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#### Counterplan Text – Member states of the World Trade Organization ought to consult the World Health Organization on whether or not the member nations of the World Trade Organization ought to eliminate patent protections for medicines. The World Health Organization ought to publicly declare that their decision will represent their future decisions on all intellectual property protections on medicines.

#### The Plan’s unilateral action by the WTO on medical IP undermines WHO legitimacy – forcing a perception of WHO action against Patents is key to re-assert it

Rimmer 4, Matthew. "The race to patent the SARS virus: the TRIPS agreement and access to essential medicines." Melbourne Journal of International Law 5.2 (2004): 335-374.

<https://law.unimelb.edu.au/__data/assets/pdf_file/0007/1681117/Rimmer.pdf> (BA (Hons), LLB (Hons) (Australian National University), PhD (New South Wales); Lecturer at ACIPA, the Faculty of Law, The Australian National University)//SidK + Elmer

The WHO has been instrumental in coordinating the international network of research on the SARS virus. It has emphasised the need for collaboration between the network participants. The WHO presented the containment of the SARS virus as ‘one of the biggest success stories in public health in recent years’.206 However, it **was less active in the debate over patent law** and public health epidemics. The 56th World Health Assembly considered the relationship between intellectual property, innovation and public health. It stressed that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.207 However, there was much disagreement amongst the member states as to what measures would be appropriate. The WHO has made a number of **aspirational statements** about patent law and access to essential medicines. Arguably, though, the organisation could be a much more informed and vocal advocate. Initially, the WHO did not view the patent issues related to SARS as being within its field of activities. The agency **did not even seem aware of the patent proceedings**, leaving individual research institutions without guidance. Spokesman Dick Thompson said: ‘What we care about is [that] the international collaboration continues to function. Patents, they don’t really concern us’.208 The director of WHO’s Global Influenza project, Klaus Stöhr, expressed his opinion that the patent filings would not interfere with the international cooperation on the SARS research: ‘I don’t think this will undermine the collaborative spirit of the network of labs’.209 However, he believed that, after the international network of researchers had identified the coronavirus, it was necessary to rely upon companies to commercialise such research. Klaus Stöhr conceded: ‘At a certain point of time you have to give way for competitive pharmaceutical companies’.210 On a policy front, the WHO **remained deferential** to the WTO over the debate over patent law and access to essential medicines, observing: Owing to the inconclusive nature of the studies conducted to date, and because of the effect that potentially significant price increases could have on access to drugs in poor countries, WHO is currently monitoring and evaluating the effects of TRIPS on the prices of medicines. It is also monitoring the TRIPS impact on other important issues such as transfer of technology, levels of research and development for drugs for neglected diseases, and the evolution of generic drug markets.211 In such a statement, the WHO appears diffident, **unwilling to take on more than a spectator** role. Such a position is arguably too timid, given the gravity of national emergencies, such as the SARS virus. The organisation could take a much stronger stance on the impact of the **TRIPS** Agreement on public health concerns. The WHO has since enunciated a position statement on the patenting of the SARS virus. A number of high ranking officials from the organisation have commented on the need to ensure that international research into the SARS virus is not impeded by competition over patents. Arguably though, the **WHO should not be limited to a mere spectator role in such policy discussions. It needs to play an active advocacy role in the debate over patent law and access to essential medicines**. The WHO released a position statement on ‘Patent Applications for the SARS Virus and Genes’ on 29 May 2003.212 The organisation stressed that it had no per se objection to the patenting of the SARS virus: Some people have objected to the SARS patent applications on the ground that the virus and its genes should not be patentable because they are mere discoveries, not inventions. This distinction no longer prevents the granting of patents; the novel claim rests not with the virus itself but with its isolation, and likewise with the identification of the genetic sequence not its mere occurrence. Many patents have been issued on viruses and genetic sequences, though the appropriate policies to follow in such cases — particularly as genomic sequencing becomes more routine and less ‘inventive’ — remain matters of dispute.213 Furthermore, it recognised that public institutions could legitimately use patents as a defensive means to prevent undue commercial exploitation of the research: The “defensive” use of patents can be a legitimate part of researchers’ efforts to make their discoveries (and further discoveries derived therefrom) widely available to other researchers, in the best collaborative traditions of biomedical science.214 The WHO affirmed the need for further cooperation between research organisations in respect of the SARS virus: ‘For continued progress against SARS, it is essential that we nurture the spirit of the unprecedented, global collaboration that rapidly discovered the novel virus and sequenced its genome’.215 The WHO announced its intention to monitor the effects of patents (and patent applications) on the speed with which SARS diagnostic tests, treatments, and vaccines are developed and made available for use, and on the manner in which prices are set for these technologies. It observed: In the longer term, the manner in which SARS patent rights are pursued could have a profound effect on the willingness of researchers and public health officials to collaborate regarding future outbreaks of new infectious diseases. WHO will therefore examine whether the terms of reference for such collaborations need to be modified to ensure that the credit for any intellectual property developed is appropriately attributed, that revenues derived from licensing such property are devoted to suitable uses, and that legitimate rewards for innovative efforts do not impose undue burdens on efforts to make tests, therapies, and preventive measure available to all.216 It maintained that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.219 The Assembly requested that the Director-General continue to support Member States in the exchange and transfer of technology and research findings, according high priority to access to antiretroviral drugs to combat HIV/AIDS and medicines to control tuberculosis, malaria and other major health problems, in the context of paragraph 7 of the Doha Declaration which promotes and encourages technology transfer.220 The WHO also considered a report on the emergence of the SARS virus and the international response to the infectious disease.221 It was ‘deeply concerned that SARS ... poses a serious threat to global health security, the livelihood of populations, the functioning of health systems, and the stability and growth of economies’.222 The Committee on Infectious Diseases requested that the Director-General ‘mobilize global scientific research to improve understanding of the disease and to develop control tools such as diagnostic tests, drugs and vaccines that are accessible to and affordable by Member States’.223 The Director-General of the WHO, Dr Gro Harlem Brundtland, **told the World Health** Assembly that there was a need to build trust and forge solidarity in the face of public health epidemics: ‘**Ensuring that patent regimes stimulate research and do not hinder international scientific cooperation** is a critical challenge — whether the target is SARS or any other threat to human health’.224 Similarly, Dr Marie-Paule Kieny, Director of the WHO Initiative for Vaccine Research, said: If we are to develop a SARS vaccine more quickly than usual, we have to continue to work together on many fronts at once, on scientific research, intellectual property and patents issues, and accessibility. It is a very complicated process, involving an unprecedented level of international cooperation, which is changing the way we work.225 She emphasised that patents and intellectual property issues and their safeguards can help rather than hinder the rapid development of SARS vaccines and ensure that, once developed, they are available in both industrialised and developing countries.226 C Summary The WHO should play a much more active role in the policy debate over patent law and access to essential medicines. James Love, the director of the Consumer Project on Technology, run by Ralph Nader, is critical of the WHO statement on ‘Intellectual Property Rights, Innovation, and Public Health’.227 He maintains that the Assembly could have addressed ‘practical examples, like SARS’ and cites the report in The Washington Post that notes that a number of commercial companies are investing in SARS research.228 The non-government organisation Médecins Sans Frontières has been critical in the past of the passive role played by the WHO in the debate over access to essential medicines: ‘As the world’s leading health agency, and armed with the clear mandate of recent World Health Assembly resolutions, the WHO can and should **do much more’**.229 The WHO should become a vocal advocate for public health concerns at the WTO and its TRIPS Council — especially in relation to patent law and the SARS virus. It must staunchly defend the rights of member states to incorporate measures in their legislation that protect access to medicines — such as compulsory licensing, parallel imports, and measures to accelerate the introduction of generic pharmaceutical drugs. It needs to develop a clearer vision on global equity pricing for essential medicines. The race to patent the SARS virus seems to be an inefficient means of allocating resources. A number of public research organisations — including the BCCA, the CDC and HKU — were compelled to file patents in respect of the genetic coding of the SARS virus. Such measures were promoted as ‘defensive patenting’ — a means to ensure that public research and communication were not jeopardised by commercial parties seeking exclusive private control. However, there are important drawbacks to such a strategy. The filing of patents by public research organisations may be prohibitively expensive. It will also be difficult to resolve the competing claims between the various parties — especially given that they were involved in an international research network together. Seth Shulman argues that there is a need for international cooperation and communication in dealing with public health emergencies such as the SARS virus: The success of a global research network in identifying the pathogen is an example of the huge payoff that can result when researchers put aside visions of patents and glory for their individual laboratories and let their work behave more like, well, a virus. After all, the hallmark of an opportunistic virus like the one that causes SARS is its ability to spread quickly. Those mounting a response need to disseminate their information and innovation just as rapidly.230 There is a danger that such competition for patent rights may undermine trust and cooperation within the research network. Hopefully, however, such concerns could be resolved through patent pooling or joint ownership of patents. Furthermore, a number of commercial companies have filed patent applications in respect of research and development into the SARS virus. There will be a need for cooperation between the public and private sectors in developing genetic tests, vaccines, and pharmaceutical drugs that deal with the SARS virus. There is also a need to reform the patent system to deal with international collaborative research networks — such as that created to combat the SARS virus. Several proposals have been put forward. There has been a renewed debate over whether patents should be granted in respect of genes and gene sequences. Some commentators have maintained that the SARS virus should fall within the scope of patentable subject matter — to promote research and development in the field. However, a number of critics of genetic technology have argued that the SARS virus should not be patentable because it is a discovery of nature, and a commercialisation of life. There has been a discussion over the lack of harmonisation over the criteria of novelty and inventive step between patent regimes. As Peter Yu comments, ‘[w]hile [the] US system awards patents to those who are the first to invent, the European system awards patents to those who are the first to file an application’.231 There have been calls for the requirement of utility to be raised. There have also been concerns about prior art, secret use and public disclosure. Representative Lamar Smith of Texas has put forward the CREATE Act, which recognises the collaborative nature of research across multiple institutions. Such reforms are intended to ensure that the patent system is better adapted to deal with the global nature of scientific inquiry. The race to patent the SARS virus also raises important questions about international treaties dealing with access to essential medicines. The public health epidemic raises similar issues to other infectious diseases — such as AIDS, malaria, tuberculosis, influenza, and so forth. The WHO made a public statement about its position on the patenting of the SARS virus. It has stated that it will continue to monitor developments in this field. Arguably, there is a need for the WHO to play a larger role in the debate **over patent law and** access to essential medicines. **Not only could it mediate legal disputes** over patents in respect of essential medicines, it could be a vocal advocate in policy discussions. The WTO has also played an important role in the debate over patent law and access to essential medicines. A number of public interest measures could be utilised to secure access to patents relating to the SARS virus including compulsory licensing, parallel importation and research exceptions. The appearance of the SARS virus shows that there should be an open-ended interpretation of the scope of diseases covered by the Doha Declaration on the TRIPS Agreement and Public Health. Important lessons should be learned from the emergence of the SARS virus, and the threat posed to global health. As the World Health Report 2003 notes: SARS will not be the last new disease to take advantage of modern global conditions. In the last two decades of the 20th century, new diseases emerged at the rate of one per year, and this trend is certain to continue. Not all of these emerging infections will transmit easily from person to person as does SARS. Some will emerge, cause illness in humans and then disappear, perhaps to recur at some time in the future. Others will emerge, cause human illness and transmit for a few generations, become attenuated, and likewise disappear. And still others will emerge, become endemic, and remain important parts of our human infectious disease ecology.232 Already, in 2004, there have been worries that pharmaceutical drug companies and patent rights are impeding efforts to prevent an outbreak of bird flu — avian influenza.233 There is a need to ensure that the patent system is sufficiently flexible and adaptable to cope with the appearance of new infectious diseases.234

#### WHO says yes

Kimball 21 [(Spencer, news editor with CNBC.com) “WHO chief urges world to follow U.S. lead and support waiving Covid vaccine patent protections,” CNBC, 5/7/2021] JL

World Health Organization Director General-Tedros Adhanom Ghebreyesus on Friday urged other countries, particularly the Group of Seven industrialized nations, to follow the U.S. example and support a World Trade Organization motion to temporarily waive Covid-19 vaccine patent protections. “Wednesday’s announcement by the U.S. that it will support a temporary waiver of intellectual property protections for Covid-19 vaccines is a significant statement of solidarity and support for vaccine equity,” Tedros said at a press briefing. “I know that this is not a politically easy thing to do, so I very much appreciate the leadership of the U.S. and we urge other countries to follow their example.”

#### WHO Cred key to Global Right to Health – medicine access is critical.

* Note the Bottom Paragraph is at the bottom of the PDF – I put a paragraph break to indicate it as such – no words are missing.

Bluestone 3, Ken. "Strengthening WHO's position should be a priority for the new Director-General." The Lancet 361.9351 (2003): 2. (Senior Policy Adviser, Voluntary Service Overseas (VSO))//Elmer

To meet these challenges, WHO must strengthen its resolve to maintain its **independence and lead its member states**, **even at the risk of causing controversy**. A meaningful example is the role that WHO can have in **ensuring access to medicines** for the world’s poorest people. WHO is the only global institution that has the **remit to drive this agenda forward**, yet has failed to do so convincingly. The new Director-General must support and reinvigorate the advocacy efforts of the organisation and provide a proper counterbalance to the interests of the pharmaceutical industry and wealthy member states. As the new Director-General takes office, they will face the dual challenge of **seeing that** the broadest possible public health interpretation of the World Trade Organization’s Doha Agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS) **is not lost, and** of seizing an opportunity to bring about an international framework for sustainable and predictable tiered pricing of medicines. Without the active intervention of a public health advocate at the level of WHO, there is a risk that both of these initiatives **could founder.** Some people in positions of power still do not have high expectations of WHO or its new Director-General. But for the world’s poorest people, the overwhelming majority of whom live in developing countries, this person’s legacy could literally make the difference between life and death. Ken Bluestone Senior Policy Adviser, Voluntary Service Overseas (VSO)

New leader should re-establish WHO’s credibility The credibility of WHO’s advocacy of the right to health for all has been eroded in recent years. A large reason is WHO’s **failure to challenge the pharmaceutical** industry on access to medicines for people with HIV/AIDS and other diseases. WHO’s collaboration with the industry in the “Accelerated Access” programme on antiretroviral medicines sounds good. In fact, the programme has served as a cover for the organisation’s frequent acceptance of industry arguments for restricting treatment access. To re-establish WHO’s credibility, the new Director-General must lead the organisation to stand consistently with those most deprived of health services. Kenneth Roth, Executive Director, Human Rights Watch.

