead, keeping R&D budgets healthy. That said, it is very possible R&D may decrease as a result of regulation. In utopia, it'd be wonderful for pharma companies to have unlimited R&D budgets. But back here in reality, tradeoffs are made. Even today, R&D budgets are not infinite. And if budgets are cut by 20%, instead of funding 100 initiatives, it may be that only the top 80 with the highest potential will be greenlit.

http://www.fgcasal.org/politicafarmaceutica/docs/Greg_Hopkins.PDF

How much of the R&D cost of a drug is borne by the manufacturing company? The percent of drugs that come from public universities in the United States is 40% **(AAU, 2002). United States pharmaceutical companies receive a 50% tax write off for their R&D expenses, and they only spend about 6% of annual revenues on R&D (Sulston).**

Kesselheim of Harvard in 2016

A number of factors weigh against these rationales for high drug prices. **First, important innovation that leads to new drug products is often performed in academic institutions and supported by investment from public sources such as the National Institutes of Health. A recent analysis of the most transformative drugs of the last 25 years found that more than half of the 26 products or product classes identified had their origins in publicly funded research in such nonprofit centers.**

https://www.healthaffairs.org/do/10.1377/hblog20150706.049097/full/

Industry figures show the public pays companies about six times R&D costs through high prices on drugs. According to a study by Consumer Reports, high costs to patients lead them to postpone visits to physicians, avoid medical tests, and be able unable to afford other, effective drugs. **For society as a whole, a leading health economist found that 80 percent of all new expenditures for drugs was spent on the minor variations, not the major advances.**

https://editorialexpress.com/cgi-bin/conference/download.cgi?db_name=EARIE45&paper_id=550

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.**