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## 1

#### Counterplan Text - The member nations of the World Trade Organization should

#### eliminate intellectual property protections for medicines except for orphan drugs.

#### prioritize distribution of orphan drugs to the Global South.

#### Orphan drug legislation is specifically key to stimulate research into rare diseases

Horgan et. al 20 D, Moss B, Boccia S, Genuardi M, Gajewski M, Capurso G, Fenaux P, Gulbis B, Pellegrini M, Mañú Pereira M, M, Gutiérrez Valle V, Gutiérrez Ibarluzea I, Kent A, Cattaneo I, Jagielska B, Belina I, Tumiene B, Ward A, Papaluca M: Time for Change? The Why, What and How of Promoting Innovation to Tackle Rare Diseases – Is It Time to Update the EU’s Orphan Regulation? And if so, What Should be Changed? Biomed Hub 2020;5:1-11. doi: 10.1159/000509272 [https://www.karger.com/Article/Fulltext/509272#](https://www.karger.com/Article/Fulltext/509272) //sid

The European Union’s (EU) Regulation (EC) No. 141/2000 on orphan medicinal products (OMPs) (referred to as “the regulation” in this paper) states that “patients suffering from rare conditions should be entitled to the same quality of treatment as other patients,” and concludes that “it is therefore necessary to stimulate the research, development and bringing to the market of appropriate medications by the pharmaceutical industry” [[1](https://www.karger.com/Article/Fulltext/509272#ref1)]. Rare diseases had already been identified as a priority area for Community action within the framework for action in the field of public health [[2](https://www.karger.com/Article/Fulltext/509272#ref2)], and the regulation’s stated aim is – “to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” It set up a mechanism to ensure that “orphan medicinal products eligible for incentives should be easily and unequivocally identified,” with the condition that “objective criteria for designation should be established” [[3](https://www.karger.com/Article/Fulltext/509272#ref3)]. The core incentive of the regulation is the granting of 10 years (+2 years for paediatric orphan medicines) of marketing exclusivity and a range of financial and scientific provisions granted via the European Medicines Agency to support product development and application for Marketing Authorisation. Nearly two decades later, the success of the measure has been demonstrated. Investment both from public research funders and from companies of all sizes in rare disease research has resulted in the approval of more than 150 orphan drugs – compared with just eight therapies for rare diseases available before the adoption of the regulation. That translates into a lot of patient benefit. With clinical research stimulated by the legislation, the EU sees some 2,000 clinical trials providing still more innovation or hope for treatments in the current R&D pipeline [[4](https://www.karger.com/Article/Fulltext/509272#ref4)]. But over the intervening years, the limitations in the functioning of the legislation have become apparent too, and these merit attention if the beneficial effects for patients and caregivers are to be maximised [[5](https://www.karger.com/Article/Fulltext/509272#ref5)]. This paper explores the successes and limitation of both the regulation and its implementation mechanisms in the current regulatory context, and suggests some improvements that could maximise its benefits and boost rare disease research even further. The discussion needs to be precise if it is to be effective. Review of the functioning of the regulation may coincide with a period of more intense scrutiny and concerns over containing the rise of expenditure to ensure sustainability of healthcare systems, with a particular focus on expensive innovation which are often developed within the orphan conditions. While there is undoubted importance in the wider but distinct debate over healthcare costs, it does not bear directly on reviewing the orphan medicines regulation [[6](https://www.karger.com/Article/Fulltext/509272#ref6)]. At the same time, economic questions do, however, have relevance to the debate on orphans, since patients’ access to the medicines that become available is conditioned by the national arrangements for reimbursement or listing of products: there is an increasing tension between the potential access to agents that can modify or even cure rare diseases, and the models for reimbursement available to European payers. Part of this hesitancy can be ascribed to the novelty of the challenges presented by many innovative treatments, which by their nature present unknowns to payers. Clearly, there is also a need to deal with uncertainty with regard to value demonstration, especially when value or values are perceived not to be sufficiently demonstrated. The risk is that such powerful economic reservations can have a cumulative negative impact on the motivation for pursuing research into rare disease treatments – thus running counter to the guiding principle of the legislation itself [[7](https://www.karger.com/Article/Fulltext/509272#ref7)]. Current value assessment rules across Europe for orphan drugs remain largely inadequate and can become a real fourth hurdle to effective patient access to those treatments [[8](https://www.karger.com/Article/Fulltext/509272#ref8)]. The regulation’s stimulation of new product development has also helped promote the development of EU biotech companies. The last two decades have witnessed the emergence of more than 150 small and medium enterprises (SMEs) focusing on rare diseases. No wonder that one of the prominent Members of the European Parliament over this period, Francoise Grossetête, emphasised the importance of the regulation in addressing “real medical needs” and generating “therapeutic breakthroughs” [[9](https://www.karger.com/Article/Fulltext/509272#ref9)]. The underlying strength of the concept of providing incentives for R&D in areas of unmet need is confirmed by the fact that Germany and other Member States are now exploring whether OMP-type incentives could contribute to solving the major risks of antimicrobial resistance (AMR), through promoting development of new anti-bacterials even where simple market economics do not provide sufficient motivation for investment [[10](https://www.karger.com/Article/Fulltext/509272#ref10)]. Thanks to increased investments and the associated efforts thus made possible, some rare diseases now benefit from effective treatments. There are leading examples in the area of haemophilia, paroxysmal nocturnal haemoglobinuria (PNH), and some lysosomal storage diseases such as Gaucher. The full list of conditions for which “orphans medicines” have been launched in Europe is too extensive to reproduce here, but by way of illustration it ranges from rare cancers to rare variants of common diseases (pulmonary hypertension, neonatal diabetes) and to rare congenital, mostly childhood-onset disorders (Gaucher, cystinosis, inherited hyperammonaemias) [[11](https://www.karger.com/Article/Fulltext/509272#ref11)]. However, these tales of success should not lead to any delusions that the process has been – or is becoming – easy. Successes in developing innovative treatments are hard-won. Without consistent and determined effort, innovation does not happen – and innovation in rare diseases is all the more challenging. The key elements of the innovation process are well documented, but the nature of the challenges is perhaps not always fully appreciated by those outside the healthcare sector, being seen as costs and not as investments. Rare diseases are categorized as “orphan diseases” because their occurrence in a small number of patients means that, despite apparent high unmet medical need, there is limited scientific understanding, making it difficult to justify the development risk and investment to develop new treatments. The OMP regulation was developed explicitly to support efforts in this field of innovation [[12](https://www.karger.com/Article/Fulltext/509272#ref12)].