#### Right to Health solves Nationalist Populism.

Friedman 17 Eric Friedman March 2017 “New WHO Leader Will Need Human Rights to Counter Nationalistic Populism” <https://www.hhrjournal.org/2017/03/new-who-leader-will-need-human-rights-to-counter-populism/> (JD, Project Leader of the Platform for a Framework Convention on Global Health at the O’Neill Institute for National and Global Health Law at the Georgetown University Law Center in Washington, DC)//Elmer

The need for WHO leadership on human rights—and for global leadership on health and human rights beyond WHO—has always been present, yet has become ever more pressing. A reactionary, nationalist populism has been gaining momentum, particularly in the United States and parts of Europe, and some of its most disturbing features, such as xenophobia and disregard for international law and institutions, are surfacing elsewhere. Persisting health challenges—such as immense national and **global health inequities**, with universal health coverage and the Sustainable Development Goals offering some hope of lessening them—and growing threats such as outbreaks of infectious disease, worsening antimicrobial resistance, and climate change demand the type of leadership that the right to health entails. In this immensely challenging environment, WHO needs to become a 21st century institution that has the gravitas and credibility to carve a path through these obstacles towards global health justice. The next WHO Director-General, to be elected in May, must lead the organization there. The right to health can light the way ahead, with reforms to, and driven by, WHO. These reforms must develop an internal governance that is far more welcoming of civil society, with WHO member states significantly increasing contributions so work on the social determinants of health can expand, and with enhanced transparency and accountability. Furthermore, reforms are needed so that WHO leads on global health equity and human rights, including through national health equity strategies and, above all, the Framework Convention on Global Health (FCGH). The FCGH could help bring the right to health to the next level by capturing core aspects of the right to health, such as: 1) participation and accountability, setting clear standards for people’s participation in health policy-making at all levels, and establishing multi-layered health accountability frameworks with standards to which all nations would be held; 2) equity, including by catalyzing national health equity strategies—which must be developed through broad participation, itself a potentially empowering process—and advancing data disaggregation and more equitable financing; 3) financial resources, with global norms on national and international health financing responsibilities; and 4) respecting and promoting the right to health in all policies, from setting standards on health impact assessments—including participatory processes in developing them, human rights standards, an equity focus, and follow-up processes—to firmly ensuring the primacy of the right to health in other legal regimes that may undermine. From an earlier WHO treaty, the Framework Convention on Tobacco Control, we know the power of international law to significantly advance health, with the transformative power of legally binding global health norms. As a treaty, the FCGH would increase political accountability and accountability through the courts, while helping protect health other treaty-based international regimes, such as trade. It would also be a bold assertion of global solidarity for global justice, as so urgently needed, “demonstrating that the community of **nations are indeed stronger together**.” One candidate for the WHO Director-General election, David Nabarro, has recognized the value and civil society support that FCGH has already received, and the need to further explore the treaty (mentioned at 1:46:38 mark). A good first step would be establishing a WHO working group on the FCGH, with broad participation, particularly from states, civil society, and representatives of communities most affected by health inequities, along with relevant international agencies. We see signs of **resistance of the dangerous nationalist populism**, from protests that persist and judicial checks on one of the administration’s vilest acts (an immigration and refugee travel ban, with its effects falling heaviest on Muslims) in the United States to the rejection of the far-right candidate in the elections in the Netherland. Such resistance can prevent some of the worst impacts on the right to health, from discrimination against migrants to cuts to programs vital for health. Meanwhile, let’s construct an edifice for the future of health and human rights, even as we stand against its destruction. WHO, right to health, and FCGH leadership ought to be a core part of that endeavor.

#### Populism is an existential threat.

de Waal 16 Alex de Waal 12-5-2016 “Garrison America and the Threat of Global War” <http://bostonreview.net/war-security-politics-global-justice/alex-de-waal-garrison-america-and-threat-global-war> (Executive Director of the World Peace Foundation at the Fletcher School at Tufts University)//Elmer

Polanyi recounts how economic and financial crisis led to global calamity. Something similar could happen today. In fact we are already in a steady unpicking of the liberal peace that glowed at the turn of the millennium. Since approximately 2008, the historic decline in the number and lethality of wars appears to have been reversed. Today’s wars are not like World War I, with formal declarations of war, clear war zones, rules of engagement, and definite endings. But they are wars nonetheless. What does a world in global, generalized war look like? We have an unwinnable “war on terror” that is metastasizing with every escalation, and which has blurred the boundaries between war and everything else. We have deep states—built on a new oligarchy of generals, spies, and private-sector suppliers—that are strangling liberalism. We have emboldened middle powers (such as Saudi Arabia) and revanchist powers (such as Russia) rearming and taking unilateral military action across borders (Ukraine and Syria). We have massive profiteering from conflicts by the arms industry, as well as through the corruption and organized crime that follow in their wake (Afghanistan). We have impoverishment and starvation through economic warfare, the worst case being Yemen. We have “peacekeeping” forces fighting wars (Somalia). We have regional rivals threatening one another, some with nuclear weapons (India and Pakistan) and others with possibilities of acquiring them (Saudi Arabia and Iran). Above all, today’s generalized war is a conflict of destabilization, with big powers intervening in the domestic politics of others, buying influence in their security establishments, bribing their way to big commercial contracts and thereby corroding respect for government, and manipulating public opinion through the media. Washington, D.C., and Moscow each does this in its own way. Put the pieces together and a global political market of rival plutocracies comes into view. Add virulent reactionary populism to the mix and it resembles a war on democracy. What more might we see? Economic liberalism is a creed of optimism and abundance; reactionary protectionism feeds on pessimistic scarcity. If we see punitive trade wars and national leaders taking preemptive action to secure strategic resources within the walls of their garrison states, then old-fashioned territorial disputes along with accelerated state-commercial grabbing of land and minerals are in prospect. We could see mobilization against immigrants and minorities as a way of enflaming and rewarding a constituency that can police borders, enforce the new political rightness, and even become electoral vigilantes. Liberal multilateralism is a system of seeking common wins through peaceful negotiation; case-by-case power dealing is a zero-sum calculus. We may see regional arms races, nuclear proliferation, and opportunistic power coalitions to exploit the weak. In such a global political marketplace, we would see middle-ranking and junior states rewarded for the toughness of their bargaining, and foreign policy and security strategy delegated to the CEOs of oil companies, defense contractors, bankers, and real estate magnates. The United Nations system appeals to leaders to live up to the highest standards. The fact that they so often conceal their transgressions is the tribute that vice pays to virtue. A cabal of plutocratic populists would revel in the opposite: applauding one another’s readiness to tear up cosmopolitan liberalism and pursue a latter-day mercantilist naked self-interest. Garrison America could opportunistically collude with similarly constituted political-military business regimes in Russia, China, Turkey, and elsewhere for a new realpolitik global concert, redolent of the early nineteenth-century era of the Congress of Vienna, bringing a façade of stability for as long as they collude—and war when they fall out. And there is a danger that, in response to a terrorist outrage or an international political crisis, President Trump will do something stupid, just as Europe’s leaders so unthinkingly strolled into World War I. The multilateral security system is in poor health and may not be able to cope. Underpinning this is a simple truth: the plutocratic populist order is a future that does not work. If illustration were needed of the logic of hiding under the blanket rather than facing difficult realities, look no further than Trump’s readiness to deny climate change. We have been here before, more or less, and from history we can gather important lessons about what we must do now. The importance of defending civility with democratic deliberation, respecting human rights and values, and maintaining a commitment to public goods and the global commons—including the future of the planet—remain evergreen. We need to find our way to a new 1945—and the global political settlement for a tamed and humane capitalism—without having to suffer the catastrophic traumas of trying everything else first.

### 1NC – OFF

#### Counterplan Text - Resolved: The member nations of the World Trade Organization ought to

#### reduce intellectual property protections for medicines excluding orphan drugs.

#### 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)].

#### Best studies conclude IP protections on Orphan Drugs work and doesn’t result in abuse.

Sencen 18 Lisa Sencen 12-18-2018 "New Study Finds Orphan Drug Exclusivity Working As Intended, On-Market Orphan Drug Prices Rise Slower than Common Drugs" (Reporter for National Organization for Rare Disorders)//Elmer

Washington, D.C., December 18, 2018 — A **new report commissioned** by the National Organization for Rare Disorders (NORD) and published today by the IQVIA Institute, **demonstrates** that the seven-year market **exclusivity granted to drugs** **designated under the Orphan Drug Act** of 1983 **for rare diseases is working** as intended. **In nearly every case**, orphan **exclusivity did not inappropriately prevent generics** and biosimilars from entering the market. Instead, the **lack of generic competitors** **can be credited to their prospective return on investment being too small**. The report’s major findings are as follows: **Adding an orphan indication to** an **on-market drug** **does not correlate with** a **higher than average price increase**. The average price of therapies grew at a slower pace in 8 out of the 10 years following the addition of an orphan indication to the label. Of the 503 approved therapies with an orphan indication at the time the research was conducted, 217 are no longer covered by orphan exclusivity or patent protection. Of these 217 therapies, 116 of them have generic or biosimilar competition. The **median spending on** the **101 orphan drugs without protection** from competition and without competitors **is only $8.6 million** per year per drug. Around one-quarter of orphan drug approvals target populations smaller than 5,000 patients in the United States. Since 2009, on-market common-disease drug prices have grown more every year, on average, than orphan drugs. “The data shows that the seven-year market exclusivity provision is working as intended as an incentive for developing rare disease therapies and is not being abused,” said NORD’s President and CEO, Peter L. Saltonstall. “The NORD-sponsored study illustrates that the dilemma of rising drug prices in our country should not be attributed to orphan drugs. It is my hope that this report will provide empirical data necessary to make informed decisions.” More than 7,000 rare diseases have been identified, affecting approximately 25-30 million Americans. Many affect only a few hundred or a few thousand individuals. Rare diseases tend to be chronic, serious and life-threatening. More than 80 percent are believed to be genetic. Information on the report, including a link to the study, is available on the NORD website at www.rarediseases.org/rareinsights. Editor’s note: Peter L. Saltonstall, President and CEO of NORD, is available for interviews on the report. Contact Laura Mullen at lmullen@rarediseases.org. ### About the National Organization for Rare Disorders (NORD)Ⓡ The National Organization for Rare Disorders (NORD) is the leading independent advocacy organization representing all patients and families affected by rare diseases. NORD is committed to the identification, treatment, and cure of the more than 7,000 rare diseases, of which approximately 5% have an FDA-approved treatment or therapy. Rare diseases affect 25-30 million Americans, or 1 in every 10 people. More than half of those affected are children. NORD began as a small group of patient advocates that formed a coalition to unify and mobilize support to pass the Orphan Drug Act of 1983. For more than 35 years, NORD has led the way in voicing the needs of the rare disease community, driving supportive policies and education, advancing medical research, and providing patient and family services for those who need them most. NORD represents more than 280 disease-specific member organizations as well as their communities and collaborates with many other organizations in specific causes of importance to the rare disease patient community.

#### 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

#### Pharma innovation in Neglected Diseases results in global linkages that revitalizes global health diplomacy.

Hotez 16, Peter J. Blue marble health: an innovative plan to fight diseases of the poor amid wealth. JHU Press, 2016. (Sabin Vaccine Institute and Texas Children’s Hospital Center for Vaccine Development, Departments of Pediatrics and Molecular Virology and Microbiology)//Elmer

