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#### Plan: The member nations of the World Trade Organization ought to reduce intellectual property protections for emergency use listing medicines during public health emergencies of international concern.

#### The intellectual property system is fundamentally mismatched with emergency pandemic conditions – creating a broad precedent that weakens restrictions lays the groundwork for future pandemics that are inevitable. Ensuring we are ready for next time is vital

Lindsey 21 [Brink Lindsey has written on a wide range of topics including trade policy, globalization, American social and cultural history, and the nature of human capital. His current research focuses on economic growth and the policy barriers that impede it. "Why intellectual property and pandemics don’t mix." https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/]

Although focusing on these immediate constraints is vital, we cannot confine our attention to the short term. First of all, the COVID-19 pandemic is far from over. Although Americans can now see the light at the end of the tunnel thanks to the rapid rollout of vaccines, most of the world isn’t so lucky. The virus is currently raging in India and throughout South America, overwhelming health care systems and inflicting suffering and loss on a horrific scale. And consider the fact that Australia, which has been successful in suppressing the virus, recently announced it was sticking to plans to keep its borders closed until mid-2022. Criticisms of the TRIPS waiver that focus only on the next few months are therefore short-sighted: this pandemic could well drag on long enough for elimination of patent restrictions to enable new vaccine producers to make a positive difference.

Furthermore, and probably even more important, this is almost certainly not the last pandemic we will face. Urbanization, the spread of factory-farming methods, and globalization all combine to increase the odds that a new virus will make the jump from animals to humans and then spread rapidly around the world. Prior to the current pandemic, the 21st century already saw outbreaks of SARS, H1N1, MERS, and Ebola. Everything we do and learn in the current crisis should be viewed from the perspective of getting ready for next time.

THE NATURE OF THE PATENT BARGAIN

When we take the longer view, we can see a fundamental mismatch between the policy design of intellectual property protection and the policy requirements of effective pandemic response. Although patent law, properly restrained, constitutes one important element of a well-designed national innovation system, the way it goes about encouraging technological progress is singularly ill-suited to the emergency conditions of a pandemic or other public health crisis. Securing a TRIPS waiver for COVID-19 vaccines and treatments would thus establish a salutary precedent that, in emergencies of this kind, governments should employ other, more direct means to incentivize the development of new drugs.

#### There is a proposal now to expand access for COVID vaccines – but tons of WTO member states will vote against it because of pressure from the pharmaceutical industry

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Developing countries lacking access to the cutting-edge treatments—or unable to afford them—have long pressed for waiving certain patents, notably for drugs treating HIV. The countries and patient groups have said sharing patents would allow local manufacturers to make the drugs for patients in those regions.

India, South Africa and other countries have limited supplies of Covid-19 vaccines, while the U.S. and other rich nations enjoy greater supplies and have vaccinated more of their populations.

They first proposed to the WTO last year temporarily waiving vaccine patents. The countries raised the volume on their request in recent months as their cases surged.

The U.S. typically objects to patent waivers. The Biden administration was facing pressure from developing countries to release more of its own vaccine supplies when it said it supports the temporary waiver.

Drugmakers fear a Covid-19 vaccine waiver could set a precedent for sharing intellectual property of other medicines.

In the two weeks since the Biden administration’s move, trade groups such as the International Federation of Pharmaceutical Manufacturers & Associations have sought to bolster the opposition of other developed countries adverse to a temporary waiver.

The groups are telling developed countries that waivers would further strain the world’s limited supply of raw materials for vaccines, the people familiar with the lobbying said. Waiving patents wouldn’t also provide an immediate solution, the groups are saying, because it would take months to transfer the technology and build manufacturing capacity.

The groups are urging the countries to instead remake government policies that restrict the export of doses and materials, and to facilitate voluntary partnerships among companies to produce vaccines, the people said.

More than 100 countries support the waiver but many don’t, including some European Union members.

Pfizer this month sent a letter to Australian government officials stating that waiving intellectual-property protections for vaccines is “a distraction from the real solutions to improve vaccine access.” The country has so far expressed opposition to a waiver.

At the same time, vaccine makers have made several announcements saying they are increasing capacity to send doses, through an international initiative called Covax, to developing nations.

#### COVID highlights just how vulnerable we are to both natural pandemics and man-made biological weapons – the deciding factor in effective response is ensuring people can be vaccinated as fast as possible

Lyon 21 [Regan F Lyon, 7-1-2021, "COVID-19 Response Has Uncovered and Increased Our Vulnerability to Biological Warfare," OUP Academic, https://academic.oup.com/milmed/article/186/7-8/193/6135020]