#### Rare diseases disproportionately affect people of color

**RDDC, No Date** (RDDC, No Date, accessed on 9-6-2021, Rare Disease Diversity Coalition, "Charting thePath Forwardfor Equity inRare Diseases", <https://3hqwxl1mqiah5r73r2q7zll1-wpengine.netdna-ssl.com/wp-content/uploads/2021/03/RDDC_Path_Forward_Final.pdf>)//sid

While the rare disease community continues to face hurdles generally, people of color face additional hurdles in their quest for care . Barriers to diagnosis and treatment for people of color often have deadly consequences . Flaws across the entire system have a compounding effect on the care that Black, Native American, Hispanic, Asian, and Pacific Islander Americans with rare diseases receive . Americans of color continue to be underrepresented in genome-wide association studies and clinical research trials, leading to a lack of understanding about effective treatments, particularly in diverse populations . Despite making up more than 38 percent of the U .S . population, people of color comprise only 16 percent of research study participants .20 On the patient side, people of color are less likely to have affordable access to health care and rare disease experts .21 To make matters worse, some rare diseases disproportionately impact people of color . For instance, sarcoidosis, sickle cell anemia, thalassemia, and some forms of lupus are known to affect minority populations at higher rates than the general population .22 And implicit bias particularly harms people of color with rare diseases .23

## 2

CP Text: The United States should increase intellectual patent protections for medicines. The member nations of the World Trade Organization except for the United States ought to eliminate patent protections for medicines.

The United States should:

- substantially increase production and global distribution of the COVID-19 Vaccine

- cooperate with allies to achieve increased production and global distribution of the COVID-19 Vaccine.

#### That solves better – IP rights don’t hinder vaccine cooperation, but manufacturing capacity is the current constraint.

Hans Sauer 6-17 [(Deputy General Counsel, Biotechnology Industry Organization.) “Web event — Confronting Joe Biden’s proposed TRIPS waiver for COVID-19 vaccines and treatments” https://www.aei.org/wp-content/uploads/2021/06/210617-Confronting-Joe-Bidens-proposed-TRIPS-waiver.pdf?x91208&x91208] TDI

But contrary to what Lori said, **there are genuine real problems in the supply chain** that are **not caused by patents**, that are simply caused by the unavailability and the constraints on existing capacity. There is in this world such a thing as maxed-out capacity that just can’t be increased on a dime. It’s not all due to intellectual property. This is true for existing vaccines as well as for vaccine raw materials. There are trade barriers. There are export restrictions that we should all be aware of and that we need to work on. And there are very real political, I think, interests in finding an explanation for how we got to this place that absolve governments around the world from their own policy decisions that they made in the past. In the United States, again, it was the declared policy of the previous administration, as well as this one, that we would vaccinate healthy college kids and go all down the line and offer a vaccine to everybody who wants it before we start sharing any with grandmothers in Burkina Faso. That was the policy. You can agree with it or disagree with it, but that was policy. We had export restrictions in place before a lot of other countries did. And that, too, contributed to unequal access of vaccines around the world. Another thing that was predictable was that politicians and governments around the world who want to be seen as proactive, on the ball, in control, for a long time were actually very indecisive, very unsure about how to address the COVID problem, which has so many dimensions. Vaccines are only one of those. But with respect to vaccines, not many governments took decisive action, put money on the table, put bets on multiple horses, before we knew whether these vaccines would work, would be approved. And it was governments in middle-income countries who now, I think, justifiably are concerned that they’re not getting fast enough access, who didn’t have the means and who didn’t have the decision-making structure to place the same bets on multiple horses, if you will, that were placed in the relatively more wealthy, global North and global West. But there is, I think, a really good and, with hindsight, predictable explanation of how we got to this place, and I think it teaches us something about how to fix the problem going forward. **So why will the waiver not work**? Well, first of all, with complex technology like vaccines, Lori touched on it, reverse engineering, like you would for a small molecule drug, is much more difficult if not impossible. But it depends very much more than small molecule drugs on cooperation, on voluntary transfer of technology, and on mutual assistance. We have seen as part of the pandemic response an unprecedented level of collaborations and cooperation and no indication that IP has stood in the way of the pandemic response. **The waiver proponents have found zero credible examples of where IP has actually been an obstacle,** where somebody has tried to block somebody else from developing a COVID vaccine or other COVID countermeasure, right? It’s not there. **Second, the myth of this vast global capacity to manufacture COVID vaccines that somehow exists** **out there is unsubstantiated** and frankly, in my opinion, untrue. But there is no such thing as vast untapped, idle capacity that could be turned around on a dime to start making COVID vaccines within weeks or even months. This capacity needs to be built; it needs to be established. And at a time when time is of the essence to beat this pandemic, starting capacity-building discussions is helpful, but it won’t be the answer to beat this pandemic. It will be the answer if we do everything right to beating the next pandemic. And if we learn any lesson of this, and then I will stop, is that the COVID waiver as well as the situation in which we find ourselves — if anything, it’s a reminder that we definitely have to take global capacity-building more seriously than we did in the past. That is true for the global North, as well as for middle-income countries — all of whom have to dedicate themselves much more determinedly to pandemic preparedness. And there’s a need to invest both in preparedness and in public health systems that hasn’t happened in the wake of past pandemic threats. This is what we will need to do. We will need to reduce export restrictions, and we will need to rededicate ourselves to preparing for the next pandemic. As far as this pandemic goes, **there are 11 vaccines around the world that are already being shot into arms, only four of which come from the global North. How many more vaccines do we want?** I don’t know, maybe 11 is enough if we start making more of them. But there are manufacturers around the world who know how to do this — including in China, including in India, and including in Russia. All developed their homegrown vaccines, apparently without interference by IP rights, right? **So let’s make more of those. I think that’s going to be the more practical and realistic answer to solving the problem**. And we need to lean on governments to stop export controls and to dedicate themselves to more global equity.

#### Infrastructure passes now with limited corporation support, but increased big Pharma backlash causes it to fail

Waldman 8/31 [Paul, opinion writer for the Plum Line blog. Before joining The Post, he worked at an advocacy group, edited an online magazine, taught at university and worked on political campaigns. He has authored or co-authored four books on media and politics, and his work has appeared in dozens of newspapers and magazines. He is also a senior writer at the American Prospect, “Opinion: Democrats, don’t knuckle under to corporations on the reconciliation bill”, 08-31-2021, Washington Post, https://www.washingtonpost.com/opinions/2021/08/31/democrats-dont-knuckle-under-corporations-reconciliation-bill/]//pranav

The infrastructure bill that passed the Senate and awaits action in the House was in some ways a model of bipartisanship, supported by some Republicans as well as all the chamber’s Democrats, and given a boost from traditionally Republican business groups. That wasn’t a surprise; big corporations need infrastructure to do business. If the government pays for better roads, a more resilient electrical grid and wider availability of broadband, it’ll probably help the bottom line. But what happens when the government suggests addressing Americans’ needs and asks those corporations to help pay for it? This is what happens: A torrent of political groups representing some of the country’s most influential corporations — including ExxonMobil, Pfizer, and the Walt Disney Company — is laying the groundwork for a massive lobbying blitz to stop Congress from enacting significant swaths of President Biden’s $3.5 trillion economic agenda. The emerging opposition appears to be vast, spanning drug manufacturers, big banks, tech titans, major retailers and oil-and-gas giants. In recent weeks, top Washington organizations representing these and other industries have started strategizing behind the scenes, seeking to battle back key elements in Democrats proposed overhaul to federal health care, education and safety net programs. This campaign will have lots of behind-the-scenes pressure: Together, these companies employ a group of lobbyists that are approximately equal in number to China’s People’s Liberation Army — as well as online and TV ads coming to a screen near you. So Democrats should now ask themselves: What are we doing here? As in, why did we decide to run for Congress? Because there are some moments that test your resolve, in which you have to ask what the purpose of public service is, and whether it’s more than just staying in your job for as long as possible. There are disagreements among Democrats about what should be in the final bill, and it’s almost certain that these corporations will have some success in stripping away some provisions they find threatening. There’s an increase in the corporate tax rate (though under every proposal, it would still be less than before the 2017 Republican tax cut). There’s money to boost Internal Revenue Service enforcement of existing tax laws, which the people who run corporations don’t like; an overstretched, overworked IRS that can’t manage to audit the super-rich is just how CEOs like things. Perhaps most threatening is the proposal to allow Medicare to negotiate prices for prescription drugs, as they are currently barred by law from doing. Democrats insist that change would pay for much of the trillions of dollars in new and beefed-up social programs this bill creates.