We also need to better understand how these NTDs are actually transmitted within US borders, and I think it is extremely important to learn more about the links between these diseases and poverty. As I noted earlier, a drive through Houston’s Fifth Ward provides some insights, as one can quickly identify predisposing risk factors, including stray animals, dilapidated houses without window screens, standing water and discarded tires, and other evi- dence of environmental degradation, but we need to conduct careful epidemiological studies to really understand the links between poverty and NTDs, as well as animal reservoirs for illnesses such as Chagas disease and others. All of this presents an important research and development agenda for the NTDs in the United States. There are no point-of-care diagnostic tests available for most of the NTDs endemic to the nation, so blood from pa- tients must be sent to the CD С or other specialty research laboratories in order to establish a diagnosis for these conditions. As I sometimes point out to general audiences, when you go to your physician and get blood work done, there is no box to check off for toxocariasis or Chagas disease as there is for blood chemistries or other routine tests. We need diagnostic tests that are easily accessible to physicians and nurses. We also need new and improved treatments and vaccines. Because the NTDs are poverty-related diseases, they often fly below the radar screen of the major pharmaceutical companies and are not prioritized. Thus, the drugs used to treat these illnesses are not widely available, so typically the CDC has to be contacted in order to access them. In addition, many of these medicines were developed decades ago and produce a lot of side effects. For instance, the two medicines for Chagas disease—benznidazole and nifurtimox—cause skin rashes, diarrhea, and other unpleasant or even dangerous symptoms and illnesses. Patients using these medications have to interrupt their treatments up to 20% of the time. Moreover, these drugs cannot be used by pregnant women. Currently, new innovations for NTDs like Chagas dis- multinational ease still rely on nonprofit PDPs. The Geneva-based Drugs pharmaceutical for Neglected Diseases Initiative is leading efforts to de- companies have velop new and safer Chagas disease medicines [60], while shown little or modest at our National School of Tropical Medicine the Sab in interest in American Vaccine Institute and Texas Childrens Hospital Center for NTDs. As a result, new Vaccine Development (Sabin PDP) is working to develop products are being a therapeutic vaccine that could be used alongside exist- developed in the ing treatments [61]. These efforts rely on major philan- nonprofit sector. thropic donors. In our case at the Sabin PDP, they include the Kleberg Foundation, the Carlos Slim Foundation, the Southwest Electronic Energy Medical Research Institute, and Texas Childrens Hospital. Summary Points 1. In the United States, 45.3 million people live below the poverty line, roughly the same number of impoverished Americans alive during the early 1960s when Michael Harrington wrote The Other America. Approximately 20 million Americans now live in extreme poverty at one-half the US poverty level, and approximately 5 million are living on less than $2 per day 2. American poverty concentrates in specific areas, especially in southern states, with Texas having the largest numbers who live in poverty Important areas in the South include the Gulf Coast, border areas with Mexico, the Mississippi Delta, and Appalachia. 3. Approximately 12 million Americans are infected with NTDs, led by toxocariasis and trichomoniasis—which disproportionately affect African Americans—and Chagas disease (American trypanosomiasis) and cysticercosis—which disproportionately affect people of Hispanic origin. Toxoplasmosis is another important NTD. Toxocariasis, cysticercosis, and toxocariasis exert important mental health effects on impoverished Americans. Many of these NTDs are transmitted within US borders (autochthonous infections). 4. Arboviral infections are also important NTDs, led by dengue fever in Gulf Coastal areas and West Nile virus infection. WNV can cause chronic, persistent viral infections linked to chronic neurologic and renal disease. 5. There is an urgent need to promote awareness about the NTDs, especially for physicians and other health-care providers. 6. New policies are needed to expand surveillance for the NTDs affecting the United States. New legislation has been adopted in Texas, while additional bills are being introduced in the US Congress. Epidemiological studies are also needed to better understand how these diseases are transmitted and how they are linked to extreme poverty in the American South and elsewhere. 7. There is an urgent need for new “control tools” for American NTDs, including point-of-care diagnostics, antiparasitic and antiviral drugs, and vaccines. Many of these products are being developed by nonprofit PDPs rather than pharmaceutical companies. he G20 "A Theory of Justice" In his landmark 1971 book A Theory of Justice, the Harvard political philosopher John Rawls articulates two overriding principles of a just and fair society, namely, (1) “equality in the assignment of basic rights and duties” and (2) allowance of some social and economic inequalities, but only if they ultimately benefit “the least advantaged members of society” [1]. In terms of Rawls’s worldview, I believe that finding widespread NTDs among the extreme poor (and least-advantaged) who live amidst wealth—the central tenet of blue marble health—might represent one of the most jarring affronts to what he terms “justice as fairness” Because NTDs are now widespread among the leastadvantaged members of the worlds wealthiest economies, and they represent a major basis for thwarting their future growth, it is urgent for these nations, especially the G20 countries, to adopt strong internal policies to combat these diseases. I envision a three-pronged strategy to best address the G20 s (and Nigeria’s) poorest citizens afflicted by NTDs: 1. Each of the G20 nations and Nigeria has the capacity to fully understand the extent of these diseases within their own borders and then provide their own impoverished populations access to essential medicines used in mass drug administration to target helminth infections, in addition to trachoma, leprosy, yaws and scabies, and to provide treatments for other high-disease burden NTDs, including leishmaniasis and Chagas disease. The G20 countries and Nigeria Three major steps are required to effectively address blue marble health. 141 142 Blue Marble Health need to allocate resources and implement programs to achieve universal coverage for these diseases. 2. Each of the G20 nations and Nigeria has the capacity to conduct research and development for new NTD biotechnologies; they need to allocate resources toward this goal. 3. Both activities should be conducted within an overall framework of health system strengthening. Mass Drug Administration in the G20 A good place to revisit MDA among the G20 countries is to more closely examine the six G20 countries with positive worm indices—Brazil, China, India, Indonesia, Mexico, and South Africa—in addition to Nigeria. Together these countries account for one-half of the worlds helminth infections [2]. An analysis of WHO s PCT database reveals that most of these nations are severely underachieving when it comes to providing MDA for people who require regular and periodic treatment for their intestinal helminth infections, schistosomiasis, and LF. Shown in table 11.1 is WHO’s estimate of the percentage that received treatment in 2013 [3-5]. Overall, the G20 nations affected by helminth infections and Nigeria perform poorly when it comes to treating their affected populations through MDA. In terms of specific countries in Latin America, Brazil is reaching only approximately one-third of its children and population at risk. And although Mexico provides complete coverage for intestinal worms, it—as previously mentioned—neither diagnoses nor treats hundreds of thousands (and possibly millions) of people with Chagas disease. In Africa, Nigeria’s MDA reaches less than 25% of its children at risk for helminth infections, and there is no information about schistosomiasis coverage in South Africa forthcoming from WHO. However, as Dr. Eyrun Kjetland (who works extensively in South Africa) has pointed out, female genital schistosomiasis remains widespread there, in part because praziquantel has been mostly unavailable in the country, owing to its drug importation laws. Schistosomiasis and other NTDs are still found among the poor in the Kingdom of Saudi Arabia. The entire MENA region severely underdiagnoses most of its NTDs, including leishmaniasis. In Asia, Indonesia largely does not promote widespread deworming for its children, and only a small percentage of its population receives treatment for LF, while India does only marginally better. Indonesia also suffers from high rates of yaws, which can also be targeted by MDA using the antibiotic azithromycin. Similarly in India, the vast majority of its children do not have access to regular and periodic deworming, and only about one-half of the population receives MDA for LF. India also has the worlds largest numbers of leprosy cases. This disease can also be attacked through MDA using a multidrug therapy regimen. WHO does not present information on China, either because it has not been determined or is unavailable. However, China has made great strides in reducing its schistosomiasis prevalence since 1949, and it has eliminated LF. Similarly, Japan and South Korea have achieved significant success both in economic development and in reducing or eliminating its NTDs. 144 Blue Marble Health Key common factors for poor performance in meeting MDA targets are vast geographies, decentralization of health care, inadequate resource allocation, and lack of political will. Overall, the six G20 countries with positive worm indices, together with Nigeria, have the means and capacity to eliminate LF within their own borders, while greatly reducing the disease burdens of their intestinal helminth infections and schistosomiasis through MDA. Some of the key common factors for poor performance in meeting MDA targets are vast geographies, decentralization of health care that results in fragmentation of drug delivery, inadequate resource allocation, and lack of political will and commitment. What about G20 countries affected by NTDs but without a positive worm index? In the United States, the 12 million Americans infected and living with NTDs are largely unrecognized, undiagnosed, and untreated. The United States also does very little in terms of conducting active surveillance for Chagas disease (and other major NTDs), and only a tiny percentage of its population receives access to diagnosis and treatment—the same is true for Argentina. In both North America and Europe, toxocariasis and other parasitic zoonotic infections are seldom diagnosed and treated. Minimal information is available on eastern ------------------- Europeans, Turks, and Russians with intestinal worms or zoonotic NTDs or their access to diagnosis and treatment. NTDs remain widespread among Aboriginal Australians, including intestinal helminth infections and scabies—both of which can be targeted through MDA. Thus, the current status of access to essential medicines for people living in poverty and with NTDs among the G20 countries and Nigeria can be summarized as abysmal. The fact that so few are being treated through MDA programs is especially sad, given its low costs. As previ- ------------------- ously mentioned, there are approximately 1.07 billion treatments required among the populations at greatest risk in the G20 countries and Nigeria. At a cost of 50 cents per person per year, approximately $500 million would be required—that is, a dollar amount representing a tiny percentage (<0.001%) of the $65 trillion combined economy of these countries. The bottom line is that each of these nations has the internal capacity to provide these low-cost treatments to its impoverished populations. WHO has now launched a Universal Health Coverage (UHC) initiative that builds on its 1978 “Health for All” Alma-Ata declaration and the MillenThe current status of access to essential medicines for people living in poverty and with NTDs among the G20 countries and Nigeria can be summarized as abysmal. The G20 145 nium Development Goals, with a focus on protecting the health of the worlds most economically vulnerable populations. The activities highlighted here clearly fall within WHO s UHC mandate. Research and Development for New Control Tools and Biotechnologies For many of the leading NTDs—including vector-borne diseases such as dengue, leishmaniasis, Chagas disease, African sleeping sickness, and malaria, and also some helminth infections such as hookworm, schistosomiasis, onchocerciasis, and foodborne trematodiases—there are equally urgent needs to develop new drugs, diagnostics, and vaccines. Each year, the Australian policy group known as Policy Cures publishes an annual G-FINDER Report that measures the global investment in new technologies for neglected diseases, defining them broadly to include both the NTDs and the “big three” diseases: HIV/ AIDS, ТВ, and malaria [6]. For the year 2014, G-FINDER determined that approximately $3.37 billion was invested globally in neglected disease R&D technology, with most of that support going toward the big three diseases [6]. A look at total government support for neglected disease R&D, almost all of it from G20 countries, is also interesting. The public sector provided 64% of the total funding, and the United States provided two-thirds of that funding, mostly from the US National Institutes of Health [6]. In all, 71% of the total government funding for neglected diseases comes from the United States, European Commission, and United Kingdom. However, as the G-FINDER Report points out, these absolute numbers do not consider the GDPs of these nations. In terms of public funding relative to GDP ratios, countries such as Ireland, Denmark, Norway, and Argentina do particularly well in this regard [6]. Shown in table 11.2 are selected estimates from G-FINDER of the percentage of their GDP that various governments have devoted to R&D on Of government funding for neglected diseases R&D, a whopping 71% comes from the United States, European Commission, and United Kingdom. We need greater involvement and support from the remainder of the G20 countries, including positive worm index G20 countries— Brazil, China, India, Indonesia, Mexico, and South Africa, in addition to Nigeria. 146 Blue Marble Health Although NTDs and other poverty-related diseases account for almost 14% of the global disease burden, they receive only a bit more than 1% of the global health-related R&D funds. neglected diseases. Using data from the G-FINDER Report combined with GDP information, I calculate that the world spends approximately 0.0028% of its GDP on neglected diseases R&D. Only three G20 countries—United States, United Kingdom, and Australia—match or exceed that percentage, ------------------- although India and France come close to it. The worstperforming countries were China and Japan. However, in 2013 the Japanese government, together with Japans major pharmaceutical companies and the Bill & Melinda Gates Foundation, formed a partnership known as the Global Health Innovative Technology (GHIT) Fund for supporting PDPs and other entities to develop and shape new biotechnologies for neglected diseases, with an emphasis on NTDs [7, 8]. China is a different matter. The New York Times has reported that China paid out $86.3 billion in foreign investments in the year 2013 [9], with much of that spent in fragile nations where health systems are broken and NTDs are widespread. Clearly, China needs to allocate some of those funds to neglected diseases, either for MDA or new technologies. In addition, the nation of Brazil could easily increase its global contribution to NTD technologies by ю -fold in order to match higher-performing nations in this regard. Germany is now looking at supporting NTD technologies as part of an overarching G7 initiative on NTDs. In 2011, the German government launched a policy roadmap for neglected and poverty-related diseases [10]. Indeed, a recent analysis conducted by German investigators has found although NTDs ------------------- and other poverty-related diseases account for almost 14% of the global disease burden, they receive only a bit more than 1% of the global health-related R&D funds [11]. As shown in figure 11.1, by presenting R&D expenditures for a particular disease divided by the disability adjusted life years (DALYs) it is possible to get a sense of ------------------- diseases that are especially underfunded—even compared with other NTDS—such as the intestinal helminth infections and other neglected enteric diseases, as well as rheumatic fever [11]. Such data argue for the great urgency needed in addressing these health disparities by increasing R&D funding and support. Recently, the Dutch and German governments and the European Union (EU) have established important initiatives to support NTD R&D. The Dutch Ministry of Foreign Affairs, for instance, has been a major partner in our human hookworm vaccine initiative, while the EU has an important Frameworks Program 7 (FP7) for supporting new technologies [12], including a HOOKVAC Consortium of partners organized through the Amster dam Institute of Global Health and Development [13]. Most recently, the EU has established an ambitious Horizon 2020 program for expanding R&D in Europe, including NTD R&D activities [14], on top of a European and Developing Countries Clinical Trials Partnership (EDCTP) for clinically evaluating new NTD technologies [15]. New German government funding for NTD R&D funding was just announced. These Dutch, German, and EU initiatives represent an important advance for shaping the next generation of products to treat and prevent NTDs. Yet another aspect of blue marble health is the rise in comorbid conditions between the NTDs, the big three diseases, and the noncommunicable diseases. Impoverished and neglected populations in the G20 countries and Nigeria are facing a double hit resulting from the convergence of NTDs and NCDs. For instance, in Texas, Mexico, and India (but presumably elsewhere) they include both ТВ and diabetes interactions and, lately, dengue and diabetes interactions. In South Africa, HIV/AIDS now flourishes amidst the high prevalence of female genital schistosomiasis. Studying the pathogenesis and epidemiology of these comorbid interactions will also be an important theme in the coming years. Shaping a Policy for the G20 The G20 began meeting in 2008 in response to that years global recession and have since convened in a summit each year to discuss the major policy issues of the day [16]. At the 2015 G20 Summit held in Turkey, the major areas of broad emphasis included strengthening the global recovery and enhancing resilience, while ensuring sustainability [17]. Clearly, lifting the bottom segments of their populations out of poverty through NTD control and elimination could fall within the G20 remit. It is imperative that the six member nations with positive worm indices commit to providing total MDA coverage for their populations affected by the major helminth infections, and also that the four Western Hemispheric countries step up surveillance, diagnosis, and treatment for Chagas disease. Leishmaniasis, both kala-azar and the cutaneous form, also represent major NTDs affecting the G20, and these diseases need to be targeted for control and elimination. The US, Dutch, German, and Japanese governments, along with the EU, stand out for their contributions toward supporting product development to counter NTDs, 150 Blue Marble Health Equally important is the R&D agenda. There are some obvious underachievers among the G20 countries that must step up and contribute to R&D for new drug, diagnostic, and vaccine products to fight the neglected diseases [18]. Toward that aim, several investigators have proposed the establishment of R&D funds to support neglected disease research. They include a global vaccine development fund [19] and a general biomedical R&D fund focused on antimicrobial resistance, emerging infectious diseases, and neglected diseases [20]. Both proposals are thoughtful, have a lot of merit, and need to be considered, but I offer an alternative or complementary solution. In 2013, the World Health Assembly passed a resolution (66.22) that proposes a “strategic work plan” to achieve sustainable funding for health R&D that could emphasize NTDs. The plan commits the director-general of the World Health Organization to establish a global “observatory” in order to identify gaps and opportunities for health R&D related to neglected diseases [21]. Through a pooled fund managed by WHO-TDR (a special program on tropical disease research and training), several pilot projects are now being supported [22]. Given that todays neglected disease R&D support comes mostly from the United States—and indeed mostly from a single agency, the National Institutes of Health—it is difficult to envision how such a fund would be created without calling on the NIH yet again. Realistically, it is unlikely the NIH leadership or the well-established community of US scientists would be willing to cede control of NIH budgets to an international body. Instead, I think it is worth considering the possibility of having each of the G20 countries establish its own version of the Japanese GHIT Fund, which builds on indigenous scientists and academic institutions and their own pharmaceutical industries. A Chinese or South Korean version of GHIT for example could become a vital and important institution. Creating twenty separate innovation funds could achieve the same goals as a global fund, while simultaneously ensuring national ownership and capacity building for indigenous academic and industrial institutions. Many of them could develop and shape new biotechnologies in collaboration with the 16 international PDPs. This approach would be especially useful for the less developed G20 countries, including Brazil, Global funds for R&D are an option. An attractive alternative is to create national funds for product development R&D in each of the G20 countries and Nigeria—ones that resemble those put forward by the Dutch and Japanese governments. The G20 151 India, Indonesia, and Mexico. These nations have indigenous vaccine manufacturers, which are represented by the Developing Country Vaccine Manufacturers Network, and therefore have a level of sophistication for producing next-generation NTD vaccines. Still another option is for smaller groups of G20 countries to come together to support R&D investments. The EU’s programs for new NTD technologies highlighted above represent important examples. In addition, if institutions from China and India (both rivals and neighbors) collaborated in the area of neglected diseases [23], some important NTD problems affecting Asia could be solved in the coming years. The United States has potential to extend its outreach on NTDs by collaborating with other G20 nations in the Americas or other countries [24]. As a UN agency, WHO could certainly partner with one or more of these G20 NTD R&D investment funds, especially through its global health R&D observatory mechanism. Another key United Nations agency might include WIPO—the World Intellectual Property Organization. Through the Patent Cooperation Treaty mechanism, the Geneva-based WIPO represents one of the few revenue-generating UN agencies. In 2011, in collaboration with BIO Ventures for Global Health, it established WIPO Re:Search to facilitate the development of products to combat NTDs by bringing together major pharmaceutical companies and academic investigators working on these diseases [25]. As a revenue-generating UN agency under the charismatic leadership of Francis Gurry, WIPO has the potential to expand this remit to support NTD product R&D. Looking beyond the G20 The major NTDs linked to wealthy countries and blue marble health could also be addressed by nongovernmental organizations, including faith-based groups. For example, in 2011 the Pew Research Centers Forum on Religion and Public Life reported that the center of the worlds Christian-majority countries has shifted from Europe and North America to the Global South, meaning Africa, Asia, and Central and South America [26]. Thus, countries such as Brazil, Philippines, Angola, Democratic Republic of Congo, and Papua New Guinea now have some of the highest percentages of Christian populations. As shown in table 11.3, from an analysis published in PLOS NTDs I found that almost all of the world s Chagas disease cases and African trypanosomiasis (sleeping sickness) can be found in Christian-majority countries, in addition to almost one-half of the schistosomiasis cases [26]. These findings suggest the possibility of bringing in new actors to combat NTDs. They could include the Vatican and Pope Francis, especially given the new popes renewed commitment to impoverished populations [19]. The Orthodox Christian Church also has opportunities to highlight NTDs in countries such as Ethiopia or those in the Middle East, as do many Christian faith-based organizations and universities. The G20 153 Summary Points 1. The six G20 countries with positive worm indices—Brazil, China, India, Indonesia, Mexico, and South Africa, together with Nigeria, have the means and capacity to eliminate LF within their own borders, while greatly reducing the disease burdens of their intestinal helminth infections and schistosomiasis through MDA. 2. G20 countries without classical worm indices, including the United States, also need to find mechanisms for promoting surveillance and access to essential medicine options for the poor living with NTDs within their own borders. 3. The G20 countries also have important biotechnology capabilities, which have yet to be adequately tapped for producing new NTD diagnostics, drugs, and vaccines. Beyond the United States, European nations, Australia, and Japan, they also include Brazil, China, India, Indonesia, Mexico, Russian Federation, Saudi Arabia, South Africa, and South Korea. 4. Yet another aspect of blue marble health is the rise in comorbid conditions between the NTDs, the big three diseases, and the NCDs. 5. The EU and the Dutch and German governments have launched important NTD technology initiatives, as has the Japanese government and its partners through a new GHIT Fund. These activities support PDPs committed to NTDs as well as indigenous academic institutions and industrial organizations. 6. Large G20 economies such as Brazil and China must increase their global commitment to support new NTD technologies and R&D. 7. There are opportunities to link these new investments with parallel activities ongoing at two UN agencies, namely, WHO and WIPO. 8. These topics should be highlighted at future G20 summits. 9. Faith-based organizations could have a future role. For instance, the Vatican and related entities have opportunities to expand commitments to control those NTDs that are found to be prevalent among Christian-majority countries. Central to the blue marble health concept is that each of the G20 nations and Nigeria need to take greater responsibility for their own neglected diseases and neglected populations. Doing so could result in the control or elimination of one-half or more of the planets NTDs, with substantial gains made against HIV/AIDS, ТВ, and malaria. Thus, while programs of overseas development assistance devoted to health, such as PEPFAR, GFATM, PMI, and USAID’s NTD Program, in which the worlds richest countries provide support to the poorest nations for their neglected diseases, must continue and should even expand, we need increasingly to recognize the hidden burden of neglected diseases among the poor living in wealthy countries. As a first step, we must expand initiatives that raise awareness about the problem of NTDs within each of the G20 countries and Nigeria. The Global Network for NTDs linked to the Sabin Vaccine Institute has been working closely with the governments of India and Nigeria, respectively, in order to explain the opportunity for mass drug administration and its potential impact on health and economic development. MDA coverage rates are disappointingly low in these nations, especially for intestinal helminth infections and LF, as well as for schistosomiasis in the case of Nigeria. An extraordinary finding is that at least three nations with positive worm indices—India, Pakistan, and China—also maintain nuclear stockpiles [1]. Could the scientific horsepower of these nuclear states be partly redirected toward reducing endemic NTDs at home? 154 A Framework for Science and Vaccine Diplomacy 155 Outside of India and Nigeria, there is a need to promote NTD awareness in each of the G20 countries. For example, in the United States, our National School of Tropical Medicine has been highlighting the plight of some 12 million Americans living with NTDs. We have now worked with the Texas Legislature to enact a bill for NTD surveillance in suspected high-prevalence areas. However, similar initiatives need to be enacted across the G20 nations, including the European Union. In addition, international cooperation between the different G20 nations and Nigeria could be critical in achieving higher population coverage for MDA. For instance, China, despite its billions of dollars of business investments in sub-Saharan Africa, has not yet promoted NTD control efforts there. Yet China has tre- mendous expertise in MDA for NTDs and could provide Africa with valuable advice in this area. China was the first country to eliminate LF and has achieved successes in re- ducing its burden of schistosomiasis more than ю -fold since the 1949 revolution. China could also share its best practices with neighboring India, where NTDs remain practically ubiquitous [ 2]. Similarly, Japan and South Korea have made great gains toward eliminating intestinal helminth infections, while the former has also successfully eliminated LF and schistosomiasis. International cooperation between these three East Asian nations and Nigeria, or with the G20 countries with positive worm indices, especially India, Indonesia, and Brazil (where they are the highest), could result in important, positive health and economic gains. Each of these activities represents examples of what some refer to as global health diplomacy. Global Health Diplomacy My former colleague at Yale University, Ilona Kickbusch, currently the director of the Global Health Programme at the Graduate Institute of International and Development Studies in Geneva, has provided several working definitions of global health diplomacy, including efforts to “position health in foreign policy negotiations,” together with the establishment of global health governance initiatives [3]. Indeed, the creation of the GAVI Alliance, GFATM, UN AIDS, and other Geneva-based organizations might be considered vital examples of organizations created under the auspices of global health diplomacy, with the first two created following the 2000 Millennial Development Goals. The MDGs themselves represent an important framework for global health diplomacy, and arguably the most successful. Since 2005, several global health diplomacy initiatives have been enacted that could facilitate NTD activities among the G20 and Nigeria, although most of these actions are more focused on emerging viral infections of pandemic potential rather than the widespread chronic and debilitating NTDs. The International Health Regulations (IHR) were enacted in 2005 as a binding legal mechanism for all member states of WHO and focused on responses to acute public health emergencies [4]. IHR demands that countries report outbreaks and other public health events, while WHO responds with measures to uphold and enforce global health security [4]. IHR also establishes an emergency committee that advises the WHO director-general on whether an unexpected event should be considered a public health emergency. It also provides recommendations on initial steps for travel restrictions, surveillance, and infection control. With the possible exception of dengue fever, it is not clear how IHR will substantively address the NTDs or other blue marble health conditions. Moreover, even with IHR in place, the global response to the 2014 emergence of Ebola in West Africa was slow and inadequate and led to a catastrophic outbreak in the fall of that year [5]. This failure may require future revisions in the IHR, as recently recommended in a 2015 Lancet article by Lawrence Gostin and his colleagues at Georgetown University [6]. The Global Health Security Agenda (GHSA) is an interagency initiative of the US government conducted in partnership with other nations and international organizations, including WHO [7]. GHSA is also focused on preventing or reducing the impact of epidemics and outbreaks of pandemic potential, such as H7N9 influenza virus or MERS coronavirus, as well as detecting emerging threats and implementing rapid and effective responses. In some respects, GHSA represents the US component or response to IHR. It also covers intentional or accidental releases of dangerous infectious disease pathogens. Global Health 203s and The Lancet Commission were launched in 2013, coinciding with the twentieth anniversary of a landmark 1993 World Development Report that helped to ignite international efforts to link investments in health with economic development [8]. The Lancet Commission identifies four key messages and actions: (1) the substantial economic return on investing in health, which can be as much as 24% in low- and middle-income countries; (2) implementation of a “grand convergence” in global health through scale-up of health technologies and strengthening health systems by the year 2035; (3) fiscal policies such as taxation of tobacco and reduction of subsidies for fossil fuels, which represent powerful forces or “levers” for elected leaders; and (4) universal health coverage as an efficient mechanism to improve health as well as to provide “financial protection” [8]. The Addis Ababa Action Agenda (AAAA) is the product of the first of three international meetings for implementing the UN s 2015 Sustainable Development Goals. However, health is at present only a minor component of the AAAA. Indeed, the SDGs have been criticized because health is now only 1 of the 17 goals, whereas it was front and center among the 2000 MDGs. So far, the AAAAs recommendations have included the promotion of the health systems strengthening component of the GFATM and GAVI Alliance and the establishment of a Global Financing Facility (GFF) for womens and childrens health that would go hand-inhand with the UN secretary generals new Global Strategy for Every Woman Every Child [9]. The emphasis of these initiatives is to reduce preventable maternal, child, and adolescent deaths by 2030. Despite the evidence that hookworm infection and Chagas disease rank among the leading complications of pregnancy among women living in poverty in low- and middle-income countries, while female genital schistosomiasis is among sub-Saharan Africa’s most common gynecologic condition, there is not yet a specific mention of NTDs in the AAAA or GFF. Ultimately, the G20 nations can identify ways to address blue marble health disparities under the auspices of the SDGs or the global health diplomacy initiatives highlighted above. However, at present there is no specific mandate for them to do so. Vaccine Science Diplomacy Concurrently, the G20 nations have opportunities to collaborate in scientific activities leading to the development of new drugs, diagnostics, and vaccines. I have used the term “vaccine science diplomacy” to refer to inter- national scientific codevelopment of lifesaving vaccines between scientists of different nations, but particularly from nations with strained or evenly openly contentious international relations. The best historical example of vaccine science diplomacy is the codevelopment of the oral polio vaccine, led on the American side by Dr. Albert B. Sabin, and his Soviet virologist counterparts, including Dr. Mikhail Petrovich Chumakov [3]. In modern times there is potential interest in explor ing vaccine science diplomacy opportunities between the United States and some of the worlds Muslim-majority nations belonging to the Organisation of Islamic Cooperation [10,11]. OIC countries include most of the Middle East and North Africa, as well as some highly populated Southeast Asian nations, including Bangladesh, Indonesia, and Malaysia, as well as most of central Asia. New estimates that we published in PLOS NTDs in 2015 indicate that the 30 most-populated OIC countries account for 35% of the worlds helminth infections comprising the global Worm Index, including 50% of the worlds children who require MDA for schistosomiasis [11]. Given that approximately 1.5 billion people live in OIC countries, or about 20% of the global population, helminth infections appear to disproportionately affect the health and economic development of Muslim-majority countries, as does leishmaniasis, trachoma, and possibly other NTDs [11]. As shown in figure 12.1, there is also tight inverse association between the worm index and human development index in the Muslim world [11]. OIC nations with strong infrastructures in science and biotechnology are potentially attractive candidates to pursue joint vaccine science diplomacy initiatives with the United States. Here the idea would be to promote scientific collaborations between US scientists and scientists from selected OIC countries in order to create new NTD technologies for some of the worst-off Muslim-majority countries. The “worst-off” might include OIC countries at the high end of the worm index, including Mali, Cote d’Ivoire, Mozambique, Cameroon, Burkina Faso, and Niger, as well as Nigeria [11].