The 2018 National Biodefense Strategy (NBS) articulated a collaborative plan to prevent, detect, and respond to biological threats to the USA.1 The NBS highlights recent, isolated outbreaks of Systemic Acute Respiratory Syndrome (SARS), Ebola, and Zika viruses as warnings to nation states and justification for enhanced biological threat responses. Although these events are not considered deliberate threats, clandestine bioweapon programs and terrorist groups seeking such programs are known to exist and capitalize on such natural outbreaks.1 The NBS’s emphasis on prevention and response drives the requirement to enhance biological weapon deterrence and defense strategies to avert the employment of biological weapons on U.S. civilians or military personnel.1 The public health crisis that ensued with SARS-associated coronavirus-2 (SARS-CoV-2) has highlighted our nation’s bioweapon vulnerabilities on the international stage and has the potential for disastrous effects on national security. Previous questions regarding how the USA would respond to a large biological outbreak (or biological weapon) have now been answered for potential adversaries across the world. The ambiguity of both our capabilities and weaknesses, which provided deterrence to adversarial employment of biological weapons before the pandemic, no longer exists. This article will provide an overview on biological weapons and the concepts of deterrence and defense in the context of bioterrorism. Then, it will analyze how the national personal protective equipment (PPE) shortage, public resistance to public health measures, the anti-vaccination movement, and USNS (United States Navy Ship) Comfort deployment to New York City have increased our vulnerability to bioterror attack by impacting our deterrence and defense measures. Finally, it will offer recommendations to restore our bioterrorism security after the detrimental effects from the events unfolding in the USA. BIOLOGICAL WEAPONS REGULATIONS, DETERRENCE, AND DEFENSE Even though biological warfare is considered a “weapon of mass destruction” and is prohibited by a treaty drafted by the 1972 United Nations Biological Weapons Convention (BWC), not all adversaries adhere to these standards. Terrorist groups and covert operations have utilized biological weapons for small operations because the actors, by nature, are either non-eligible to ratify the treaty or would not do so if they could. Although there have been no intentional large-scale attacks, especially by adversarial nation states, this is not guaranteed to be the case in the future.2 The BWC does not prohibit ratified nations from having pathogens or toxins for peaceful purposes, such as the development of vaccines. After the natural outbreak of smallpox and its subsequent eradication accomplished by the World Health Organization in 1980, less virulent poxviruses have continued to be used in a variety of laboratories for research and development of vaccines for a variety of diseases.3 The original, more deadly strain of smallpox has been retained at two facilities in Russia and Atlanta.4 Because smallpox’s virology makes it an ideal biological weapon, the samples in Atlanta and Russia offer defense through researching countermeasures should an attack occur and simultaneously provide a repository from which a biological weapon can be acquired. “Deterrence” and “defense” are two concepts which are typically described in terms of nuclear warfare, but they can also be applied to national security from a biological attack.5 Deterrence is the ability to prevent an adversary from taking some action during peacetime.5 For biological warfare deterrence, vaccines and preventative medicine measures prevent susceptibility to a microbe. For a largely vaccinated and/or health-conscious population, the costs of production, storage, and dissemination of a bioweapon greatly outweighs the rare chance of the target contracting the disease. New Zealand’s robust public health measures, citizen compliance, and continued efforts to sustain a caseload under 20 since April is a strong deterrent for biological attack.6 Defense mechanisms decrease the effectiveness of the attack, putting a high cost-to-benefit burden on the adversary.5 A defense measure for bioterrorism would be an adequate medical treatment response to casualties of the bioweapon, decreasing mortality and the overall effectiveness of the weapon. COVID-19 PANDEMIC ANALYSIS The novel SARS-CoV-2 has several characteristics of an ideal biological weapon, including high transmission rate, long incubation period, airborne transmission, and significant morbidity/mortality.7 In fact, early in the pandemic, suspicion was cast that the virus was being developed as a biological weapon by a laboratory in Wuhan, China.8 Although these allegations have been deemed conspiracy theories as a result of misinformation operations, the resulting pandemic and the panicked public share similarities to a bioterror attack. The events occurring within the USA during the coronavirus disease 2019 (COVID-19) pandemic create a global narrative on how we respond to a biological crisis. The 2018 NBS emphasized the continued threat of biological weapons to national security and identified the need to deter and defend against bioterrorism acts.1 This section will analyze events in the USA during the pandemic, how they bolstered or negated our current bioterrorism deterrence or defense strategies, and offer areas for improvement to restore our bioterror security.

#### Reducing IP restrictions on medicine is essential for expanding access – especially in developing countries, where lack of capital and domestic industry makes the same people who are most vulnerable to diseases the least likely to have access to expensive brand-name drugs

Baird 13 [Sean, Boston College of Law. Magic and Hope: Relaxing Trips-Plus Provisions to Promote Access to Affordable Pharmaceuticals. Boston College Journal of Law & Social Justice, 33(1), 107-145, 2013, http://lawdigitalcommons.bc.edu/jlsj/vol33/iss1/4, accessed 7-31-21]

TRIPS-Plus provisions in U.S. FTAs impede access to pharmaceuticals for indigent populations.42 The similarities between U.S. patent law and the TRIPS Agreement demonstrate the United States's influence in establishing global intellectual property standards.43 Despite the suc- cess of the United States in shaping global intellectual property stan- dards, the TRIPS Agreement maintains several flexibilities, namely data exclusivity and compulsory licensing, which were affirmed by the Doha Declaration.44 The United States's dissatisfaction with the level of intellectual property protection afforded by the TRIPS Agreement prompted the proliferation of TRIPS-Plus provisions in U.S. FTAs.45

A. Values and Ideals in U.S. Patent Law

The preeminence of patents in the United States is evidenced by the fact that patents are constitutionally protected to promote innova- tion and discovery.46 A patent is a grant of property issued by a gov- ernment that provides limited rights to the patent owner.47 A patent owner in the United States is granted monopolistic control over his or her invention for twenty years, during which time no one may make, sell, or use the patented product, absent permission from the patent holder.48 This exclusive right promotes innovation by enabling the pat- ent owner to avoid pricing competition when selling the patented product.49 In return for monopolistic power to exclude, a patent owner must disclose the technological processes and data behind the prod- uct.50 Other producers use this information, saving on the cost of re- search and development while also expediting the regulatory process, in order to offer competitive pricing when the patent terminates.51

Patents are particularly valuable to the drug industry given the plethora of research and development required to produce pharma- ceuticals.52 When a drug is no longer under patent, pharmaceutical companies must compete with generic producers who provide medi- cines at much lower prices.53 Pharmaceutical companies assert that re- search and development challenges require a rigid patent system to recover investment, turn profit, and promote continued innovation.54

In the context of international trade, pharmaceutical companies have much at stake as LMICs produce generic versions of patented drugs and sell these medications around the world, undercutting brand- name profitability.55 Although the pharmaceutical industry ranks as one of the most profitable industries in the United States, these patent con- cerns have led to the development of powerful special interest groups that the United States relies on when considering trade agreements, in- cluding the TRIPS Agreement.56