#### Big Pharma hates the plan – empirics – err neg our ev literally cites their press releases

PhRMA ’21 [The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone, “PhRMA Statement on WTO TRIPS Intellectual Property Waiver”, 05-05-2021, https://www.phrma.org/coronavirus/phrma-statement-on-wto-trips-intellectual-property-waiver]//pranav

WASHINGTON, D.C. (May 5, 2021) – Pharmaceutical Research and Manufacturers of America (PhRMA) president and CEO Stephen J. Ubl made the following statement after the United States Trade Representative expressed support for a proposal to waive patent protections for COVID-19 medicines: “In the midst of a deadly pandemic, the Biden Administration has taken an unprecedented step that will undermine our global response to the pandemic and compromise safety. This decision will sow confusion between public and private partners, further weaken already strained supply chains and foster the proliferation of counterfeit vaccines. “This change in longstanding American policy will not save lives. It also flies in the face of President Biden’s stated policy of building up American infrastructure and creating jobs by handing over American innovations to countries looking to undermine our leadership in biomedical discovery. This decision does nothing to address the real challenges to getting more shots in arms, including last-mile distribution and limited availability of raw materials. These are the real challenges we face that this empty promise ignores. “In the past few days alone, we’ve seen more American vaccine exports, increased production targets from manufacturers, new commitments to COVAX and unprecedented aid for India during its devastating COVID-19 surge. Biopharmaceutical manufacturers are fully committed to providing global access to COVID-19 vaccines, and they are collaborating at a scale that was previously unimaginable, including more than 200 manufacturing and other partnerships to date. The biopharmaceutical industry shares the goal to get as many people vaccinated as quickly as possible, and we hope we can all re-focus on that shared objective.”

#### They lash out against infra and use COVID clout to kill it – they have public support, and a win now postpones reform indefinitely which turns case

Fuchs et al. 09/02 [Hailey Fuchsattended Yale University and was an inaugural Bradlee Fellow for The Washington Post, where she reported on national politics**,** Alice Ollstein is a health care reporter for POLITICO Pro, covering the Capitol Hill beat. Prior to joining POLITICO, she covered federal policy and politics for Talking Points Memo, Megan Wilson is a health care and influence reporter at POLITICO, “Drug industry banks on its Covid clout to halt Dems’ push on prices”, 09-02-2021, https://www.politico.com/news/2021/09/02/drug-prices-democrats-lobbying-508127]//pranav

As Democrats prepare a massive overhaul of prescription drug policy, major pharmaceutical companies are mounting a lobbying campaign against it, arguing that the effort could undermine a Covid fight likely to last far longer than originally expected. In meetings with lawmakers, lobbyists for the pharmaceutical industry have issued warnings about the reconciliation package now moving through both chambers of Congress that is set to include language allowing Medicare to negotiate the price of some drugs, which could generate billions of dollars in savings. In those conversations, K Street insiders say, lobbyists have explicitly mentioned that the fight against the coronavirus will almost certainly extend beyond the current surge of the Delta variant. And they’re arguing that now isn’t the time to hit the industry with new regulations or taxes, particularly in light of its successful efforts to swiftly develop vaccines for the virus. “For years, politicians have been saying that the federal government can interfere in the price of medicines and patients won’t suffer any harm,” said Brian Newell, a spokesperson for the Pharmaceutical Research and Manufacturers of America, or PhRMA, in a statement. “But in countries where this already happens, people experience fewer choices and less access to prescription medicines. Patients know if something sounds too good to be true, then it usually is.” The escalating warnings from the pharmaceutical industry are part of what is expected to be one of the more dramatic and expensive lobbying fights in recent memory, and a heightened repeat of the industry’s pushback to actions by former President Donald Trump to target drug prices. The proposal now under consideration in Democrats’ reconciliation package could save the federal government hundreds of billions of dollars by leveraging its ability to purchase prescription drugs, according to a report from the Congressional Budget Office. Without those funds, Democrats won’t be able to pay for the rest of the health care agenda they’ve promised to voters, including expansions of Medicare, Medicaid and Obamacare. But the plan has political power as more than a revenue raiser. Party leaders — from President Joe Biden to Senate Budget Chair Bernie Sanders (I-Vt.) — are touting it as one of the most important components of the $3.5 trillion package, with the potential to lower out-of-pocket health spending for tens if not hundreds of millions of people. Outside advocates have also zeroed in on it as the most consequential policy fight on the horizon. “This is the best chance that we have seen in a couple of decades to enact meaningful reforms to drug pricing policy in the United States that will lower the prices of prescription drugs, and it’s very clear that the drug companies are going all out to stop it,” said David Mitchell, founder of Patients for Affordable Drugs. “This is Armageddon for pharma.” Progressive Democrats and their outside allies believe they’re closer than they’ve been in decades to imposing some price controls, and worry that failure to do so this year will delay progress indefinitely given the possibility of the party losing one or more chambers of Congress in the 2022 midterms. In April, the House passed a fairly aggressive version — H.R. 3 (117) — though a handful of moderate Democrats friendly to the industry have threatened to block it when it comes back to the floor for a vote later this fall. Leadership has largely shrugged off this threat, banking on the fact that the most vulnerable frontline Democrats are vocally in favor of the policy, while most of the dissenters sit in safe blue districts. The Senate is designing its own version, outlined by Sen. Ron Wyden (D-Ore.) in June, as a middle ground between HR3 and the more narrow, bipartisan bill he and Sen. Chuck Grassley (R-Iowa) put forward last Congress. A senior Senate Democratic aide confirmed to POLITICO that the bill is nearly complete and that they’re in the process of shopping it around to undecided senators to make sure it has enough support to move forward in the 50-50 upper chamber. “It makes sense to get buy-in before releasing it rather than releasing it with fingers crossed and then tweaking it once members complain,” the aide said. But the reform push is coming at a time when the pharmaceutical industry is working hand-in-hand with government officials to combat the pandemic and enjoying a boost in public opinion as a result, even as drug costs continue to rise. The companies claim that fundamental changes to their bottom line — in addition to the Medicare provision, the reconciliation bill will likely raise corporate tax rate significantly, as high as 28 percent (a jump of 7 percentage points) — will threaten its current investments in research and development at a historically critical juncture. With the final draft of the bill expected in the coming weeks, the Pharmaceutical Research and Manufacturers of America, the lobbying arm of the pharmaceutical industry, is taking its case public. The group has recently spent at least seven figures on ads pressuring Congress not to change Medicare drug policy.