#### Public Health Diplomacy solves Existential Threats.

James 17 Wilmot James 4-2-2017 “In an Age of Zika and a Threat of Biochemical Terror, Health Security Must Be Everybody’s Concern” https://archive.is/tUlRX#selection-927.0-930.0 (Honorary Professor in the Division of Human Genetics at the University of Cape Town's Medical School and Non-residential Senior Fellow at Bard College’s Hannah Arendt Centre, Ph.D. from University of Wisconsin at Madison)//re-cut by Elmer

With Zika there too was political failure to act quickly, give honest advice and confront the abortion conundrum head-on, the result being that 3,000 and likely more children with microcephaly will test the emotional resilience and financial resources of their families to breaking point. We should never cease to invest in the public health and medical science of disease, but it seems to me that our fundamental problem is not the quality of the health sciences but the grim mediocrity of our politics. Party-political bickering for short-term gain paralyses and drains the national effort in South Africa as much as it does in the United States, undermining our ability to see with compelling clarity the solutions the issues of the day deserve. **Health** security **is humanity’s shared concern**. Promoting health and preventing death define us at our most altruistic and advanced. The Hippocratic Ideal, the concept of the physician as the guardian of human health, encapsulates a fundamental human quality common to all the world’s great religions. **Medicine** is one of the earliest and greatest human achievements because it is a **co-operative enterprise** involving highly skilled individuals; and it is **as a result** of cooperation – and our unusual ability for complex language – that cumulative **civilisation is possible**. In the age of globalisation, it is **health security**, a recent Lancet editorial stated, that “is now the **most important foreign policy issue** of our time”. The rapid emergence and re-emergence of pathogenic infectious **disease**, of which Zika is the most recent, the slow but steady cumulative acts of nature associated with **climate change**, high-risk **forced migration** caused by desperation and war, the creeping reality of **biochemical terror and** the threat of **nuclear war, propel human survival** and well-being **to the frontline** of what today must be everybody’s concern. The field of **health diplomacy provides** an **unprecedented opportunity to build** human **solidarity**. It is an area of human endeavour that **cuts through** inherited **antagonisms**. Governments that offer **health improvements** as part of aid to nations with whom they wish to **develop** stronger **diplomatic links** succeed in cultivating deeper cultural relationships precisely because of their direct benefit to citizens. To advance health diplomacy requires health leaders with an inclusive global vision...