B. Global Expansion of U.S. Patent Ideals Through the TRIPS Agreement

The combination of special interests and traditional value placed on patent protection has encouraged the United States to enforce its patent ideals globally by linking patent protection and international trade through the TRIPS Agreement.57 Touted as "unquestionably the most important development in international intellectual property law [in a century]," the TRIPS Agreement "attempts to strike a balance be- tween the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing peo- ple to use existing inventions and creations."58 To accomplish this, the agreement requires all WTO signatories to implement minimum stan- dards of intellectual property law.59

The United States's influence is acutely evident throughout the TRIPS Agreement's patent provisions, which practically mirror U.S. patent law.60 For example, like U.S. patent law, the TRIPS Agreement grants patent owners exclusive rights to prevent others from making, using, selling, or importing the patented product for twenty years.61 Moreover, neither the TRIPS Agreement nor U.S. patent law permits exceptions for patenting pharmaceuticals or pharmaceutical proc- esses.62 Both the United States and the TRIPS Agreement prohibit the use of compulsory licensing for products not developed locally.63 Lastly, both the United States and the TRIPS Agreement stipulate that in ex- change for a period of monopolistic control, the patent owner must disclose the invention "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art . . . ."64

Although the United States was largely successful in expanding its patent ideals through the TRIPS Agreement, LMICs maintained considerable flexibility to promote access to drugs.65 This success is highlighted by the TRIPS Agreement's treatment of data exclusivity and compulsory licensing.66

1. Data Exclusivity

The TRIPS Agreement requires patent holders to disclose relevant information regarding the development of the patented product, in- cluding clinical data.67 Pharmaceutical companies invest a significant amount of time and money to develop the clinical data required to patent new drugs.68 Generic drug companies rely on the clinical data collected by brand-name drug companies in order to demonstrate that the generic drug is pharmacologically equivalent to the brand-name pharmaceutical.69 In doing so, generic producers avoid the inordinate time and expense required to generate this data, enabling expeditious regulatory approval and delivery of affordable medicines upon the ex- piration of brand-name patents.70 The TRIPS Agreement requires pro- tection of such data but affords signatories broad discretion to utilize clinical data to protect the public and promote public health, as long as steps are taken to prevent unfair commercial use.71 Moreover, scholars contend that in light of the TRIPS Agreement's purpose and objectives, the agreement does not require a period of data exclusivity, contrary to U.S. patent law.72

2. Compulsory Licensing

A compulsory license is a government authorized license to a third party for the purpose of manufacturing and producing a patented in- novation without consent from the patent owner.73 Article 31 governs compulsory licenses under the TRIPS Agreement, granting a govern- ment broad discretion in issuing these licenses.74 The following re- quirements must be met in order to obtain a compulsory license: (1) the country must ensure that the third party seeking the license at- tempts to obtain authorization from the patent holder on reasonable commercial grounds; (2) the scope and duration of the compulsory license must be limited to the purpose for which the license was author- ized; (3) the compulsory license must be predominately used "for the supply of the domestic market of the Member authorizing such use;" and finally (4) the country must provide the patent holder with "ade- quate remuneration . . . taking into account the economic value of the authorization."75 Article 31 may be waived in cases of extreme urgency, national emergency, or public non-commercial use.76

Although HICs and LMICs reached a compromise on compulsory licensing, the issue became increasingly contentious upon implementa- tion.77 HICs were dismayed with the lack of clarity surrounding terms like "adequate remuneration" and "national emergency."78 LMICs were frustrated with Article 31(f) which stipulates that compulsory licenses must be predominately used for distribution within the domestic mar- ket.79 Because many low-income countries lack manufacturing capacity, compulsory licensing under Article 31 does not provide a viable method of obtaining pharmaceuticals at a competitive price.80 At the same time, alarm over HIV/AIDS, malaria, and tuberculosis grew as developing countries struggled to contain and treat infectious disease epidemics.81 These concerns led to the signing of the Doha Declaration at the WTO Ministerial Conference in 2001.82

C. A Blow to U.S. Interests: The Doha Declaration and Article 31bis

As WTO signatories began implementing the TRIPS Agreement, the scourge of HIV/AIDS proliferated and infections increased by ten percent from 2000 to 2001.83 At that time, the World Health Organization estimated that less than four percent of those in need of HAART had access.84 It is in this context that the Doha Declaration "recog- nize[d] the gravity of the public health problems afflicting many [LMICs], especially those resulting from HIV/AIDS, tuberculosis, ma- laria and other epidemics."85 WTO delegates agreed that signatories should interpret and implement the TRIPS Agreement in a way that promotes public health and access to medicines for all.86

Intellectual property flexibilities promoted by the TRIPS Agree- ment were reaffirmed in the Doha Declaration.87 Specifically, the Doha Declaration implicitly affirmed the TRIPS Agreement's deferential data exclusivity provisions and explicitly confirmed the use of compulsory licenses.88 The Doha Declaration granted broad discretion with regard to compulsory licensing, asserting that WTO signatories have "the right to grant compulsory licences [sic] and the freedom to determine the grounds upon which such licences [sic] can be granted."89 Perhaps most importantly, the Doha Declaration recognized the ineffectiveness of compulsory licensing for countries with limited or no manufacturing capacity.90 To address this weakness, WTO signatories amended the TRIPS Agreement with Article 31bis, which enables countries with lim- ited or no manufacturing capacity to import generic drugs from other countries, thereby promoting access to more affordable medicines.91

Despite the Doha Declaration's affirmance of deferential data exclusivity and compulsory licensing as valuable mechanisms to promote access to medicine, the United States dominated the TRIPS Agreement negotiations.92 A World Bank study concluded that low-income countries stand to lose twenty billion dollars from transfers of technology, including pharmaceuticals, if the TRIPS Agreement is fully imple- mented.93 Still, the United States had to accept compromises during the negotiations and has remained discontent with the level of protection afforded to pharmaceutical patents by the TRIPS Agreement.94 This dissatisfaction spurred the proliferation of TRIPS-Plus provisions in bilateral U.S. FTAs.95