#### Big pharma always wins – independently kills aff solvency bc it causes the plan to be watered down so much that de facto monopolies can survive

Florko & Facher ‘19 [Nicholas Florko is a Stat News Washington correspondent and Lev Facher is Stat News health and life sciences writer, “How pharma, under attack from all sides, keeps winning in Washington”, 07-16-2019, Stat News, https://www.statnews.com/2019/07/16/pharma-still-winning/]//pranav

It does not seem to matter how angrily President Trump tweets, how pointedly House Speaker Nancy Pelosi lobs a critique, or how shrewdly health secretary Alex Azar drafts a regulatory change. The pharmaceutical industry is still winning in Washington. In the past month alone, drug makers and the army of lobbyists they employ pressured a Republican senator not to push forward a bill that would have limited some of their intellectual property rights, according to lobbyists and industry representatives. They managed to water down another before it was added to a legislative package aimed at lowering health care costs. Lobbyists also convinced yet another GOP lawmaker — once bombastically opposed to the industry’s patent tactics — to publicly commit to softening his own legislation on the topic, as STAT reported last month. Even off Capitol Hill, they found a way to block perhaps the Trump administration’s most substantial anti-industry accomplishment in the past two years: a rule that would have required drug companies to list their prices in television ads. To pick their way through the policy minefield, drug makers have successfully deployed dozens of lobbyists and devoted record-breaking sums to their federal advocacy efforts. But there is also a seemingly new strategy in play: industry CEOs have targeted their campaign donations this year on a pair of vulnerable Republican lawmakers — and then called on them not to upend the industry’s business model. In more than a dozen interviews by STAT with an array of industry employees, Capitol Hill staff, lobbyists, policy analysts, and advocates for lower drug prices, however, an unmistakable disconnect emerges. Even though Washington has stepped up its rhetorical attacks on the industry, and focused its policymaking efforts on reining in high drug prices, the pharmaceutical industry’s time-honored lobbying and advocacy strategies have kept both lawmakers and the Trump administration from landing any of their prescription-drug punches. “Big Pharma has replaced Big Tobacco as the most powerful brute in the ranks of Washington power brokers,” Sen. Dick Durbin (D-Ill.) said in a statement to STAT. Durbin, who recently saw the industry successfully oppose his proposal to curtail some of the industry’s patent maneuvering, added that, “Pharma’s billions allow them to continue to rip off American families and taxpayers.” The industry doesn’t get all the credit; it has also benefited from a fractured Congress and discord between President Trump’s most senior health care advisers. PhRMA, the drug industry’s largest lobbying group here, declined to comment for this article. But industry leaders have broadly argued against efforts to rein in the industry’s practices in terms of price hikes and patents, making the case that that could irreparably stifle medical innovation. The battle is far from over, and industry representatives and lobbyists are quick to hypothesize that the worst, for them, is yet to come. They point to several ongoing legislative initiatives, including in the Senate Finance Committee, that could take more concerted direct aim at their pricing strategies in Medicare. They’re waiting, too, to see if House Democrats can cut a drug pricing deal with the White House to empower Medicare to negotiate at least some drug prices. Another pending regulation, loathed by drug makers, might tie their pricing decisions in Medicare to an index of international prices. They’ve also bemoaned the Trump administration’s decision last week to abandon a policy change that would have ended drug rebates — which, the pharmaceutical industry has said, could have given drug makers more space to lower their prices voluntarily. “We’re getting killed!” one pharma lobbyist told STAT. Of course, the Trump administration’s supposedly devastating decision to abandon that proposal simply maintains the status quo. “Big Pharma has replaced Big Tobacco as the most powerful brute in the ranks of Washington power brokers.” n Valentine’s Day, Sen. Thom Tillis (R-N.C.) enjoyed a showering of love that is familiar in Washington: a flood of campaign contributions, many at the federal limit of $2,800 for a candidate or $5,000 for an affiliated political committee. One donation came from Pfizer’s CEO, Albert Bourla, who donated $5,000 to Tillis and another $10,000 to Sen. John Cornyn (R-Texas) and associated campaign committees. Another came from Kenneth Frazier, the top executive at Merck. The Tillis campaign committee eventually cashed checks from CEOs and other high-ranking executives at those companies as well as Amgen, Eli Lilly, Sanofi, and Bristol Myers-Squibb, plus two high-ranking officials at the advocacy group PhRMA. Six lobbyists at one firm that works with PhRMA, BGR, also combined to contribute $100,000 to a bevy of Republican lawmakers and the party’s campaign arms. Tillis raised an additional $64,500 from drug industry political action committees in the past quarter, according to disclosures released on Monday. A Pfizer spokeswoman declined to comment about Bourla’s contributions, and representatives for the other companies did not respond to STAT’s request for comment. Tills was one of few individual lawmakers — in many cases, the only one — to whom the executives had written personal checks during the current election cycle. While drug industry CEOs frequently contribute to political committees for congressional leadership, the breadth of executives who donated Tillis specifically is notable, particularly considering his outspoken role on pharmaceutical industry issues. While lobbyists pushed back on the notion that campaign contributions directly influence votes, the donations targeted so specifically to a particular candidate could be seen as a prime example of Washington’s system for rewarding loyalty and how industries protect their interests. The same PhRMA PAC that donated to Tillis has given generously in recent years: nearly $200,000 in the 2018 campaign cycle, roughly 58% of which was targeted toward Republicans. Drug industry PACs donated $10.3 million in total in that cycle, according to the Center for Responsive Politics. The figure two years before was even higher: a total of $12.2 million from industry-aligned PACs alone. It is no accident that the pharmaceutical industry has maintained its reputation among the nation’s most powerful lobbies, said Sheila Krumholz, the executive director of the Center for Responsive Politics, an organization that tracks political influence. “Their access and influence goes beyond this Congress or even the administration,” Krumholz said in an interview, adding that she “was struggling to think of evidence” it had waned. Pharma has a reputation here for winning on policy — often thanks to the lawmakers who are among the biggest recipients of the millions that drug corporations, employees, and the industry political arms donate each year. Even as the rhetoric has escalated, the industry has quietly worked to insulate itself from any major legislative changes. Take, for example, a recent about-face from Cornyn, the Texas Republican who took in some campaign cash alongside Tillis. As recently as February, Cornyn seemed to be positioning himself as a rare Republican figurehead for anti-pharma congressional wrath. At a widely publicized hearing before the Senate Finance Committee, he went head-to-head with AbbVie CEO Richard Gonzalez, pressing him to explain why the company had filed more than 100 patents on its blockbuster arthritis drug Humira. Cornyn introduced legislation soon after the skirmish to crack down on patent “thicketing,” a term for a drug company tactic to accumulate tens, if not hundreds, of patents to shield a drug from potential generic competition. Pharma sprung into action. They recruited congressional allies, including Tillis, to pressure Cornyn to significantly rework the bill, and they succeeded. The version of the bill that eventually cleared the Senate Judiciary Committee was stripped of language that would have empowered the Federal Trade Commission to go after patent thicketing. Instead, the bill limited how many patents a drug maker could assert in a patent lawsuit. The new version of the bill lost “a lot of teeth” and “solves a narrower problem in a narrow way,” advocates told STAT when the change was first introduced. It is far from the only example of the industry’s aggressive interventions to water down legislation. “In lots of ways they’re like the [National Rifle Association], because they have an incredible power to squash out any negative opinion, nor to feel any of the ill effects of those things,” said Pallavi Damani Kumar, an American University crisis communications professor who once worked in media relations for drug manufacturers. “It just speaks to how incredibly savvy they are.” Pharmaceutical industry lobbyists also successfully fought to keep another anti-drug industry patent proposal from Sen. Bill Cassidy (R-La.) and Dick Durbin (D-Ill.) out of a bipartisan drug pricing package moving through the Senate HELP Committee. The legislation would have allowed the FDA to approve cheaper versions of drugs, even when the more expensive product was protected by certain patents. Cassidy’s proposal never even made it into the HELP package. As the lobbyist who bemoaned the withdrawal of the rebate rule put it, Cassidy “simmered down” in the face of industry pressure. In recent weeks, the industry had targeted Cassidy in particular, in recent weeks, for fear he would break with many of his GOP colleagues to support a cap on some price hikes for drugs purchased under Medicare, a proposal so far pushed only by Democrats. “Sen. Cassidy doesn’t care what lobbyists think — he is going to do what’s best for patients,” said Ty Bofferding, a Cassidy spokesman. “Sen. Cassidy fought for the committee to include the REMEDY Act in the package, despite strong opposition from the pharmaceutical industry.” The committee eventually included half the bill’s provisions, he added, as well as four other pieces of legislation meant to prevent the industry from taking advantage of the patent system. The drug industry also notched a win by watering down another proposal in that package from Sen. Susan Collins (R-Maine) that would have blocked drug makers from suing over patents they didn’t disclose to the FDA. The version of the bill that actually made it into the package doesn’t block drug makers from suing, but instead directs the FDA to create a public list of companies that fail to disclose their patents. “This change is a big win for drug makers,” Michael Carrier, a Rutgers University professor and expert on patent gaming, told STAT. “Shaming is something drug makers don’t seem worried about.” Matthew Lane, the executive director of the Coalition Against Patent Abuse, likewise added that the altered bill “doesn’t seem to be doing much anymore.” Not all of the pharma-endorsed changes, however, are self-serving. Patent experts and federal regulators too had raised concerns with some of the bill being proposed. Cornyn’s patent bill was particularly controversial. “These provisions encourage ‘fishing expeditions’ by zealous bureaucrats, politically motivated by the popularity of efforts to reduce drug prices and garner the political benefits of being seen to be pursuing these ends,” Kevin Noonan, a patent lawyer at McDonnell Boehnen Hulbert & Berghoff wrote in a recent blog post, referring to the original Cornyn bill. Drug-pricing advocates said lobbyists have even managed to convince lawmakers to introduce some legislation they say has explicitly favored the drug industry, including intellectual property-focused legislation that would allow drug makers to patent human genes. That particular bill would “undo the bipartisan effort underway to fix pharma’s exploitation of the patent system,” said the Coalition Against Patent Abuse. And they were far from the only group raising concerns. The American Civil Liberties Union and more than 150 other groups wrote to lawmakers last month opposing the bill. Pharma’s list of policy victories goes on: Drug companies and allied patient groups forced the Trump administration to back off a proposal to make relatively minor changes to Medicare’s so-called protected classes policy. Currently, Medicare is required to cover all drugs for certain conditions, including depression and HIV. The Trump administration proposed in November that private Medicare plans should be able to remove certain drugs in those classes from their formularies, if the drugs were just new formulations of a cheaper, older version of the same drug, or when a drug spiked in price. But drug industry opposition helped convince the administration to spike that effort. A week ago, the industry struck its biggest blow yet. Three of the country’s largest pharmaceutical companies —Amgen, Eli Lilly, and Merck — prevailed in a lawsuit to strike down a Trump administration requirement that they disclose list prices in television advertisements. The lack of congressional action — despite the Democratic enthusiasm and bipartisan appetite — is still further evidence of industry’s ability to stave off defeat. As the dozens of Democrats running for president ramp up their anti-pharma rhetoric, both Trump and progressives have begun to fret that Washington’s efforts have proven to be all bark and no bite. With two weeks remaining before the August recess and an escalating 2020 campaign, some advocates fear that the window for bold action is closing quickly. “It’s appalling that we are six months into this Congress and we haven’t seen meaningful legislation passed on American’s number one issue for this congress,” said Peter Maybarduk, who leads drug-pricing initiatives for the advocacy group Public Citizen. “Congress needs to get its act together.”