#### Only health cooperation solves diseases – specifically key to protect developing nations

Long 11 (William J., professor and chair at the Sam Nunn School of International Affairs at the Georgia Institute of Technology. He is the author of three books and numerous articles on conflict resolution, international cooperation, and trade and technology transfer policy and Jennings Randolph fellow at the U.S. Institute of Peace in 2009-10, “Pandemics and Peace: Cooperation in Zones of Conflict”, USIP Press Books) JA

The spread of avian influenza and other naturally occurring or man-made biological threats presents a grave security and humanitarian threat region-ally and globally." Dramatic increases in the worldwide movement of people, animals, and goods; growing population density; and uneven public health systems worldwide are the driving forces behind heightened vulnerability to the spread of both old and new infectious diseases." Since the global spread of the human immunodeficiency virus (HIV) began in the early 1980s, twenty-nine new bacteria or viruses have been identified, many of which are capable of global reach." Commenting on this trend in 2007, the United Nations' World Health Organization warned, "Since the 1970s, newly emerging diseases have been identified at the unprecedented rate of one or more per year. .. . It would be extremely naive and complacent to assume that there will not be another disease like AIDS, another Ebola, or another SARS, sooner or later."" Senior World Health officials have noted that In-adequate surveillance and response capacity in a single country can endanger national populations and public health security of the entire world."" With more than a million travelers flying across national boundaries ev-ery day, it is not an exaggeration to say that a health problem in any part of the world can rapidly become a health threat to many or 21122—v/hat one author calls the microbial unification of the world." The outbreak of severe acute respiratory syndrome (SARS) in 2002 and 2003 demonstrated how a previously unknown but lethal virus could spread by modern air trans-port, traveling from Hong Kong to Toronto in fifteen hours and eventually reaching twenty-seven countries? The increased speed of transmission also means that contagion is likely to be well established before governments and international organizations are aware of the presence of the disease.° SARS, in turn, focused attention on the ability of public health systems worldwide to cope with an anticipated pandemic associated with the next major antigenic shift in the influenza A virus. Although the influenza A virus mutates regularly (antigenic drift), every decade or so the virus undergoes a major change, or shift, for which most people have little or no protection. The threat is magnified today by the ability of such diseases to spread worldwide very rapidly.2 For example, since emerging in 1997, avian influenza—which to date has infected more than 400 people and killed more than 200—could create, if it becomes capable of human-to-human transmission as a new influ-enza A virus, a global pandemic of unprecedented lethality. Avian influenza could, if it becomes capable of human-to-human transmission as SARS did in 2002, kill somewhere between 200,000 to 16 million Americans. Countries with less robust public health systems would lose an even larger percentage of their population to such a disease. The relatively benign H1N1, or swine flu, outbreak provides a harbinger of this future danger. Global economic and political stability could fall victim to a pandemic too. Today, nations must provide for their citizens' health and well-being and protect them from disease. Health provision has become a primary public good and part of the social contract between a people and its government? Accelerating transnational flows, especially pathogens, can stress and could overwhelm a state's capacity to meet this essential function. Weak states could fail economically or politically, thereby creating regional instability and a breeding ground for terrorism or human rights violations. Statistical studies reveal that declining public health substantially increases the probability of state failure," and historical examples of the correlation between disease outbreak and political instability and violence extend from the fall of ancient Athens to recent violence in Zimbabwe. Even in the strongest states, leaders must be prepared, in an integrated way, to respond to the full spectrum of biological threats that could impede essential social functions such as food supply, transportation, education, and workforce operation and result in huge economic costs." Reducing the danger of influenza or other infectious diseases requires a focus on preparedness and monitoring. Rapidly identifying the problem, sharing information, and coordinating response are each critical to limit-ing the perils of pathogenic threats. Although the peril is great, so too is the promise of building cooperation through regional disease surveillance, detection, and response. Here is the positive potential of globalization: it can facilitate the rapid response to health challenges by quickly mobilizing health professionals, medicines, and supplies, and by deploying information technology for disease surveillance and sharing best health practices across nations." These exchanges, between neighboring states and even between traditional adver-saries, could contribute to reducing disparities in health and help improve regional relations. Armed with a theoretical understanding of the basis for such cooperation, the regional and international practitioner and policy com-munities can respond more effectively to this critical transnational security and humanitarian concern."

#### Extinction – defense is wrong

Piers Millett 17, Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization.

A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6

While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and theWestern Abenaki (which suffered a staggering 98% loss of population).

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-2

### 1NC – OFF

#### Climate Patents and Innovation high now and solving Warming but patent waivers set a dangerous precedent for appropriations – the mere threat is sufficient is enough to kill investment.

Brand 5-26, Melissa. “Trips Ip Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors.” IPWatchdog.com | Patents & Patent Law, 26 May 2021, www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/. //sid

The biotech industry is making remarkable advancestowards climate change solutions, and it is precisely for this reason that it can expect to be in the crosshairs of potential IP waiver discussions. President Biden is correct to refer to climate change as an existential crisis. Yet it does not take too much effort to connect the dots between President Biden’s focus on climate change and his Administration’s recent commitment to waive global IP rights for Covid vaccines (TRIPS IP Waiver). “This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures.” If an IP waiver is purportedly necessary to solve the COVID-19 global health crisis (and of course [we dispute this notion](https://www.ipwatchdog.com/2021/04/19/waiving-ip-rights-during-times-of-covid-a-false-good-idea/id=132399/)), can we really feel confident that this or some future Administration will not apply the same logic to the climate crisis? And, without the confidence in the underlying IP for such solutions, what does this mean for U.S. innovation and economic growth? United States Trade Representative (USTR) [Katherine Tai](https://www.ipwatchdog.com/2021/05/05/tai-says-united-states-will-back-india-southafrica-proposal-waive-ip-rights-trips/id=133224/) was subject to questioning along this very line during a recent Senate Finance Committee hearing. And while Ambassador Tai did not affirmatively state that an IP waiver would be in the future for climate change technology, she surely did not assuage the concerns of interested parties. The United States has historically supported robust IP protection. This support is one reason the United States is the center of biotechnology innovation and leading the fight against COVID-19. However, a brief review of the domestic legislation arguably most relevant to this discussion shows just how far the international campaign against IP rights has eroded our normative position. The Clean Air Act, for example, contains a provision allowing for the mandatory licensing of patents covering certain devices for reducing air pollution. Importantly, however, the patent owner is accorded due process and the statute lays out a detailed process regulating the manner in which any such license can be issued, including findings of necessity and that no reasonable alternative method to accomplish the legislated goal exists. Also of critical importance is that the statute requires compensation to the patent holder. Similarly, the Atomic Energy Act contemplates mandatory licensing of patents covering inventions of primary importance in producing or utilizing atomic energy. This statute, too, requires due process, findings of importance to the statutory goals and compensation to the rights holder. A TRIPS IP waiver would operate outside of these types of frameworks. There would be no due process, no particularized findings, no compensationand no recourse. Indeed, the fact that the World Trade Organization (WTO) already has a process under the TRIPS agreement to address public health crises, including the compulsory licensing provisions, with necessary guardrails and compensation, makes quite clear that the waiver would operate as a free for all. Forced Tech Transfer Could Be on The Table When being questioned about the scope of a potential TRIPS IP waiver, Ambassador Tai invoked the proverb “Give a man a fish and you feed him for a day. Teach a man to fish and you feed him for a lifetime.” While this answer suggests primarily that, in times of famine, the Administration would rather give away other people’s fishing rods than share its own plentiful supply of fish (here: actual COVID-19 vaccine stocks), it is apparent that in Ambassador Tai’s view waiving patent rights alone would not help lower- and middle-income countries produce their own vaccines. Rather, they would need to be taught how to make the vaccines and given the biotech industry’s manufacturing know-how, sensitive cell lines, and proprietary cell culture media in order to do so. In other words, Ambassador Tai acknowledged that the scope of the current TRIPS IP waiver discussions includes the concept of forced tech transfer. In the context of climate change, the idea would be that companies who develop successful methods for producing new seed technologies and sustainable biomass**,** reducing greenhouse gases in manufacturing and transportation, capturing and sequestering carbon in soil and products, and more, would be required to turn over their proprietaryknow-how to global competitors. While it is unclear how this concept would work in practice and under the constitutions of certain countries, the suggestion alone could be devastating to voluntary internationalcollaborations. Even if one could assume that the United States could not implement forced tech transfer on its own soil, what about the governments of our international development partners? It is not hard to understand that a U.S.-based company developing climate change technologies would be unenthusiastic about partnering with a company abroad knowing that the foreign country’s government is on track – with the assent of the U.S. government – to change its laws and seize proprietary materials and know-how that had been voluntarily transferred to the local company. Necessary Investment Could Diminish Developing climate change solutions is not an easy endeavor and bad policy positions threaten the likelihood that they will materialize. These products have long lead times from research and development to market introduction, owing not only to a high rate of failure but also rigorous regulatory oversight. Significant investment is required to sustain and drive these challenging and long-enduring endeavors. For example, synthetic biology companies critical to this area of innovation [raised over $1 billion in investment in the second quarter of 2019 alone](https://www.bio.org/sites/default/files/2021-04/Climate%20Report_FINAL.pdf). If investors cannot be confident that IP will be in place to protect important climate change technologies after their long road from bench to market, it is unlikely they will continue to investat the current and required levels**.**

#### Climate change destroys the world.

Specktor 19 [Brandon writes about the science of everyday life for Live Science, and previously for Reader's Digest magazine, where he served as an editor for five years] 6-4-2019, "Human Civilization Will Crumble by 2050 If We Don't Stop Climate Change Now, New Paper Claims," livescience, <https://www.livescience.com/65633-climate-change-dooms-humans-by-2050.html> Justin

The current climate crisis, they say, is larger and more complex than any humans have ever dealt with before. General climate models — like the one that the [United Nations' Panel on Climate Change](https://www.ipcc.ch/sr15/) (IPCC) used in 2018 to predict that a global temperature increase of 3.6 degrees Fahrenheit (2 degrees Celsius) could put hundreds of millions of people at risk — fail to account for the **sheer complexity of Earth's many interlinked geological processes**; as such, they fail to adequately predict the scale of the potential consequences. The truth, the authors wrote, is probably far worse than any models can fathom. How the world ends What might an accurate worst-case picture of the planet's climate-addled future actually look like, then? The authors provide one particularly grim scenario that begins with world governments "politely ignoring" the advice of scientists and the will of the public to decarbonize the economy (finding alternative energy sources), resulting in a global temperature increase 5.4 F (3 C) by the year 2050. At this point, the world's ice sheets vanish; brutal droughts kill many of the trees in the [Amazon rainforest](https://www.livescience.com/57266-amazon-river.html) (removing one of the world's largest carbon offsets); and the planet plunges into a feedback loop of ever-hotter, ever-deadlier conditions. "Thirty-five percent of the global land area, and **55 percent of the global population, are subject to more than 20 days a year of** [**lethal heat conditions**](https://www.livescience.com/55129-how-heat-waves-kill-so-quickly.html), beyond the threshold of human survivability," the authors hypothesized. Meanwhile, droughts, floods and wildfires regularly ravage the land. Nearly **one-third of the world's land surface turns to desert**. Entire **ecosystems collapse**, beginning with the **planet's coral reefs**, the **rainforest and the Arctic ice sheets.** The world's tropics are hit hardest by these new climate extremes, destroying the region's agriculture and turning more than 1 billion people into refugees. This mass movement of refugees — coupled with [shrinking coastlines](https://www.livescience.com/51990-sea-level-rise-unknowns.html) and severe drops in food and water availability — begin to **stress the fabric of the world's largest nations**, including the United States. Armed conflicts over resources, perhaps culminating in **nuclear war, are likely**. The result, according to the new paper, is "outright chaos" and perhaps "the end of human global civilization as we know it."

### 1NC – OFF

#### Counterplan Text – the United States ought to

#### anonymously invest $25 billion into 25 production lines dedicated solely to COVID-19 vaccines to boost global vaccine production managed by the Biomedical Advanced Research and Development Authority.

#### anonymously pre-order and distribute 8 billion doses of COVID vaccines using an equitable distribution framework prioritizing developing countries in the Global South.