D. The Proliferation of TRIPS-Plus Provisions in U.S. FTAs

The TRIPS Agreement creates a regulatory "floor," consisting of minimum levels of protection that must be afforded to intellectual property by all WTO signatories.96 Countries are therefore permitted to seek higher levels of protection in FTAs, and the United States has done so in negotiating bilateral FTAs with numerous countries.97 These trade agreements are commonly called TRIPS-Plus U.S. FTAs because they incorporate more stringent intellectual property protection provisions than the TRIPS Agreement, while also limiting the freedoms and flexibilities provided by the TRIPS Agreement.98

Beginning with the Bush administration and continuing through the Obama administration, the U.S. has sought to "ensur[e] that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the United States re- flect a standard of protection similar to that found in United States law."99 Pressure from the pharmaceutical industry led to the implementation of several TRIPS-Plus provisions, including rigid data exclusivity policies and limitations on compulsory licensing, thereby impeding access to affordable medicines for indigent populations in desperate need.100

1. TRIPS-Plus Impact on Data Exclusivity Provisions

TRIPS-Plus data exclusivity provisions in U.S. FTAs constrict the flexibilities afforded by the TRIPS Agreement.101 Whereas the TRIPS Agreement applies a deferential approach towards data exclusivity, U.S. FTAs apply the same level of protection afforded under U.S. patent law.102 In U.S. FTAs, competing manufacturers are prohibited from relying on clinical data for five to fifteen years after the date of a pharmaceutical's initial regulatory approval.103 Brand-name pharmaceutical companies favor data exclusivity provisions because they enable drug companies to exploit profits by suspending competition.104

Clinical data is costly and time consuming, and data exclusivity provisions may prohibit generic producers from introducing more affordable medication immediately following a patent's expiration by prohibiting access to data previously gathered by the patent holder.105 To compete, generic producers may be forced to conduct their own costly research and development, negating their ability to provide affordable drugs.106 Alternatively, generic companies would have to delay regulatory approval and production of generic drugs.107 Thus, TRIPS- Plus data exclusivity provisions in U.S. FTAs effectively empower patent holders to extend monopolistic control of pharmaceuticals by obstructing generic competition, consequently diminishing access to medicines for indigent populations.108

2. TRIPS-Plus Impact on Compulsory Licensing

Although to the TRIPS Agreement enables WTO signatories to es- tablish their own national compulsory licensing scheme, TRIPS-Plus provisions in U.S. FTAs significantly limit compulsory licensing.109 Under U.S. FTAs, parties may typically only grant compulsory licenses in emergency situations, as an anti-trust remedy, or for public non- commercial use.110 Notably, U.S. FTAs do not define "emergency situa- tions" or "public non-commercial use."111 Some TRIPS-Plus provisions require "reasonable and entire" remuneration for patent owners as op- posed to "adequate remuneration" required by the TRIPS Agree- ment.112 Finally, U.S. FTAs permit challenges to compulsory licenses on the grounds that a license was not warranted under the specific circum- stances.113 By confining a government's ability to issue compulsory licenses and providing an opportunity for the patent holder to challenge the issuance of compulsory licenses, TRIPS-Plus compulsory licensing provisions diminish a generic producer's ability to compete and enable the patent holder to manipulate drug pricing.114 The net result is diminished access to medicines for Hope Tukahirwa and millions like her.115

II. Why TRIPS-Plus Provisions are Problematic: Rigid Data Exclusivity Provisions and Compulsory Licensing Provisions Obstruct Access to Medicine

TRIPS-Plus provisions promote unyielding data exclusivity and limit compulsory licensing to the detriment of indigent populations lacking access to affordable pharmaceuticals.116 Data exclusivity provisions in U.S. FTAs with Guatemala and Vietnam, two countries struggling with staggering poverty, have led to increased pharmaceutical prices by delaying generic competition.117 Moreover, the exclusion of compulsory licensing from FTAs or proposed FTAs with the Dominican Republic, Thailand, and the Southern African Customs Union (SACU) could lead to overwhelming public health challenges as generic competition is strangled from the market while patent holders maintain monopolistic control over pharmaceutical prices.118

A. Examples of How Rigid TRIPS-Plus Data Exclusivity Provisions Have Had a Deleterious Effect on Public Health

U.S. FTAs include rigid data exclusivity provisions that ultimately obstruct generic drug competition, resulting in disastrous public health consequences for destitute populations.119 Trade agreements with Gua- temala and Vietnam illustrate the injurious effect that data exclusivity provisions have on access to affordable drugs.120

1. Guatemala

The number of people living with HIV/AIDS in Guatemala has doubled since 2001; an estimated 62,000 people are living with the dis- ease and less than 11,000 are receiving antiretroviral therapy.121 Fur- thermore, approximately twenty percent of Guatemala's largely rural population lacks regular access to health facilities and services.122 TRIPS-Plus data exclusivity provisions exacerbate these public health concerns by restricting access to affordable pharmaceuticals in Guate- mala where over fifty percent of the population lives below the national poverty line.123

The U.S.-Dominican Republic-Central American Free Trade Agreement (DR-CAFTA) came into effect in Guatemala in 2006.124 The DR-CAFTA is an agreement between the United States and six Central American countries, namely Costa Rica, El Salvador, Guatemala, Hon- duras, Nicaragua, and the Dominican Republic.125 Rigid data exclusiv- ity provisions in the DR-CAFTA have prohibited a number of generic drugs from entering the Guatemalan pharmaceutical market, despite the fact that many of these drugs may successfully treat major causes of morbidity and mortality.126 For example, Pfizer's Vfend, which is used to treat invasive fungal infections generally found in patients with com- promised immune systems (like those suffering from HIV/AIDS), costs 810% more than the generic version.127 Vfend, however, is subject to fifteen years of data exclusivity, thus barring generic producers' access to clinical information, quashing competition, and granting Pfizer mo- nopolistic pricing control.128