#### Infra’s k2 stopping existential climate change – warming is incremental and every change in temperature is vital

Higgins 8/16 [Trevor, Senior Director, Domestic Climate and Energy, “Budget Reconciliation Is the Key to Stopping Climate Change”, 08-16-2021, https://www.americanprogress.org/issues/green/news/2021/08/16/502681/budget-reconciliation-key-stopping-climate-change/]//pranav

The United States is suffering acutely from the chaotic changes in climate that scientists now directly attribute to the burning of fossil fuels and other human activity. The drought, fires, extreme heat, and floods that have already killed hundreds this summer across the continent and around the world are a tragedy—and a warning of worsening instability yet to come. However, this week, the Senate initiated an extraordinary legislative response that would set the world on a different path. Enacting the full scope of President Joe Biden’s Build Back Better agenda would put the American economy to work leading a global transition to clean energy and stabilizing the climate. A look at what’s coming next through the budget reconciliation process reveals a ray of hope that is easy to miss amid the fitful negotiations of recent months: At long last, Congress is on the verge of major legislation that would build a more equitable, just, and inclusive clean energy economy. This is our shot to stop climate change. Building a clean energy future must start now Until the global economy stops polluting the air and instead starts to draw down the emissions of years past, the world will continue to heat up, blundering past perilous tipping points that threaten irreversible and catastrophic consequences. Stemming the extent of warming at 1.5 degrees Celsius rather 2 degrees or worse will reduce the risk of crossing such tipping points or otherwise exceeding the adaptive capacity of human society. Every degree matters. Stabilizing global warming at 1.5 degrees Celsius starts with cutting annual greenhouse gas emissions in the United States to half of peak levels by 2030. This isn’t about temporary offsets or incremental gains in efficiency—it’s about the rapid adoption of scalable solutions that will work throughout the world to eliminate global net emissions by 2050 and sustain net-negative emissions thereafter. Building this better future will tackle climate change, deliver on environmental justice, and create good jobs. It will give us a shot to stop the planet from continuously warming. It will alleviate the concentrated burdens of fossil fuel pollution, which are concentrated in systemically disadvantaged, often majority Black and brown communities. It will empower American workers to compete in the global clean energy economy of the 21st century. There is no time to lose in the work of building a clean energy future.

## 3

Interpretation – the affirmative debater may not read two mechanisms to evaluate offense in the 1AC. To clarify, you cant read a role of the ballot and a framework

Violation – they defend util & a rob

Pre round prep – it becomes atrocious when you don’t know if your offense will function under their framing which kills argument innovation against their affirmative – cx is too late to check bc pre-round prep is when the majority of 1nc strategic thinking is done.