#### The CP solves the entirety of the case and does it faster.

Stankiewicz 21 Mike Stankiewicz 5-6-2021"Opinion: For just $25 billion, the U.S. could jump-start a project to quickly vaccinate the entire world against COVID" <https://www.marketwatch.com/story/for-just-25-billion-the-u-s-could-jump-start-a-project-to-quickly-vaccinate-the-entire-world-against-covid-11614898552> (a press officer in Public Citizen's communication's department, where he focuses on legislative policy and health-orientated advocacy)//Elmer

Despite wealthy countries such as the U.S. ramping up COVID-19 vaccination efforts, **it** still **may** **take years to vaccinate the world**, especially poorer countries, and the economic and humanitarian impacts could be devastating. But **an injection of** **just $25 billion** **into global vaccine production efforts by the U.S.** government **could save millions of lives** and help prevent economic disaster. The most up-to-date numbers paint incredibly different futures between wealthy and low-income countries. At the current rate of vaccination, analysts predict that developing countries, including almost all of Southeast Asia, may not reach meaningful vaccine coverage until 2023. Comparatively, President Joe Biden has promised that the U.S. will have enough vaccine doses to inoculate every adult within the next three months. Increased fatalities And as wealthy countries such as the U.S. are starting to see lower death, transmission and hospitalization rates, low-income countries are experiencing increased hardship and fatalities. Countries such as Hungry are being forced to tighten restrictions as infection rates increase, and deaths in Africa have spiked by 40% in the past month, according to the World Health Organization (WHO). No country can be left behind in this global pandemic, and the U.S. is in a unique position to make sure every country gets the ample amount of vaccines they need. **Public Citizen research has found that just a $25 billion investment in COVID-19 vaccine production by the U.S. government would produce enough vaccine for developing countries, potentially shaving years from the global pandemic**. Public Citizen estimates that **8 billion doses of** National Institutes of Health-**Moderna MRNA**, +1.98% vaccine can be **produced** **for** just over **$3 per dose**. To bolster production and supply the necessary 8 billion doses, it would take **$1.9 billion to fund** the necessary **25 production lines**. Another **$19 billion** would pay **for materials and labor**, and **$3 billion** would **compensate** **Moderna** **for making technology available to manufacturers** in other countries. An additional $500 million would cover costs to staff and run **a rapid-response federal program that provides technical assistance and facilitates technology transfer to manufacturers and works with the WHO’s technology hub.** In total, vaccinating the world would cost less than 1.4% the total of Biden’s $1.9 trillion COVID relief plan. But such a program also needs to be properly managed to be successful. To help facilitate these efforts, the Biden administration should also **designate** the government’s Biomedical Advanced Research and Development Authority (**BARDA**) **to lead** the world-wide **vaccine manufacturing effort**. BARDA has the **necessary experience to coordinate** **an initiative of this scale** with the WHO, building on its partnership to build pandemic flu manufacturing capacity in developing countries after the bird-flu scare of 2006. Widespread vaccines would help U.S. economy These efforts would dramatically increase access to vaccines in developing countries and speed up global vaccination by years, saving countless lives. But allowing the current vaccine supply crisis to continue is not just inhumane, it is also not in our own economic interest to do so.

## Case

### 1NC – AT: Framework

#### Extinction is the only coherent and egalitarian framework – prefer it

Khan 18 (Risalat, activist and entrepreneur from Bangladesh passionate about addressing climate change, biodiversity loss, and other existential challenges. He was featured by The Guardian as one of the “young climate campaigners to watch” (2015). As a campaigner with the global civic movement Avaaz (2014-17), Risalat was part of a small core team that spearheaded the largest climate marches in history with a turnout of over 800,000 across 2,000 cities. After fighting for the Paris Agreement, Risalat led a campaign joined by over a million people to stop the Rampal coal plant in Bangladesh to protect the Sundarbans World Heritage forest, and elicited criticism of the plant from Crédit Agricolé through targeted advocacy. Currently, Risalat is pursuing an MPA in Environmental Science and Policy at Columbia University as a SIPA Environmental Fellow, “5 reasons why we need to start talking about existential risks,” https://www.weforum.org/agenda/2018/01/5-reasons-start-talking-existential-risks-extinction-moriori/)

Infinite future possibilities I find the story of the Moriori profound. It teaches me two lessons. Firstly, that human culture is far from immutable. That we can struggle against our baser instincts. That we can master them and rise to unprecedented challenges. Secondly, that even this does not make us masters of our own destiny. We can make visionary choices, but the future can still surprise us. This is a humbling realization. Because faced with an uncertain future, the only wise thing we can do is prepare for possibilities. Standing at the launch pad of the Fourth Industrial Revolution, the possibilities seem endless. They range from an era of abundance to the end of humanity, and everything in between. How do we navigate such a wide and divergent spectrum? I am an optimist. From my bubble of privilege, life feels like a rollercoaster ride full of ever more impressive wonders, even as I try to fight the many social injustices that still blight us. However, the accelerating pace of change amid uncertainty elicits one fundamental observation. Among the infinite future possibilities, only one outcome is truly irreversible: extinction. Concerns about extinction are often dismissed as apocalyptic alarmism. Sometimes, they are. But repeating that mankind is still here after 70 years of existential warning about nuclear warfare is a straw man argument. The fact that a 1000-year flood has not happened does not negate its possibility. And there have been far too many nuclear near-misses to rest easy. As the World Economic Forum’s Annual Meeting in Davos discusses how to create a shared future in a fractured world, here are five reasons why the possibility of existential risks should raise the stakes of conversation: 1. Extinction is the rule, not the exception More than 99.9% of all the species that ever existed are gone. Deep time is unfathomable to the human brain. But if one cares to take a tour of the billions of years of life’s history, we find a litany of forgotten species. And we have only discovered a mere fraction of the extinct species that once roamed the planet. In the speck of time since the first humans evolved, more than 99.9% of all the distinct human cultures that have ever existed are extinct. Each hunter-gatherer tribe had its own mythologies, traditions and norms. They wiped each other out, or coalesced into larger formations following the agricultural revolution. However, as major civilizations emerged, even those that reached incredible heights, such as the Egyptians and the Romans, eventually collapsed. It is only in the very recent past that we became a truly global civilization. Our interconnectedness continues to grow rapidly. “Stand or fall, we are the last civilization”, as Ricken Patel, the founder of the global civic movement Avaaz, put it. 2. Environmental pressures can drive extinction More than 15,000 scientists just issued a ‘warning to humanity’. They called on us to reduce our impact on the biosphere, 25 years after their first such appeal. The warning notes that we are far outstripping the capacity of our planet in all but one measure of ozone depletion, including emissions, biodiversity, freshwater availability and more. The scientists, not a crowd known to overstate facts, conclude: “soon it will be too late to shift course away from our failing trajectory, and time is running out”. In his 2005 book Collapse, Jared Diamond charts the history of past societies. He makes the case that overpopulation and resource use beyond the carrying capacity have often been important, if not the only, drivers of collapse. Even though we are making important incremental progress in battles such as climate change, we must still achieve tremendous step changes in our response to several major environmental crises. We must do this even while the world’s population continues to grow. These pressures are bound to exert great stress on our global civilization. 3. Superintelligence: unplanned obsolescence? Imagine a monkey society that foresaw the ascendance of humans. Fearing a loss of status and power, it decided to kill the proverbial Adam and Eve. It crafted the most ingenious plan it could: starve the humans by taking away all their bananas. Foolproof plan, right? This story describes the fundamental difficulty with superintelligence. A superintelligent being may always do something entirely different from what we, with our mere mortal intelligence, can foresee. In his 2014 book Superintelligence, Swedish philosopher Nick Bostrom presents the challenge in thought-provoking detail, and advises caution. Bostrom cites a survey of industry experts that projected a 50% chance of the development of artificial superintelligence by 2050, and a 90% chance by 2075. The latter date is within the life expectancy of many alive today. Visionaries like Stephen Hawking and Elon Musk have warned of the existential risks from artificial superintelligence. Their opposite camp includes Larry Page and Mark Zuckerberg. But on an issue that concerns the future of humanity, is it really wise to ignore the guy who explained the nature of space to us and another guy who just put a reusable rocket in it? 4. Technology: known knowns and unknown unknowns Many fundamentally disruptive technologies are coming of age, from bioengineering to quantum computing, 3-D printing, robotics, nanotechnology and more. Lord Martin Rees describes potential existential challenges from some of these technologies, such as a bioengineered pandemic, in his book Our Final Century. Imagine if North Korea, feeling secure in its isolation, could release a virulent strain of Ebola, engineered to be airborne. Would it do it? Would ISIS? Projecting decades forward, we will likely develop capabilities that are unthinkable even now. The unknown unknowns of our technological path are profoundly humbling. 5. 'The Trump Factor' Despite our scientific ingenuity, we are still a confused and confusing species. Think back to two years ago, and how you thought the world worked then. Has that not been upended by the election of Donald Trump as US President, and everything that has happened since? The mix of billions of messy humans will forever be unpredictable. When the combustible forces described above are added to this melee, we find ourselves on a tightrope. What choices must we now make now to create a shared future, in which we are not at perpetual risk of destroying ourselves? Common enemy to common cause Throughout history, we have rallied against the ‘other’. Tribes have overpowered tribes, empires have conquered rivals. Even today, our fiercest displays of unity typically happen at wartime. We give our lives for our motherland and defend nationalistic pride like a wounded lion. But like the early Morioris, we 21st-century citizens find ourselves on an increasingly unstable island. We may have a violent past, but we have no more dangerous enemy than ourselves. Our task is to find our own Nunuku’s Law. Our own shared contract, based on equity, would help us navigate safely. It would ensure a future that unleashes the full potential of our still-budding human civilization, in all its diversity. We cannot do this unless we are humbly grounded in the possibility of our own destruction. Survival is life’s primal instinct. In the absence of a common enemy, we must find common cause in survival. Our future may depend on whether we realize this.

#### 1 – Forecloses future improvement – we can never improve society because our impact is irreversible which proves moral uncertainty

#### 2 – Turns suffering – mass death causes suffering because people can’t get access to resources and basic necessities

#### 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 policy freeze 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

#### AT: Winter and Leighton

#### 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---Their 10 word highlighting of the ev only includes 1 argument about how institutions normalize structural violence with no warrant but insofar we prove that util is a better alternative it has no implication

#### AT: Racism First

#### 1---Requires winning a tradeoff between their framing and ours solving ongoing/racially discriminatory harms which is false since governments are able to do multiple things at once and we have just isolated specific existential risks to solve for

#### 2---Links back to them – they inevitably have to choose between different conflicts of racism that will cause the exclusion of certain impacts

#### AT: Predictions fail

#### 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

#### 2---Goes both ways – your ev says people are wired to think about probability as well as magnitude – at best it’s a reason to err neg since we could be underestimating the threat

### 1NC – AT: Advantage

#### Top-Level:

#### 1] IP Waivers aren’t enough – alt causes to vaccine production outweigh

**Bolle and Obstfeld 21** [Monica de Bolle and Maurice Obstfeld, VIEW SHARING OPTIONS Monica de Bolle, senior fellow at the Peterson Institute for International Economics since January 2017, is adjunct lecturer and former director for Latin American studies and emerging markets at the School of Advanced International Studies at Johns Hopkins University. De Bolle was nonresident senior fellow at the Institute between March 2015 and January 2017. Maurice Obstfeld has been nonresident senior fellow at the Peterson Institute for International Economics since February 2019. He is the Class of 1958 Professor of Economics and former chair of the department of economics (1998–2001) at the University of California, Berkeley. He previously taught at Harvard University (1989–90), the University of Pennsylvania (1986–89), and Columbia University (1979–86). Obstfeld served at the International Monetary Fund (IMF) as economic counsellor and director of the research department (2015–18) and as a member of the US President's Council of Economic Advisors (2014–15). Obstfeld was an honorary adviser to the Bank of Japan's Institute of Monetary and Economic Studies (2002–14) and has consulted and taught at the IMF, the World Bank, and numerous central banks around the world. 5-12-2021, accessed on 9-12-2021, PIIE, "Waiving patent and intellectual property protections is not a panacea for global vaccine distribution", <https://www.piie.com/blogs/realtime-economic-issues-watch/waiving-patent-and-intellectual-property-protections-not>] Adam

Navigating the procedural obstacles to get WTO agreement on a streamlined mechanism for suspending IP protections is not as easy as it would seem. It is already possible to waive protections in the 1994 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). But the WTO's track record suggests that roadblocks may lie ahead in expanding the scope of its waiver procedure.

Since August 2003, the WTO has explicitly allowed emergency departures from the TRIPS agreement, enabling countries with manufacturing capacity to suspend IP protections to produce life-saving drugs and vaccines, not just for domestic use but also for export to countries that lack manufacturing capacity of their own. However, the process of negotiating the August 2003 decision—which created a temporary procedure for export waivers—took 14 months, and it was not until January 2017 that two-thirds of WTO members had[ratified](https://www.ip-watch.org/2017/01/23/official-trips-health-amendment-effect-first-ever-wto-agreement/) it as a formal amendment to the TRIPS agreement.

Because of this painful negotiation process, the bureaucratic procedures for exercising IP flexibility are so cumbersome that there are very few instances of its use. The best known (though not very successful) example occurred with Canadian exports of an AIDS treatment to [Rwanda](https://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and#_edn1) in 2007. Complicating matters further has been the opposition of some major countries to revisiting the issue, as well as the likely need for WTO members to revise their domestic legal frameworks to accommodate patent waivers. These factors make it clear that renewed negotiations within the WTO are unlikely to yield results with the speed that the current health emergency demands or result in a meaningfully better framework. Recognizing the likely difficulty of negotiations, WTO Director-General Ngozi Okonjo-Iweala has suggested a December 3, 2021 [deadline](https://www.washingtonpost.com/us-policy/2021/05/06/biden-patent-waiver-developing-world-long-road/) for completion—but like past initial deadlines in this space, this one could well prove overoptimistic.

The second, and arguably more intractable, challenge is technical: Even if they overcome IP obstacles and get permission to produce vaccines, less prosperous countries lack the know-how, facilities, and trained personnel to produce them. Despite the abysmal decades-long record of vaccine distribution in those countries, existing TRIPS flexibilities have done nothing to improve the situation. A smoother IP waiver process might help, but only as a component of a [broader effort.](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6291766/)

True, patent protection is the main obstacle to creation of generic small-molecule drugs, which chemists can synthesize. But other major obstacles exist for vaccines, which are biologics. For the latter category of drugs, an identical product requires an identical production technology, with most steps categorized as hard-to-replicate trade secrets rather than patentable innovations. Thus, Moderna [announced](https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19) in October 2020 that it would not enforce its COVID-19-related patents during the pandemic. But this step, however laudable, is of limited immediate help to would-be producers of a "generic" version of the Moderna vaccine. Without precisely replicating all steps of Moderna's production process, including the many quality controls, a generic version would have untested immunogenicity (the ability to induce the body to generate an immune response) and thus would require extensive clinical trials before release. Production glitches—such as those that afflicted the Janssen/Johnson & Johnson vaccine in the United States—could prompt widespread vaccine skepticism, damaging pandemic control efforts.

The replication hurdle is especially high for the new and more sophisticated messenger ribonucleic acid (mRNA) vaccines, which have proven most effective against SARS-CoV-2 (the virus that causes COVID-19) and which are likely to provide the most adaptable platforms for the vaccines of the future. The genetic vaccines produced by Pfizer-BioNTech and Moderna require considerable technical knowledge and [sophisticated techniques](https://www.nytimes.com/interactive/2021/health/pfizer-coronavirus-vaccine.html) to generate a version of the viral spike protein that elicits a strong immune response.[1](https://www.piie.com/blogs/realtime-economic-issues-watch/waiving-patent-and-intellectual-property-protections-not" \l "_ftn1" \o ") Therefore, from a biological standpoint, patent and IP waivers alone cannot resolve the existing lack of capacity in most countries to produce genetic vaccines at scale locally.