Similarly, data exclusivity provisions have restricted access to af- fordable antiretrovirals.129 For example, the Guatemalan government provides a list of drugs that public organizations may procure at subsi- dized costs.130 A generic antiretroviral was registered in 2004, yet when Abbott Laboratories' patented version of the same drug, Kaletra, which costs 166% more than the generic pharmacological equivalent, was reg- istered a year later, it was granted retroactive data exclusivity through 2000-the patent expires in 2015.131 Accordingly, only Kaletra, and not the generic version, has been listed by the Guatemalan government as available through subsidized costs.132 Public organizations seeking the more affordable generic drug are required to procure the drug else- where.133 Thus, rigid TRIPS-Plus data exclusivity provisions in the DR- CAFTA have reduced or eliminated generic pharmaceutical competi- tion, resulting in an inordinate pricing structure making critical drugs unavailable to much of Guatemala's indigent population.134

2. Vietnam

The United States signed a trade agreement with Vietnam in 2000.135 When Vietnam adopted data exclusivity provisions as part of the agreement, the United States praised the country for its alignment with U.S. data exclusivity standards.136 From 2000 through 2005, the Vietnamese government saw a threefold increase in health spending, much of which was attributed to rising pharmaceutical costs.137 This is particularly evident in the pricing of antiretrovirals produced in Viet- nam, which cost five to seven times more than the lowest international prices for the same pharmaceuticals.138

The precipitous increase in the cost of antiretrovirals occurred as HIV/AIDS became increasingly problematic in Vietnam.139 In 2009, an estimated 280,000 people were living with HIV/AIDS, a figure that has doubled since 2001, shortly after the U.S.-Vietnam Trade Agreement was reached.140 Nearly seven percent of all people living with HIV/AIDS in Southeast Asia live in Vietnam.141 In 2009, over fourteen thousand Vietnamese died from AIDS related causes.142 Additionally, only half of those in need of HAART currently receive antiretroviral therapy.143 Un- der these conditions, stringent data exclusivity provisions limit access to medicines in Vietnam, exacerbating an already dire public health situa- tion in a country where fifteen percent of the population lives below the national poverty line.144

For example, like many LMICs, Vietnam requires greater access to second-line antiretroviral treatment.145 As HIV/AIDS evolves, it may grow resistant to first-line treatment, requiring second-line drugs, many of which are patented by multinational pharmaceutical companies.146 One of these second-line pharmaceuticals is Kaletra from Abbott Labo- ratories.147 It was recently reported that Abbott Laboratories has a pat- ent pending for Kaletra in Vietnam, and it intends to use that patent to prevent the procurement of generic alternatives.148 Unyielding TRIPS- Plus data exclusivity provisions prohibit the use of clinical data for at least five years (and upwards of fifteen years, as seen in Guatemala), thereby eliminating generic competition for a pharmacological equiva- lent to Kaletra.149 Thus, Abbott Laboratories will be able to charge in- ordinate prices, rendering access to affordable pharmaceuticals unat- tainable for low-income populations gravely in need of second-line antiretroviral therapy.150

B. U.S. Policy Towards Compulsory Licensing Severely Harms Public Health in Middle and Low-Income Countries

TRIPS-Plus provisions in U.S. FTAs discourage the use of compulsory licensing thereby restricting generic competition and furthering a patent holder's monopolistic control of pricing, which results in restricted access to affordable drugs.151 These potentially negative effects of U.S. policy towards compulsory licensing are illustrated in two proposed, but stalled, FTAs with Thailand and the Southern African Customs Union.152