Shiftiness – a 2-1 skew in framing lets them to just reclarify whats offense or not under their framing till the 1AR which means they can de link all negative offense cuz its not part of their offense

Paradigm Issues:

Drop the debater – they have a 7-6 rebuttal advantage and the 2ar to make args I can’t respond to,

Use competing interps reasonability invites arbitrary judge intervention since we don’t know your bs meter,

No RVIs –illogical – you shouldn’t win for being fair – it’s a litmus test for engaging in substance,

Evaluate T before 1AR theory – norms – we only have a couple months to set T norms but can set 1AR theory norms anytime,

## Case

### Framework

#### Reducing existential risks is the top priority in any coherent moral theory

Plummer 15 (Theron, Philosophy @St. Andrews http://blog.practicalethics.ox.ac.uk/2015/05/moral-agreement-on-saving-the-world/)

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But that is a huge mistake. Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; it is not the view that the latter don’t matter. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. We should also take into account moral uncertainty. What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. It is enough for my claim that there is moral agreement in the relevant sense if, at least given certain empirical claims about what future lives would most likely be like, all minimally plausible moral views would converge on the conclusion that we should try to save the world. While there are some non-crazy views that place significantly greater moral weight on avoiding suffering than on promoting happiness, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless seem to be fairly implausible views. And even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve. Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast. We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period. Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.” (From chapter 36 of On What Matters)

#### AT – Kessler

#### 1---Probability 1st Collapses – everything can be more probable in the absolute AND impossible to measure risk of probability which links to the paralysis argument

#### 2---We’re not the “most absurd scenarios”---we have robust proof of our internal links, and impacts---the bright line is arbitrary and low

#### 3---Weigh magnitude times probability---“probability first” framing is rooted in psychological biases and leads to mass death

Clarke 08 [Lee, member of a National Academy of Science committee that considered decision-making models, Anschutz Distinguished Scholar at Princeton University, Fellow of AAAS, Professor Sociology (Rutgers), Ph.D. (SUNY), “Possibilistic Thinking: A New Conceptual Tool for Thinking about Extreme Events,” Fall, Social Research 75.3, JSTOR]

In scholarly work, the subfield of disasters is often seen as narrow. One reason for this is that a lot of scholarship on disasters is practically oriented, for obvious reasons, and the social sciences have a deep-seated suspicion of practical work. This is especially true in sociology. Tierney (2007b) has treated this topic at length, so there is no reason to repeat the point here. There is another, somewhat unappreciated reason that work on disaster is seen as narrow, a reason that holds some irony for the main thrust of my argument here: disasters are unusual and the social sciences are generally biased toward phenomena that are frequent. Methods textbooks caution against using case stud- ies as representative of anything, and articles in mainstreams journals that are not based on probability samples must issue similar obligatory caveats. The premise, itself narrow, is that the only way to be certain that we know something about the social world, and the only way to control for subjective influences in data acquisition, is to follow the tenets of probabilistic sampling. This view is a correlate of the central way of defining rational action and rational policy in academic work of all varieties and also in much practical work, which is to say in terms of probabilities. The irony is that probabilistic thinking has its own biases, which, if unacknowledged and uncorrected for, lead to a conceptual neglect of extreme events. This leaves us, as scholars, paying attention to disasters only when they happen and doing that makes the accumulation of good ideas about disaster vulnerable to issue-attention cycles (Birkland, 2007). These conceptual blinders lead to a neglect of disasters as "strategic research sites" (Merton, 1987), which results in learning less about disaster than we could and in missing opportunities to use disaster to learn about society (cf. Sorokin, 1942). We need new conceptual tools because of an upward trend in frequency and severity of disaster since 1970 (Perrow, 2007), and because of a growing intellectual attention to the idea of worst cases (Clarke, 2006b; Clarke, in press). For instance, the chief scientist in charge of studying earthquakes for the US Geological Service, Lucile Jones, has worked on the combination of events that could happen in California that would constitute a "give up scenario": a very long-shaking earthquake in southern California just when the Santa Anna winds are making everything dry and likely to burn. In such conditions, meaningful response to the fires would be impossible and recovery would take an extraordinarily long time. There are other similar pockets of scholarly interest in extreme events, some spurred by September 11 and many catalyzed by Katrina. The consequences of disasters are also becoming more severe, both in terms of lives lost and property damaged. People and their places are becoming more vulnerable. The most important reason that vulnerabilities are increasing is population concentration (Clarke, 2006b). This is a general phenomenon and includes, for example, flying in jumbo jets, working in tall buildings, and attending events in large capacity sports arenas. Considering disasters whose origin is a natural hazard, the specific cause of increased vulnerability is that people are moving to where hazards originate, and most especially to where the water is. In some places, this makes them vulnerable to hurricanes that can create devastating storm surges; in others it makes them vulnerable to earthquakes that can create tsunamis. In any case, the general problem is that people concentrate themselves in dangerous places, so when the hazard comes disasters are intensified. More than one-half of Florida's population lives within 20 miles of the sea. Additionally, Florida's population grows every year, along with increasing development along the coasts. The risk of exposure to a devastating hurricane is obviously high in Florida. No one should be surprised if during the next hurricane season Florida becomes the scene of great tragedy. The demographic pressures and attendant development are wide- spread. People are concentrating along the coasts of the United States, and, like Florida, this puts people at risk of water-related hazards. Or consider the Pacific Rim, the coastline down the west coasts of North and South America, south to Oceania, and then up the eastern coast- line of Asia. There the hazards are particularly threatening. Maps of population concentration around the Pacific Rim should be seen as target maps, because along those shorelines are some of the most active tectonic plates in the world. The 2004 Indonesian earthquake and tsunami, which killed at least 250,000 people, demonstrated the kind of damage that issues from the movement of tectonic plates. (Few in the United States recognize that there is a subduction zone just off the coast of Oregon and Washington that is quite similar to the one in Indonesia.) Additionally, volcanoes reside atop the meeting of tectonic plates; the typhoons that originate in the Pacific Ocean generate furiously fatal winds. Perrow (2007) has generalized the point about concentration, arguing not only that we increase vulnerabilities by increasing the breadth and depth of exposure to hazards but also by concentrating industrial facilities with catastrophic potential. Some of Perrow's most important examples concern chemical production facilities. These are facilities that bring together in a single place multiple stages of production used in the production of toxic substances. Key to Perrow's argument is that there is no technically necessary reason for such concentration, although there may be good economic reasons for it. The general point is that we can expect more disasters, whether their origins are "natural" or "technological." We can also expect more death and destruction from them. I predict we will continue to be poorly prepared to deal with disaster. People around the world were appalled with the incompetence of America's leaders and orga- nizations in the wake of Hurricanes Katrina and Rita. Day after day we watched people suffering unnecessarily. Leaders were slow to grasp the importance of the event. With a few notable exceptions, organi- zations lumbered to a late rescue. Setting aside our moral reaction to the official neglect, perhaps we ought to ask why we should have expected a competent response at all? Are US leaders and organiza- tions particularly attuned to the suffering of people in disasters? Is the political economy of the United States organized so that people, espe- cially poor people, are attended to quickly and effectively in noncri- sis situations? The answers to these questions are obvious. If social systems are not arranged to ensure people's well-being in normal times, there is no good reason to expect them to be so inclined in disastrous times. Still, if we are ever going to be reasonably well prepared to avoid or respond to the next Katrina-like event, we need to identify the barriers to effective thinking about, and effective response to, disas- ters. One of those barriers is that we do not have a set of concepts that would help us think rigorously about out-sized events. The chief toolkit of concepts that we have for thinking about important social events comes from probability theory. There are good reasons for this, as probability theory has obviously served social research well. Still, the toolkit is incomplete when it comes to extreme events, especially when it is used as a base whence to make normative judgments about what people, organizations, and governments should and should not do. As a complement to probabilistic thinking I propose that we need possibilistic thinking. In this paper I explicate the notion of possibilistic thinking. I first discuss the equation of probabilism with rationality in scholarly thought, followed by a section that shows the ubiquity of possibilis- tic thinking in everyday life. Demonstrating the latter will provide an opportunity to explore the limits of the probabilistic approach: that possibilistic thinking is widespread suggests it could be used more rigorously in social research. I will then address the most vexing prob- lem with advancing and employing possibilistic thinking: the prob- lem of infinite imagination. I argue that possibilism can be used with discipline, and that we can be smarter about responding to disasters by doing so.