A final challenge is that vaccine supply chains are intricate and global in scope. Different stages of vaccine manufacturing are spread across different parts of the globe, with various countries supplying key inputs and equipment. Patent and IP waivers cannot resolve export restrictions that these countries may decide to impose—and in fact have imposed—throughout the pandemic. Nor can poor countries with production waivers easily integrate into global supply chains. At the moment, current production capacity and quality standards continue to constrain global supply.

#### 2] Hurts Innovation

**Value Ingenuity 20** [Value Ingenuity, (The Value Ingenuity project is telling the story of innovation, its roots, its impact, its social and moral imperatives, and the public policy prescriptions that will assure a continued upward trajectory for the generations to follow. Our objective is to advance globally a shared purpose of mutual investment in sustainable innovation.)]. "WTO IP Waiver Would Undermine Covid Innovation." 10-2-2020, Accessed 8-5-2021. https://www.valueingenuity.com/2021/05/18/wto-ip-waiver-would-undermine-covid-innovation/ // duongie

A TRIPS waiver for vaccines would do nothing to help — and could in fact hurt — the effort to produce billions of vaccine doses and get them in arms. Supply of these high-tech products is ramping up quickly, with about 10 billion doses projected to be produced by the end of 2021 — we shouldn’t distract attention away from that all-important goal. IP is not a barrier to vaccine access. It already enabled the creation of three vaccines, in record-breaking time, that have received FDA authorization. IP is also safely facilitating international partnerships (275+ to date) to share technology and information more easily with trusted partners across borders. An IP waiver could lead to untested and unregulated copycats. Some nations are looking to manufacture sophisticated vaccines without permission, exacerbating the shortage of the critical materials (raw materials, tubing, vials etc.) and increasing vaccine hesitancy due to the development of unsafe products and medicines. The proposal jeopardizes U.S. manufacturing & jobs. Allowing other countries to take and commercialize American-made technologies conflicts with President Biden’s goal to build up American infrastructure and create manufacturing jobs. In the U.S. alone, biopharmaceutical companies support 4 million jobs across all 50 states, with many more across innovation ecosystems in labs, finance, and SMEs. Waiving IP undermines America’s leadership in the life sciences. We should not be forfeiting IP to countries looking to undermine America’s global leadership in biomedical technology and innovation. IP protections enabled decades of R&D by biopharmaceutical research companies, allowing them to move quickly and effectively against COVID-19. Business welcomes the Biden Administration’s support for the global vaccine program, COVAX. This type of program can have a significant positive, practical impact on global rollout of vaccines and therapies without disrupting the incredible IP-enabled progress that has been made to date to defeat the pandemic. Its effects will be even more effective as trade barriers are removed and all countries allow vaccines to be exported internationally. GOOD TO KNOW: Today 57% of all new medicines globally come from the United States with its world-class IP ecosystem, and private companies in the life sciences community make up more than 80% of the investment in the research and development of those new drugs. The U.S. biopharmaceutical industry directly and indirectly supports over 4 million American jobs. SCIENTISTS, ACADEMICS, ADVOCATES AND POLITICAL LEADERS SKEPTICAL OF WAIVING IP RIGHTS “The goal is noble, but the demand [for an IP waiver] is more slogan than solution … patents on vaccines are not the central bottleneck, and even if turned over to other nations, would not quickly result in more shots. This is because vaccine manufacturing is exacting and time-consuming. Look at the production difficulties encountered by Emergent BioSolutions, a vaccine manufacturer in Baltimore, where 15 million doses were contaminated. That was caught before the shots were distributed, but one can imagine the horrific consequences of a failure to maintain quality control elsewhere in the world.” WASHINGTON POST EDITORIAL BOARD, May 4, 2021 “The goal is noble, but the demand [for an IP waiver] is more slogan than solution … patents on vaccines are not the central bottleneck, and even if turned over to other nations, would not quickly result in more shots. This is because vaccine manufacturing is exacting and time-consuming. Look at the production difficulties encountered by Emergent BioSolutions, a vaccine manufacturer in Baltimore, where 15 million doses were contaminated. That was caught before the shots were distributed, but one can imagine the horrific consequences of a failure to maintain quality control elsewhere in the world.” WALL STREET JOURNAL EDITORIAL BOARD, May 6, 2021 “The U.S. decision to support a temporary waiver of intellectual-property protections for Covid-19 vaccines won’t end debate on the issue, much less end the pandemic. Reaching a formal agreement could take months and even then may not accelerate vaccine production; opposition from countries such as Germany could yet doom any compromise.” BLOOMBERG EDITORIAL BOARD, May 12, 2021 “The collaboration that’s happened in the midst of this pandemic I think points to the ways in which IP has actually not been a barrier, but a facilitator of critical, cutting-edge innovation […] I don’t think that waiving IP rights will suddenly enable other countries to ramp up the manufacturing of complex vaccines.” SEN. CHRIS COONS (D-DE), CSIS: April 22, 2021 “There are only so many vaccine manufacturers in the world […] people are very careful about the safety of vaccines […] The thing that is holding us back is not IP. There is no idle factory with regulatory approval that makes magically safe vaccines […] we have all the rights from the vaccine companies and the work is going at full speed” BILL GATES, Sky News: April 25, 2021 “There are enough manufacturers, it just takes time to scale up. And by the way, I have been blown away by the cooperation between the public and private sectors in the last year, in developing these vaccines.” ADAR POONAWALLA, CEO SERUM INSTITUTE OF INDIA, February 14, 2021 “These [vaccines] are complex to make so just waiving IP and patents isn’t going to help […] you can only get trade secrets and knowhow with the cooperation of the originator companies, and they don’t have the bandwidth to do this in every part of the world … the only immediate solution is for rich countries to donate or sell their surplus vaccine to COVAX or other countries.” JAYASHREE WATAL, GEORGETOWN LAW PROFESSOR & FORMER WTO IP COUNSELOR, April 22, 2021 “It is also unclear whether a waiver of IP rights will make a difference […] Furthermore, as others have pointed out, IP rights are only a piece of what is needed to produce vaccines. There is currently a global shortage of raw materials and proper manufacturing facilities.” SAPAN KUMAR, LAW FOUNDATION PROFESSOR OF LAW AT THE UNIVERSITY OF HOUSTON LAW CENTER, May 9, 2021 “This is technology that’s every bit as critical as munitions and encryption codes […] It’s a platform technology that can be used to make all manner of treatments going forward, including vaccines.” DAVID KAPPOS, FORMER U.S. PATENT AND TRADEMARK OFFICE FOR PRESIDENT OBAMA, April 22, 2021 “The notion that we would then turn around and go to the World Trade Organization and basically endorse a policy of DARPA-funded technology transfer to China is just inconceivable. You’re basically aiding and abetting China’s ‘Made in China 2025’ plans for technological dominance.” CLETE WILLEMS, FORMER SPECIAL ASSISTANT TO THE PRESIDENT FOR INTERNATIONAL TRADE, INVESTMENT, AND DEVELOPMENT, April 22, 2021.

#### Turns the Aff – Delta Variant proves current vaccines aren’t enough – we need new innovations.

Guarino 8-18 Ben Guarino 8-18-2021 “Vaccines show declining effectiveness against infection overall but strong protection against hospitalization amid delta variant” <https://archive.is/pvuzL#selection-747.0-750.0> (Education: University of Pennsylvania, BSE in bioengineering; New York University, MA in journalism)//Elmer

**Results** from a trio of studies, published in the CDC’s weekly report, **motivated** the **Biden** administration **to** **consider** **booster shots**. **Three studies published** Wednesday by the Centers for Disease Control and Prevention **show** that **protection against the** **coronavirus from vaccines** **declined** in the midsummer months **when** the more contagious **delta variant rose** to dominance in the United States. At the same time, protection against hospitalization was strong for weeks after vaccination, indicating the shots will generate immune fighters that stave off the worst effects of the virus and its current variations. Data from these studies persuaded the Biden administration to develop a plan for additional doses to bolster the immune systems of people vaccinated months earlier. The trio of reports, published Wednesday in the Morbidity and Mortality Weekly Report, the CDC’s scientific digest, also **reinforce** the **idea** that **vaccines** **alone will be unable to lift the nation out of the pandemic**. Masks and other precautions should be part of “a layered approach centered on vaccination,” wrote researchers from the New York State Department of Health and the University at Albany School of Public Health in their study of vaccine effectiveness across New York state. All three reports measure vaccine effectiveness, which compares the rates of infection or hospitalization among vaccinated people with the rates among people who had not been vaccinated. Until now, evaluations of vaccine effectiveness amid delta largely relied on observations from outside the United States. A recent New England Journal of Medicine study concluded the Pfizer vaccine was 88 percent effective against infections that caused symptoms in England. Others, such as **a study in Israel**, **found** **larger declines in protection against infection**. One U.S. report that has not yet gone through peer review, collecting data from Mayo Clinic Health System facilities in five states, **found** a **drop in** the **Pfizer**-BioNTech **vaccine’s** **effectiveness** **against delta infections to 42 percent**. The other mRNA vaccine, made by Moderna, was 76 percent effective. The new study from New York is the first to assess vaccine protection against coronavirus infection across the entirety of a U.S. state amid delta. The study authors found a modest drop in effectiveness: It descended from 92 percent in May to 80 percent in late July. Twenty percent of new infections and 15 percent of hospitalizations from covid-19, the disease caused by the coronavirus, were among vaccinated people. The second of the three studies published Wednesday by the CDC found effectiveness against infection declined for nursing home residents after delta emerged. It dropped from 75 percent in March through May to 53 percent in June and July. Vaccination for visitors and staff is crucial, the study authors wrote, and “additional doses of COVID-19 vaccine might be considered for nursing home and long-term care facility residents.” The third report, an analysis of patients at 21 hospitals in 18 states, found sustained protection against hospitalization. Effectiveness was steady at 86 percent, even in the midsummer months when delta outcompeted other variants of concern. For adults who do not have compromised immune systems, that effectiveness stood at 90 percent.

#### 3] Skill Disparities and Trade Secrets outweigh – Moderna proves IP isn’t the root cause.

Silverman 3-15 Rachel Silverman 3-15-2021 "Waiving vaccine patents won’t help inoculate poorer nations" <https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/> (Rachel Silverman is a policy fellow at the Center for Global Development)//Duong

Reality is more complicated, however. Because of the technical complexity of manufacturing coronavirus vaccines, waiving intellectual-property rights, by itself, would have **little effect**. It could even backfire, with companies using the move as an excuse to disengage from global access efforts. There are more effective ways to entice — and to pressure — companies to license and share their intellectual property and the associated know-how, without broadly nullifying patents. The Moderna vaccine illustrates the limits of freeing up intellectual property. Moderna announced in October that it would **not enforce IP rights** on its coronavirus vaccine — and yet it has **taken no steps to share information** about the vaccine’s design or manufacture, citing commercial interests in the underlying technology. Five months later, production of the Moderna vaccine remains entirely under the **company’s direct control** within its owned and contracted facilities. Notably, Moderna is also the only manufacturer of a U.S.- or British-approved vaccine not yet participating in Covax, a global-aid-funded effort (including a pledged $4 billion from the United States) to purchase vaccines for use in low- and middle-income countries. It is true, however, that activist pressure — including threats to infringe upon IP rights — can encourage originators to enter into voluntary licensing arrangements. So the global movement to liberate the vaccine patents may be useful, even if some advocates make exaggerated claims about the effects of waivers on their own. We focused on covid. Now our other patients are suffering. One reason patent waivers are unlikely to help much in this case is that vaccines are harder to make than ordinary drugs. Because most drugs are simple chemical compounds, and because the composition of the compounds is easily analyzable, competent chemists can usually reverse-engineer a production process with relative ease. When a drug patent expires, therefore — or is waived — generic companies can readily enter the market and produce competitive products, lowering prices dramatically. Vaccines, in contrast, are complex biological products. Observing their contents is insufficient to allow for imitation. Instead, to produce the vaccine, manufacturers need access to the developer’s “soft” IP — the proprietary recipe, cell lines, manufacturing processes and so forth. While some of this information is confidentially submitted to regulators and might theoretically be released in an extraordinary situation (though not without legal challenge), manufacturers are at an enormous disadvantage without the originator’s cooperation to help them set up their process and kick-start production. Even with the nonconsensual release of the soft IP held by the regulator, the process of trial and error would cause long delays in a best-case scenario. Most likely, the effort would end in expensive failure. Manufacturers also need certain raw ingredients and other materials, like glass vials and filtration equipment; overwhelming demand, paired with disruptive export restrictions, has constricted the global availability of some of these items.