1. Dominican Republic The island of Hispaniola, comprised of the Dominican Republic and Haiti, contains approximately eighty-five percent of all HIV/AIDS cases in the Caribbean, the region with the second highest per capita prevalence of HIV/AIDS after sub-Saharan Africa.153 In 2009, an esti- mated 57,000 people living with HIV/AIDS were domiciled in the Do- minican Republic, with 3,200 new infections that year.154 Also in 2009, an estimated 2,300 people died from AIDS-related causes.155 TRIPS- Plus compulsory licensing provisions further exacerbate the Dominican Republic's public health landscape by contributing to rising pharma- ceutical costs and discouraging generic competition, thereby limiting access to affordable drugs in a country where fifty percent of the popu- lation lives below the national poverty line.156 Although it has never issued a compulsory license, the Dominican Republic maintains liberal compulsory licensing provisions in its na- tional intellectual property law.157 Moreover, the Dominican Republic's commitment to compulsory licensing as a vital mechanism for securing access to medicines is evidenced by the fact that the Dominican Repub- lic was a sponsor of both the Doha Declaration and the Article 31bis Amendment, which sought to ease the process for issuing compulsory licenses.158 The Dominican Republic also maintains a strong generic pharmaceutical industry with generic firms controlling approximately fifty percent of the domestic pharmaceutical market.159 In fact, the in- troduction of generic antiretrovirals in the Dominican Republic led to a ninety-nine percent decrease in their cost.160 The Dominican Republic ratified the DR-CAFTA on March 1, 2007.161 TRIPS-Plus provisions in the DR-CAFTA have been character- ized as the most "onerous" protections among all U.S. FTAs with LMICs.162 Researchers assert that by 2027, the Dominican Republic will experience a nine to fifteen percent increase in pharmaceutical prices as a result of the DR-CAFTA.163 Evidence of TRIPS-Plus compulsory licensing provisions on price increases and diminished access to phar- maceuticals, however, is already prevalent as illustrated by the second- line antiretroviral Efavirenz, which costs three times more than its ge- neric pharmacological equivalent.164 TRIPS-Plus patent provisions in the DR-CAFTA effectively bar com- pulsory licensing by linking marketing approval of generic pharmaceu- ticals to the consent of patent holders.165 Thus, if a generic drug com- pany developed the pharmacological equivalent to Efavirenz under a compulsory license issued by the Dominican Republic, the generic pro- ducer would still be required to obtain consent from the patent holder to sell the generic version of the drug, which is highly unlikely.166 Be- cause debilitating poverty prohibits procurement of brand name Efavirenz and compulsory licensing provisions constrict generic compe- tition, Dominicans are forced to use a similar but slightly more harmful drug, Nevirapine.167 Nevirapine may weaken a patient's immune system if provided too early in the progression of HIV/AIDS, thereby further compromising the patient's health.168 By delaying treatment, however, individuals diagnosed with HIV/AIDS face the same risk of a weakened immune system.169 Given rampant poverty and rising pharmaceutical costs, one healthcare provider suggested that Dominicans have the bleak choice of, "[buying] medication [or] buying lunch."170 TRIPS-Plus compulsory licensing standards included in the DR-CAFTA have paralyzed the Do- minican Republic from utilizing this TRIPS-compliant method of pro- viding affordable access to antiretrovirals and other drugs.171 2. Thailand In 2002, an estimated 670,000 people were living with HIV/AIDS in Thailand.172 The Thai government recognized the threat posed by the pandemic and initiated a national HIV/AIDS program aiming to provide its citizens with universal access to HAART.173 The program has been widely successful; the number of people receiving treatment rose from 3,000 in 2002 to 52,000 by 2005.174 The annual number of HIV/AIDS related deaths prior to the universal access program was ap- proximately 52,000, but in 2009, after several years of universal access, that number decreased by nearly fifty percent.175 By 2010, nearly sev- enty percent of those in need of antiretroviral therapy received treat- ment.176 Thailand's commitment to universal access to antiretroviral therapy has been praised by the World Health Organization and non- governmental organizations from around the world.177 The most criti- cal aspect to the success of the universal access program has been the Thai government's ability to promote the availability of inexpensive generic antiretrovirals.178 To ensure the success of the HIV/AIDS program, however, Thai- land required access to patented second-line pharmaceuticals.179 These patented medications are significantly more expensive than the generic alternatives.180 For example, Abbott's Kaletra cost well over two thou- sand dollars per patient per year, limiting the Thai government's provi- sion of the medication to six hundred patients out of eight thousand in need.181 The World Bank reported that by issuing compulsory licenses, Thailand could reduce the cost of second-line antiretroviral treatments by ninety percent.182 Thailand attempted to negotiate reduced prices for several pharmaceuticals, including Kaletra, but failed to reach an agreement.183 Thus, in late 2006 and early 2007, the Thai government issued compulsory licenses for two antiretrovirals, including Kaletra, and a third compulsory license for Plavix, a pharmaceutical used to treat cardiovascular disease.184 The United States and Thailand began negotiating a trade agree- ment in 2004, but suspended negotiations in 2006 following a military coup in Thailand.185 The World Bank concluded that TRIPS-Plus provi- sions in the proposed U.S.-Thailand FTA would have crippled Thai- land's ability to issue compulsory licenses, resulting in costs exceeding 3.2 billion dollars over twenty years.186 U.S. FTAs permit challenges to compulsory licenses on the grounds that the license was not warranted under the specific circumstances.187 Given that Abbott Laboratories and Thailand were unable to reach an agreement about the price of Kaletra, it is likely that Abbott Laborato- ries challenged the Thai government's decision to issue a compulsory license.188 In fact, Abbott was so furious with Thailand's issuance of a compulsory license for Kaletra, that it withdrew several pending phar- maceutical patents from Thailand-an unprecedented move in which a U.S. drug company retaliated against a foreign government by cutting off the supply of certain pharmaceuticals.189 If Abbott Laboratories were to prevail in such a challenge, Thailand may have been subject to U.S. sanctions and may have been required to discontinue the license.190 Thus, rigid TRIPS-Plus compulsory licensing provisions in the proposed U.S.-Thailand FTA may have curbed Thailand's use of this critical mechanism for improving access to affordable antiretrovirals necessary for Thailand's remarkably successful HIV/AIDS program.191 3. The Southern African Customs Union Perhaps nowhere on Earth has the scourge of HIV/AIDS afflicted more people than the members of the Southern African Customs Un- ion (SACU), which is comprised of Botswana, Lesotho, Namibia, South Africa, and Swaziland.192 The SACU is burdened by over twenty percent of the global HIV/AIDS epidemic, as approximately seven million peo- ple living with HIV/AIDS inhabit SACU member countries.193 The SACU member countries are rife with poverty as nearly one-quarter of the population in each country live below the national poverty line.194 This rampant poverty has quashed access to antiretrovirals, with less than sixty percent of those in need of treatment currently receiving therapy.195 Despite extreme poverty, the SACU forms a formidable trad- ing block and has agreed to treaties with several European countries, South American countries, and is in the midst of negotiating a trade agreement with India.196 In fact, in 2003, the United States and the SACU entered negotia- tions to establish a U.S.-SACU FTA.197 The United States insisted on sev- eral TRIPS-Plus provisions, many of which are similar to those included in current U.S. FTAs.198 The SACU nations expressed particular con- cern over the proposed compulsory licensing provisions.199 The United States sought to impose a ban on exportation of pharmaceuticals devel- oped by compulsory licenses, which would have prohibited South Af- rica's generic pharmaceutical industry from supplying SACU nations with affordable drugs, including antiretrovirals.200 Thus, rigid TRIPS- Plus compulsory licensing provisions in the proposed U.S.-SACU FTA would have compromised access to generic drugs that SACU nations rely on to handle the scourge of HIV/AIDS in sub-Saharan Africa.201 The SACU refused the TRIPS-Plus provisions that the United States obstinately sought, recognizing that such compulsory license provisions would limit the delivery of affordable medicines, and as a result, nego- tiations stalled in 2006.202 Nevertheless, in 2008, the United States and the SACU signed a Trade, Investment, and Development Cooperative Agreement that "establishes a forum for consultative discussions, coop- erative work, and possible agreements on a wide range of trade issues" which would "[i]deally . . . put in place the 'building blocks' for a future FTA. . . ."203 Given the tremendous burden of HIV/AIDS on SACU na- tions, standard U.S. TRIPS-Plus compulsory licensing provisions could provoke devastating consequences.204 III. Promoting Access to Medicine Through Amendment of U.S. FTAs