#### AT SV First -

#### 1---Prefer util---even if its flawed, alternatives are worse because they justify the same ends but create decision paralysis, and requires saying some lives are more valuable than others, which turns all their impacts

#### 2---Tautological---devolves into consequentialism---either their maxims are created to minimize harm, which means they’re utilitarian consequentialist, or they’re inflexible in cases of moral atrocity worse than utilitarianism because they requires saving some people over others

#### 3---Not our util---utilitarian framework wouldn’t justify atrocities like slavery because the magnitude of the harm to a smaller group still outweighs

#### AT: Matheson

#### 1---Make them indict our internal links---their interp justifies arbitrarily lowering the risk of dropped args, which breaks the game and collapses into endless judge intervention based on how likely you think the DA is

AT: Memmi

1 – irresolvable – if both debaters have racism impacts the round becomes a comparison of which forms of racism is worse which makes the debate unsafe

2 – body count is the only objective metric

AT: Medina

1 – CROB is to vote for the better debater – anything else is infinitely unpredictable, arbitrary, and self-serving

2 – extinction turns the warrants – makes it impossible to build resistance movements – proves it’s a lexical pre-req

### Solvency

Sell ev -

[1] ab IP writ large – proves TONS of alt causes

[2] aff can’t solve all capitalism – makes it impossible

Hold the line – the 1AC can’t solve ALL medical inequality – ie – doctors viewing black people’s pain levels differently – only grant them access to the total amount of inequality they solve.

### Advantage

**Multiple alt causes to high drug prices and limited access**

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The Panel Is Poised To Ignore Real Access Problems The Panel’s misguided focus on patents has led the U.S. State Department to encourage the Panel to abandon its “narrow mandate” and instead focus on actual obstacles that stand in the way of persons obtaining life-saving drugs. Echoing the WHO, the State Department has pointed to four main reasons that the developing world lacks access to healthcare: (1) an inability to select and use medicines rationally; (2) unaffordable drug prices; (3) unreliable health and supply systems; and (4) inadequate financing. **None of these barriers are directly related to patents**. First, irrational drug use is a serious barrier to access. The WHO defines “irrational use” as any use that is not “appropriate to [patients’] clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.” Two recent studies conducted in Africa illustrate this problem. One study conducted at Kapiri Mposhi District Hospital in Central province, Zambia found a high prevalence of irrational drug use. Fifty percent of 680 patient records surveyed showed some form of inappropriate drug use. And a study in Sudan found that 73% of participants reported to have acquired and used medication without a prescription at least a month prior to the study. Second, there is no doubt that affordability is a barrier to access. But patent protections are not to blame. In fact, patents do not protect the vast majority of essential medicines, which the WHO defines as “those drugs that satisfy the health care needs of the majority of the population.” 350 of these 375 “essential medicines” are available in generic versions and are thus sold at a much lower price point. Moreover, data shows that patent-holding companies do not frequently make use of patent laws in developing countries, even where they could. Moreover, **patent rights do not explain the high cost of drugs in the developing world.** The WHO itself points out that **taxes, tariffs** and other government policies play a significant role in keeping drug prices high in emerging markets. And, in fact, reports have concluded that excessive tariffs and taxes on imported medicines **may inflate the cost of medicines by up to one-third.** When combined with taxes on medicines, government-imposed levies account for an additional 55% in India; 40% in Sierra Leone; 34% in Nigeria; and 29% in Bangladesh. In any event, contrary to the Panel’s suggestion, patent protections ultimately help keep the costs of drugs low. To be sure, patented drug prices will often decline only after a patent expires. But the decline in price after patent expiration is not evidence that the drug manufacturer charged too much for the product. To the contrary, the decline in price of a formerly patented medicine is consistent with an efficient market. Patents expire after a certain period of time fixed by law. As economists have explained, during this period, prices will reflect both the costs of production and the company’s research and development costs. The exclusivity period that the patent creates attracts investment, which enables the innovator company to recoup its research and development costs. Once the patent expires, other companies may create generics that are priced lower. But these lower costs reflect the fact that copycat companies only need to recoup production costs, not research and development. In other words, a patent’s provision of an opportunity for an innovator company to recover costs enables it to produce the medicine in the first place. And the patent’s eventual expiration allows for robust competition that drives prices down. Third, as many experts point out, structural and economic barriers are a significant barrier to access to medicine in the developing world. Poor infrastructure and weak healthcare systems plague third-world countries. Several countries’ medical centers are located in remote areas that may only be reached through impassable roads. Also, many drugs and vaccines must be stored at certain temperatures. But many developing countries lack reliable electricity and sanitary facilities to enable proper storage. In India, for example, a quality-control study followed a series of vaccine vials through the supply-chain delivery process. The study found that 76 percent of the vaccines could not be used because they were stored in substandard storage facilities. Fourth, experts also acknowledge that developing countries tend to underinvest in health. In 2001, for example, African leaders met in Abuja, Nigeria, and pledged to allocate 15 percent of their national budgets to health. The 2015 DATA Report found, however, that between 2011 and 2013, just eight of the 47 countries for which there was data available spent 15 percent or more on health: Uganda, Rwanda, Malawi, Swaziland, Nigeria, Ethiopia, Liberia, and Togo. Twenty countries did not reach even the 10 percent level. If anything, patent protections could incentivize further investment in health in these countries. \* \* \* The UN has a real opportunity to address the critical issue of healthcare access. As it stands now, however, it seems poised to do more damage than good.