#### 4] Pharma backlashes to the Plan – they’re aggressive lobbyists and will do anything to preserve patent rights.

Huetteman 19 Emmarie Huetteman 2-26-2019 “Senators Who Led Pharma-Friendly Patent Reform Also Prime Targets For Pharma Cash” <https://khn.org/news/senators-who-led-pharma-friendly-patent-reform-also-prime-targets-for-pharma-cash/> (former NYT Congressional correspondent with an MA in public affairs reporting from Northwestern University’s Medill School)//Elmer

Early last year, as lawmakers vowed to curb rising drug prices, Sen. Thom Tillis was named chairman of the Senate Judiciary Committee’s subcommittee on intellectual property rights, a committee that had not met since 2007. As the new gatekeeper for laws and oversight of the nation’s patent system, the North Carolina Republican signaled he was determined to make it easier for American businesses to benefit from it — a welcome message to the drugmakers who already leverage patents to block competitors and keep prices high. Less than three weeks after introducing a bill that would make it harder for generic drugmakers to compete with patent-holding drugmakers, Tillis opened the subcommittee’s first meeting on Feb. 26, 2019, with his own vow. “From the United States Patent and Trademark Office to the State Department’s Office of Intellectual Property Enforcement, no department or bureau is too big or too small for this subcommittee to take interest,” he said. “And we will.” In the months that followed, tens of thousands of dollars flowed from pharmaceutical companies toward his campaign, as well as to the campaigns of other subcommittee members — including some who promised to stop drugmakers from playing money-making games with the patent system, like Sen. John Cornyn (R-Texas). Tillis received more than $156,000 from political action committees tied to drug manufacturers in 2019, more than any other member of Congress, a new analysis of KHN’s Pharma Cash to Congress database shows. Sen. Chris Coons (D-Del.), the top Democrat on the subcommittee who worked side by side with Tillis, received more than $124,000 in drugmaker contributions last year, making him the No. 3 recipient in Congress. No. 2 was Sen. Mitch McConnell (R-Ky.), who took in about $139,000. As the Senate majority leader, he controls what legislation gets voted on by the Senate. Neither Tillis nor Coons sits on the Senate committees that introduced legislation last year to lower drug prices through methods like capping price increases to the rate of inflation. Of the four senators who drafted those bills, none received more than $76,000 from drug manufacturers in 2019. Tillis and Coons spent much of last year working on significant legislation that would expand the range of items eligible to be patented — a change that some experts say would make it easier for companies developing medical tests and treatments to own things that aren’t traditionally inventions, like genetic code. They have not yet officially introduced a bill. As obscure as patents might seem in an era of public **outrage** **over** drug prices, the fact that **drugmakers** gave most **to** the **lawmakers working to change the patent system** belies how important securing **the exclusive right to market a drug, and keep competitors at bay, is to their bottom line**. “**Pharma will fight to the death to preserve patent rights**,” said Robin Feldman, a professor at the UC Hastings College of the Law in San Francisco who is an expert in intellectual property rights and drug pricing. “Strong patent rights are central to the games drug companies play to extend their monopolies and keep prices high.” Campaign contributions, closely tracked by the Federal Election Commission, are among the few windows into how much money flows from the political groups of drugmakers and other companies to the lawmakers and their campaigns. Private companies generally give money to members of Congress to encourage them to listen to the companies, typically through lobbyists, whose activities are difficult to track. They may also communicate through so-called dark money groups, which are not required to report who gives them money. Over the past 10 years, the **pharmaceutical industry** has **spent** about $**233 million per year on lobbying**, according to a new study published in JAMA Internal Medicine. That is more than any other industry, including the oil and gas industry. Why Patents Matter Developing and testing a new drug, and gaining approval from the Food and Drug Administration, can take years and cost hundreds of millions of dollars. Drugmakers are generally granted a six- or seven-year exclusivity period to recoup their investments. But drugmakers have found ways to extend that period of exclusivity, sometimes accumulating hundreds of patents on the same drug and blocking competition for decades. One method is to patent many inventions beyond a drug’s active ingredient, such as patenting the injection device that administers the drug. Keeping that arrangement intact, or expanding what can be patented, is where lawmakers come in. Lawmakers Dig In Tillis’ home state of North Carolina is also home to three major research universities and, not coincidentally, multiple drugmakers’ headquarters, factories and other facilities. From his swearing-in in 2015 to the end of 2018, Tillis received about $160,000 from drugmakers based there or beyond. He almost matched that four-year total in 2019 alone, in the midst of a difficult reelection campaign to be decided this fall. He has raised nearly $10 million for his campaign, with lobbyists among his biggest contributors, according to OpenSecrets. Daniel Keylin, a spokesperson for Tillis, said Tillis and Coons, the subcommittee’s top Democrat, are working to overhaul the country’s “antiquated intellectual property laws.” Keylin said the bipartisan effort protects the development and access to affordable, lifesaving medication for patients,” adding: “No contribution has any impact on how [Tillis] votes or legislates.” Tillis signaled his openness to the drug industry early on. The day before being named chairman, he reintroduced a bill that would limit the options generic drugmakers have to challenge allegedly invalid patents, effectively helping brand-name drugmakers protect their monopolies. Former Sen. Orrin Hatch (R-Utah), whose warm relationship with the drug industry was well-known, had introduced the legislation, the Hatch-Waxman Integrity Act, just days before his retirement in 2018. At his subcommittee’s first hearing, Tillis said the members would rely on testimony from private businesses to guide them. He promised to hold hearings on patent eligibility standards and “reforms to the Patent Trial and Appeal Board.” In practice, the Hatch-Waxman Integrity Act would require generics makers challenging another drugmaker’s patent to either take their claim to the Patent Trial and Appeal Board, which acts as a sort of cheaper, faster quality check to catch bad patents, or file a lawsuit. A study released last year found that, since Congress created the Patent Trial and Appeal Board in 2011, it has narrowed or overturned about 51% of the drugmaker patents that generics makers have challenged. Feldman said the drug industry “went berserk” over the number of patents the board changed and has been eager to limit use of the board as much as possible. Patent reviewers are often stretched thin and sometimes make mistakes, said Aaron Kesselheim, a Harvard Medical School professor who is an expert in intellectual property rights and drug development. Limiting the ways to challenge patents, as Tillis’ bill would, does not strengthen the patent system, he said. “You want overlapping oversight for a system that is as important and fundamental as this system is,” he said. As promised, Tillis and Coons also spent much of the year working on so-called Section 101 reform regarding what is eligible to be patented — “a very major change” that “would overturn more than a century of Supreme Court law,” Feldman said. Sean Coit, Coons’ spokesperson, said lowering drug prices is one of the senator’s top priorities and pointed to Coon’s support for legislation the pharmaceutical industry opposes. “One of the reasons Senator Coons is leading efforts in Congress to fix our broken patent system is so that life-saving medicines can actually be developed and produced at affordable prices for every American,” Coit wrote in an email, adding that “his work on Section 101 reform has brought together advocates from across the spectrum, including academics and health experts.” In August, when much of Capitol Hill had emptied for summer recess, Tillis and Coons held closed-door meetings to preview their legislation to stakeholders, including the Pharmaceutical Research and Manufacturers of America, or PhRMA, the brand-name drug industry’s lobbying group. “We regularly engage with members of Congress in both parties to advance practical policy solutions that will lower medicine costs for patients,” said Holly Campbell, a PhRMA spokesperson. Neither proposal has received a public hearing. In the 30 days before Tillis and Coons were named leaders of the revived subcommittee, drug manufacturers gave them $21,000 from their political action committees. In the 30 days following that first hearing, Tillis and Coons received $60,000. Among their donors were PhRMA; the Biotechnology Innovation Organization, the biotech lobbying group; and five of the seven drugmakers whose executives — as Tillis laid out a pharma-friendly agenda for his new subcommittee — were getting chewed out by senators in a different hearing room over patent abuse. Cornyn Goes After Patent Abuse Richard Gonzalez, chief executive of AbbVie Inc., the company known for its top-selling drug, Humira, had spent the morning sitting stone-faced before the Senate Finance Committee as, one after another, senators excoriated him and six other executives of brand-name drug manufacturers over how they price their products. Cornyn brought up AbbVie’s more than 130 patents on Humira. Hadn’t the company blocked its competition? Cornyn asked Gonzalez, who carefully explained how AbbVie’s lawsuit against a generics competitor and subsequent licensing deal was not what he would describe as anti-competitive behavior. “I realize it may not be popular,” Gonzalez said. “But I think it is a reasonable balance.” A minute later, Cornyn turned to Sen. Chuck Grassley (R-Iowa), who, like Cornyn, was also a member of the revived intellectual property subcommittee. This is worth looking into with “our Judiciary Committee authorities as well,” Cornyn said, effectively threatening legislation on patent abuse. The next day, Mylan, one of the largest producers of generic drugs, gave Cornyn $5,000, FEC records show. The company had not donated to Cornyn in years. By midsummer, every drug company that sent an executive to that hearing had given money to Cornyn, including AbbVie. Cornyn, who faces perhaps the most difficult reelection fight of his career this fall, ranks No. 6 among members of Congress in drugmaker PAC contributions last year, KHN’s analysis shows. He received about $104,000. Cornyn has received about $708,500 from drugmakers since 2007, KHN’s database shows. According to OpenSecrets, he has raised more than $17 million for this year’s reelection campaign. Cornyn’s office declined to comment. On May 9, Cornyn and Sen. Richard Blumenthal (D-Conn.) introduced the **Affordable Prescriptions for Patients Act,** which proposed to define two tactics used by drug companies to make it easier for the Federal Trade Commission to **prosecute** them: “**product-hopping**,” when drugmakers withdraw older versions of their drugs from the market to push patients toward newer, more expensive ones, and “**patent-thicketing**,” when drugmakers amass a series of patents to drag out their exclusivity and slow rival generics makers, who must challenge those patents to enter the market once the initial exclusivity ends. **PhRMA opposed the bill.** **The next day, it gave Cornyn $1,000**. Cornyn and Blumenthal’s bill would have been “very tough on the techniques that pharmaceutical companies use to extend patent protections and to keep prices high,” Feldman said. “The **pharmaceutical industry lobbied tooth and nail against it**,” she said. “And **when the bill finally came** out of committee, the strongest provisions — the **patent-thicketing provisions — had been stripped**.” In the months after the bill cleared committee and waited to be taken up by the Senate, Cornyn blamed Senate Democrats for blocking the bill while trying to secure votes on legislation with more direct controls on drug prices. The Senate has not voted on the bill.

#### List of supply shortages – there is no way the aff solves, but they decrease available vaccines.

[Laurie Garrett 21, (Columnist at Foreign Policy and former senior fellow for global health at the Council on Foreign Relations). 5/7/21, Stopping Drug Patents Has Stopped Pandemics Before, Foreign Policy, <https://foreignpolicy.com/2021/05/07/stopping-drug-patents-pandemics-coronavirus-hiv-aids/>] Justin

The vaccines aren’t easy to make. Manufacturing errors in a Maryland Emergent BioSolutions factory caused an 86 percent plummet in Johnson & Johnson vaccine supplies in early April. Complex steps in the process of isolating, purifying, preserving, storing, and delivering COVID-19 immunizations are each error-prone and require long lists of specialized chemicals and machinery.

The world is in the grips now of pipette tips shortages—used to suck out chemicals and viral samples from test tubes in key steps of vaccine making. Syringes are in short supply, prompting vaccinators to toss vaccine supplies for lack of means to administer them. The sterile containers used to hold vaccines are running out. From the earliest days of the 2020 pandemic, the sorts of protective gear and machinery vaccine researchers and makers require have been in short supply, exacerbated by trade tensions between the United States and China. Swabs used for COVID-19 testing and all aspects of equipment cleaning in sterile conditions are held up in a grotesque family dispute in Maine. There aren’t enough centrifuge tubes made worldwide to spin down cell samples. Moderna and Pfizer are constantly scrambling to find the ingredients used to make the microscopic fatty balls, called liposomes, that house the mRNA molecules and carry them safely into the bloodstream. Even the nucleic acids used to construct mRNA and a long list of special enzymes used to purify those samples are in horribly short supply, largely because their use overlaps with the manufacture of COVID-19 tests. Because such delicate chemicals and proteins must be handled at deep-freeze temperatures and transported swiftly for immediate use, the entire supply chain is vulnerable to the simplest of catastrophes: weather at an airport, a car crash that blocks truck traffic, power outages, or competition for cargo space.

Although waiving TRIPS requirements on COVID-19 vaccines is a spectacular, historic gesture, would-be generic makers worldwide will soon discover their efforts are stymied not by patents but for want of Avanti Polar Lipids’ liposome ingredients, Flexsafe RM special bags to hold liquid vaccines in bulk, phosphate-buffered saline solution, Distearoylphosphatidylcholine for liposome-making, 5’ cap for mRNA made by TriLink BioTechnologies, RNA polymerases—the list goes on, and on, and on. As the number of would-be vaccine makers grows, so will demand for thousands of such items, putting pressure on companies that are, in many cases, mom-and-pop operations. Worse, pressure on supplies critical for COVID-19 vaccine making is already resulting in a production loss of vital medicines for other diseases.

#### WTO Credibility is on the brink – patent waivers are the make-it-or-break it issue – failure to pass the Plan dooms the WTO BUT passage signals success that generate momentum for structural change.

Meyer 6-18 David Meyer 6-18-2021 "The WTO's survival hinges on the COVID-19 vaccine patent debate, waiver advocates warn" <https://archive.is/etPtf> (Senior Writer at Fortune Magazine; Covers mostly European Business Affairs)//Elmer

The World Trade Organization **knows all about crises**. Former U.S. President Donald Trump threw a wrench into its core function of resolving trade disputes—a blocker that President Joe Biden has not yet removed—and there is widespread dissatisfaction over the fairness of the global trade rulebook. The 164-country organization, under the fresh leadership of Nigeria's Ngozi Okonjo-Iweala, has a lot to fix. However, one crisis is **more pressing than the others**: the battle over COVID-19 vaccines, and whether the protection of their patents and other intellectual property should be temporarily lifted to boost production and end the pandemic sooner rather than later. According to some of those pushing for the waiver—which was originally proposed last year by India and South Africa—**the WTO's future rests on what happens next**. "The credibility of the WTO will depend on its **ability to find a meaningful outcome** on this issue that truly ramps-up and diversifies production," says Xolelwa Mlumbi-Peter, South Africa's ambassador to the WTO. "**Final nail in the coffin**" The Geneva-based WTO isn't an organization with power, as such—it's a framework within which countries make big decisions about trade, generally by consensus. It's supposed to be the forum where disputes get settled, because all its members have signed up to the same rules. And one of its most important rulebooks is the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS, which sprang to life alongside the WTO in 1995. The WTO's founding agreement allows for rules to be waived in exceptional circumstances, and indeed this has happened before: its members agreed in 2003 to waive TRIPS obligations that were blocking the importation of cheap, generic drugs into developing countries that lack manufacturing capacity. (That waiver was effectively made permanent in 2017.) Consensus is the key here. Although the failure to **reach consensus on a waiver could be overcome with a 75% supermajority vote by the WTO's membership, this would be an unprecedented and seismic event**. In the case of the COVID-19 vaccine IP waiver, it would mean standing up to the European Union, and Germany in particular, as well as countries such as Canada and the U.K.—the U.S. recently flipped from opposing the idea of a waiver to supporting it, as did France. It's a dispute between countries, but the result **will be on the WTO as a whole**, say waiver advocates. "If, in the face of one of humanity's greatest challenges in a century, the WTO functionally **becomes an obstacle** as in contrast to part of the solution, I think **it could be the final nail in the coffin**" for the organization, says Lori Wallach, the founder of Public Citizen's Global Trade Watch, a U.S. campaigning group that focuses on the WTO and trade agreements. "If the TRIPS waiver is successful, and people see the WTO as being part of the solution—saving lives and livelihoods—it could create goodwill and momentum to address what are still daunting structural problems."

#### Yes Link – the Plan is perceptively seen as bolstering the WTO since its by all WTO Members.