TRIPS-Plus provisions in U.S. FTAs have come under fire and have even been criticized by Congress.205 The congressional response to TRIPS-Plus provisions in the Bipartisan Agreement on Trade Policy has fallen short of addressing the burdensome data exclusivity and compulsory licensing provisions in U.S. FTAs.206 To remedy these shortcom- ings, the United States should amend all U.S. FTAs to incorporate a balancing test that would provide review panels an opportunity to weigh the benefits and detriments associated with relaxing data exclu- sivity and compulsory licensing provisions for various drugs.207

#### Expansion enables domestic manufacturing and innovation that decentralizes pharma supply chains

HRW 6/3 — (Human Rights Watch, “Seven Reasons the EU is Wrong to Oppose the TRIPS Waiver“, 6-3-2021, Available Online at https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver, accessed 10-5-2021, HKR-AR)

The European Commission claims that intellectual property (IP) is not a barrier to scaling up the manufacturing of vaccines or other health products needed for the Covid-19 response, suggesting that sharing IP would not immediately speed up manufacturing. Right now, there are manufacturers with capacity to produce additional Covid-19 vaccines and other health products at factories in Bangladesh, Canada, Denmark, India, and Israel, but they are unable to contribute because they do not yet have the right licenses. So, **IP is a barrier to them.** The TRIPS waiver proposal sponsors and experts at the leading science journal Nature, Médecins Sans Frontières (MSF) Access Campaign, the Third World Network, and others have presented many other concrete examples of how enforcement of IP rules blocked, delayed, or limited production of chemical reagents for Covid-19 tests, ventilator valves, Covid-19 treatments, and elements of Covid-19 vaccines. IP constraints have not only led to vaccine shortages but have also led to shortages of key raw materials like bioreactor bags and filters.

Rather than manufacturers being held back by an inherent lack of manufacturing and technological capability, studies have shown that transnational claims to IP impede new manufacturers from entering and competing in the market. The same dynamics are playing out today with Covid-19.

Even though a waiver will not automatically expand production overnight, it paves the way for speedy technology transfers and manufacturing.

The waiver by itself will not automatically result in widespread and diversified manufacturing, but it will ease complex global rules governing IP and exports and give governments freedom to collaborate on technology transfers and exports **without fearing trade-based retaliation.** It will help reduce the dependence on any one country or region for medical products and mitigate the risks of export restrictions. With new variants emerging and some evidence that repeat vaccine boosters may be needed, the waiver will enable governments around the world to be prepared for a long-term response to Covid-19.

Experts have mapped out plans for how the manufacturing of mRNA and other vaccines, could be dramatically expanded in a relatively short period of time. Waiving certain IP rules in the TRIPS agreement over the next three years could help create diverse regional manufacturing hubs and protect the EU and the rest of the world from future pandemics, supply chain disruptions, and resulting economic disaster.

Concerns that widening the universe of producers may lower or compromise quality standards are unfounded because stringent regulatory authorities and the World Health Organization (WHO) would continue to play their existing role as arbiters of quality and safety for vaccines, which have a very stringent process for approval.

Dose-sharing and COVAX will not be enough to deliver universal and equitable vaccine access.

The European Commission points to its participation in COVAX to suggest that it is effectively leading efforts to promote equitable access to vaccines. Individual member states have begun to use COVAX to share some of the doses they prebooked with countries in need.

However, COVAX currently only aims to provide vaccines for 20 percent of participants’ populations, far from the coverage needed to end the pandemic. Vaccine supply shortages have already hampered COVAX’s ability to reach that target. The facility began delivering vaccine doses in late February, but has only been able to deliver 71 million vaccine doses to over 100 countries as of May 25, 2021 barely enough to cover 1 percent of the combined populations of those countries.

Further, COVAX is heavily dependent on AstraZeneca’s vaccines manufactured at the Serum Institute of India. Because of the huge surge in Covid-19 in India, the Indian government has currently restricted export of vaccines, and COVAX is facing a shortfall of 190 million vaccine doses. Serum Institute of India recently announced that it expects to resume supplying COVAX only by the end of 2021.

Finally, COVAX only applies to procurement and allocation of vaccines. India and South Africa’s proposal would cover a broader range of health products and technologies needed for the Covid-19 response including tests, treatments, personal protective equipment, and more. The devastating recent surge in infections and deaths in India, Brazil, and Nepal shows that we need more than vaccines to save lives.

Temporarily waiving patent monopolies will not end all future innovation to develop vaccines and drugs.

Pharmaceutical companies and their lobbying groups claim that patent monopolies to commercialize their inventions spur innovation and that waiving such monopoly rights during a devastating global pandemic, “would jeopardize future medical innovation, making us more vulnerable to other diseases.”

The UN Committee on Economic, Social and Cultural Rights stated in April 2020 that “[P]andemics are a crucial example of the need for scientific international cooperation to face transnational threats … [i]f a pandemic develops, sharing the best scientific knowledge and its applications, especially in the medical field, becomes crucial to mitigate the impact of the disease and to expedite the discovery of effective treatments and vaccines…. The Committee reiterates that ultimately, intellectual property is a social product and has a social function and consequently, States parties have a duty to prevent unreasonably high costs for access to essential medicines.”