**IP allows reverse engineering – fosters medical innovation**

**Brander et al 17**, James A Brander, Sauder School of Business, University of British Columbia, 2053 Main Mall, Vancouver V6T 1Z2, Canada, Victor Cui, Asper School of Business, University of Manitoba, Winnipeg, Canada, “China and intellectual property rights: A challenge to the rule of law”, <https://umanitoba.ca/faculties/management/media/China_and_intellectual_property_rights.pdf>, accessed by apark 6/27/21

As described in the WIPO Intellectual Property Handbook, there are two primary rationales for intellectual property rights (WIPO, 2017). One rationale relates to ‘‘moral’’ rights of creators. The other relates to ‘‘economic and social development.’’ Economists normally describe these two objectives as relating to ‘‘equity’’ and ‘‘efficiency.’’ The equity rationale is based on the view that it would be inequitable or at least ethically wrong to, for example, copy a new invention or new piece of music created by someone else without some form of permission or compensation – that creators or innovators have some intrinsic or natural rights regarding their creations or innovations. The efficiency rationale is based on the market failure that would result if innovators had insufficient incentives to create intellectual property due to an expectation that it would be appropriated by others. Both rationales for IPR protection are important, but we focus here on efficiency – the need for IPRs to create incentives for desirable levels of innovation. For example, tremendous benefits have arisen from the development of modern pharmaceuticals. However, developing a new drug is very costly, normally requiring at least hundreds of millions and often billions of dollars for a new drug (Adams & Brantner, 2006). In particular, the biopharmaceuticals approved since 2000 are estimated to have cost an average of about $2.6 billion each and typically take 10–15 years to develop (Pharmaceutical Research and Manufacturers of America, 2015). On the other hand, new drugs are relatively easy to ‘‘reverse engineer’’ and copy, and are typically inexpensive to produce. If drug companies did not have patent protection, they would quickly be undercut by generic producers and be unable to recoup drug development costs. It is hard to see how significant drug development would be possible without IPR protection in the form of patents or something similar.

#### TRIPs waiver doesn’t solve- it doesn’t obligate countries to do anything, just makes it legal.

Mercurio 21 [Bryan; Professor of Law, The Chinese University of Hong Kong; "The IP Waiver for COVID-19: Bad Policy, Bad Precedent," 2021; 1-6. International Review of Intellectual Property and Competition Law.] Justin

It is not only the length of time which is an issue but also the ultimate impact of the waiver. A waiver simply means that a WTO Member would not be in violation of its WTO obligations if it does not protect and enforce the COVID-19-related IPRs for the duration of the waiver. The waiver would thus allow Members to deviate from their international obligations but not obligate Members to suspend protection and enforcement of the IPRs. Members like the US who support the waiver may not implement the necessary domestic legislation to waive IPRs within the jurisdiction. It is questionable whether the US could even legally implement the waiver given that IPRs are a matter of constitutional law.17

#### The first piece of Vanni evidence has no warrants for IP being the cause – rather it’s saying that lack of access to healthcare is what is causing disproportionate minority deaths.

#### Vote neg on presumption, the squo solves all of their impacts – it provides less developed countries with access to patent protected drugs

Enrico Bonadio 15 [11-24-2015, "World's poorest countries allowed to keep copying patent-protected drugs," Conversation, <https://theconversation.com/worlds-poorest-countries-allowed-to-keep-copying-patent-protected-drugs-50799>] // WW DL

The World Trade Organisation has agreed to extend a waiver that allows poor countries to copy patented medicines. The waiver, which was due to expire in January 2016, has now been extended to 2033. The countries that will benefit from the waiver are the 48 poorest nations, classified by the United Nations as “Least Developed Countries” or LDCs, and include many African and some Asian countries. About half of the 900m population across these countries live on less than US$1.25 a day. All other countries, including developing countries such as India and China, are still bound by the WTO’s agreement on trade-related intellectual property rights (or TRIPS) with respect to drug patents. Higher disease burden The waiver is critical for the least developed countries. Compared with richer countries, they have a much higher disease burden, especially infectious diseases such as HIV and malaria. In 2011, about 9.7m people in these countries were living with HIV. We believe good journalism is good for democracy and necessary for it. Keeping antiretrovirals affordable. jonrawlinson/flickr Many of the drugs that treat these diseases are still under patent protection. Drug patents last for 20 years and allow drugs companies time to recoup their investment into research and development and turn a profit. Once the patent protection period ends, other drugs companies can then copy the drug and sell it as a generic medicine. These generics are much cheaper than branded drugs. Developing a local pharma industry Countries such as Uganda, Cambodia and Rwanda have already taken advantage of the WTO’s temporary waiver and begun to develop their own pharmaceutical industry. This has been helped by investments from drug companies in the developing world. For example, Uganda-based Cipla Quality Chemicals was originally a joint-venture between Cipla, a large Indian generics manufacturer, and the Ugandan government. It is the only company in Africa that makes triple-combination antiretroviral drugs. Developing and strengthening manufacturing capacities in LDCs is important as these countries are often unable to import cheap copies of patent protected drugs from countries like India. India has many large generics firms within its borders and, although it ratified TRIPS in 1995, it only brought its patent laws in line with the treaty in 2005. It too now has to respect international drug patents. So the extension of the waiver is important, but it is only temporary, which doesn’t please everybody. Least developed countries and some NGOs would have preferred an indefinite extension or at least an extension until a country is no longer classified as a least developed country, rather than the set date of 2033. This position is supported by the European Union, but not by the US. Patents don’t work for poor countries It costs pharmaceuticals companies about US$2.6 billioin to develop a new drug. If these companies were not allowed to protect their investment with patents, it is doubtful that any new drugs would be developed. So patents are an important incentive. But patent protection doesn’t work for poor countries. Intellectual property (IP) rights, like patents, aren’t an effective incentive in countries which have not reached an adequate level of economic development because they have no intellectual property to protect. IP rights might be effective over the long term, but only after a local and relatively strong pharmaceutical industry is developed. The exemption could be dropped once countries that have benefited from it have developed enough, and the industry reaches a self-sustaining size. Although building a home grown pharmaceuticals industry is not a requirement of the WTO waiver, a strong local industry would give poor countries direct access to much needed cheap medicines. The WTO’s transitional waiver makes sense. By temporarily allowing LDCs to ignore patents on drugs, it gives them time to develop their own pharmaceuticals industries. And we are already seeing evidence of this happening. According to the UN agencies, UNDP and UNAids, the proportion of people with HIV who are not receiving antiretrovirals reduced from 90% in 2006 to 63% in 2013 thanks to the availability of drugs made by LDCs. Despite some criticisms, the WTO’s decision to extend the waiver should be praised. It seems fair and reasonable, and it doesn’t excessively jeopardise companies that make branded (non-generic) drugs. They don’t seem to lose much from missed royalties. Overall, the poorest countries account for less than 2% of the world’s gross domestic product and about 1% of global trade in goods. Not a big business opportunity for big pharma.

#### TRIPS reduces global health inequality

Samir Raheem Alsoodani 15, “"The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) may offered an access to essential pharmaceutical drugs for developing countries,” Journal Of the College of law /Al-Nahrain University 2015, Volume 17, Issue 2, Pages 393-410, <https://www.iasj.net/iasj/article/109180>

To conclude, it is beyond doubt that the TRIPS Agreement and its later, permanent amendment of 2005 attempted in good faith to address an urgent issue faced by many developing countries with regards to accessing essential medicine. To a certain extent in its basic tenets, it has had a profound and positive effect on the system

, as it has made permanently possible the opportunity for the poorest countries to obtain medications more cheaply through manufacture in developing countries under a compulsory licensing system. Certain positive outcomes arguably include the fact that disputes have been brought under the jurisdiction of one regulatory body, and the least developed Members have found some redress in the power balance regarding costs paid to the pharmaceutical industries based in the wealthier, developed countries (even if this redress has only been to the extent of facilitating increased bargaining capability). This can be considered a triumph from the perspective of universal human rights.