It is a disservice to humanity to claim scientists and researchers would have no interest in developing lifesaving vaccines and drugs without the promise of patent monopolies. Jonas Salk, the inventor of the polio vaccine, did not claim any monopoly over it and gave it away for free. When he was asked who owned the patent for his vaccine, he reportedly said, “Well, the people, I would say. There is no patent. Could you patent the sun?”

Economists Mariana Mazzucato and Jayati Ghosh, and public health activist Els Torreele, argue that IP rights were never designed to be used during pandemics. “Patents erect barriers against competitors when what is needed is technological co-operation, harnessing our global scientific and technological capabilities to fight the virus together,” they explain. The 1994 Marrakesh Agreement, which established the WTO allows for waivers in exceptional circumstances. What could be a more exceptional circumstance than a global pandemic that has claimed the lives of 3.5 million people? Dr. Tedros Adhanom Ghebreyesus, the director-general of the WHO, supported the waiver, asking poignantly: “If not now, when?”

The argument that we need market-based incentives like patents to spur innovation also ignores the fact that billions of Euros of public money have funded research, development, and delivery of Covid-19 vaccines and other health technologies. For example, a recent study found that public money from government and philanthropic sources accounted for 97.1 to 99 percent of the funding toward research and development of the Oxford-AstraZeneca vaccine. Johnson & Johnson received an estimated US$1 billion (€820 million) in funding from the US government for development of its Covid-19 vaccine; Moderna’s vaccine was also significantly funded by public money from the US government. Even where public money was not directly given for research and development, experts say that governments’ advance market commitments significantly de-risked the investments of pharmaceutical companies, by providing them a guaranteed market even before their vaccines were proven to be safe and effective.

#### Building domestic productive capacity is key to future pandemic resilience after COVID

UNCTAD 20 [The United Nations Conference on Trade and Development was established in 1964 as an intergovernmental organization intended to promote the interests of developing states in world trade. UNCTAD is the part of the United Nations Secretariat dealing with trade, investment, and development issues. "COVID-19 heightens need for pharmaceutical production in poor countries." https://unctad.org/news/covid-19-heightens-need-pharmaceutical-production-poor-countries]

With more than 100 projects to develop a COVID-19 vaccine underway around the globe – eight of which have entered the clinical stage – hope is growing for a miracle breakthrough. But so is concern over who would and would not have access to the shot, if and when one is approved. “Once a vaccine for COVID-19 is available, the massive demand is likely to outstrip supply quickly,” said James Zhan, UNCTAD’s director of investment and enterprise. “If the pharmaceutical industry cannot keep up with demand, populations in poor countries will be the ones left behind,” he said while opening a webinar organized with the World Health Organization (WHO). Lack of access to essential medicines is a tragic reality for many families in developing nations. For example, nearly half a million children in sub-Saharan Africa die each year from vaccine-preventable diseases, according to the WHO. Back in the spotlight COVID-19 has thrust the issue back in the spotlight. Fears that access would be based on some sort of pecking order peaked on 13 May when French pharmaceutical giant Sanofi Pasteur said the first doses of their vaccine, if approved, would go to the United States because its government had invested first in the required research and development. The following day, more than 140 world leaders and public figures signed an open letter calling for global public health interests to be given priority over nationalism and corporate profits. The call for a “people’s vaccine” followed a European Union-led event that a week earlier had secured nearly $8 billion from governments within and outside the bloc to help ensure universal and affordable access to COVID-19 medication. And on 19 May, the World Health Assembly adopted a historic resolution co-sponsored by more than 130 countries calling for equitable access to vaccines and treatments against the virus. Untapped local production While the resolution and funds will help, they provide a temporary solution. And with discussions focused on the issue of patents and profits, a fundamental issue is being overlooked: the lack of productive capacity in developing countries. Vaccine production is currently concentrated in a few developed countries, in the hands of a few major players. According to the WHO, nearly one third (32%) of vaccines have fewer than four suppliers, while nearly two thirds (63%) have two or fewer prequalified products. “COVID-19 has shown just how vulnerable medical product supply chains are when relying on a small number of manufacturers for raw materials and final products,” said Emer Cooke, director of the WHO’s regulation and prequalification department. According to UNCTAD and the WHO, many developing countries need help to build their capacity to produce essential medical products, whether they are vaccines, antibiotics or personal protective equipment. Those that have so far succeeded in establishing a local pharmaceutical industry capable of complying with international quality standards are mostly middle-income and low middle-income countries in Asia, such as India and Thailand. Productive capacity has remained largely untapped in Africa, where the majority of the least developed countries are located. 25 million doses Of the 40 vaccine manufacturers in 14 nations that are part of The Developing Countries Vaccine Manufactures Network, only one is African: the Biovac Institute based in Cape Town, South Africa, which currently delivers over 25 million doses of vaccines each year for illness such as measles, polio and tuberculosis. Biovac’s chief executive officer, Morena Makhoana, said Africa’s public health security requires ramped-up local production. Otherwise, the continent’s 1.2 billion people remain vulnerable to shocks in global supply chains and foreign governments’ trade policies. Since the pandemic began, nearly 80 countries have imposed some form of restriction on the export of medical supplies. “African governments should look at domestic capacity as an insurance for the next pandemic,” Mr. Makhoana said. “We cannot continue to rely on external sources.”

#### Drug access solves AMR and 15 million deaths a year

AMI 21 [Access to Medicine Index. The 2021 Index analyses how 20 of the world's largest pharmaceutical companies are addressing access to medicine in 106 low- and middle-income countries for 82 diseases, conditions and pathogens. Find out more about the scope of the Index research. "Why access matters." https://accesstomedicinefoundation.org/access-to-medicine-index/about-the-index/why-access-matters#]

Achieving universal healthcare is critical to help populations access health services they need without financial constraint. Access to medicines is an important part of this. Increasing access depends on a range of factors and involves action from a variety of parties. The pharmaceutical industry, in collaboration with the global health community, plays a critical role in responding to defined priorities for global health, developing much-needed innovative products, expanding access to those products that already exist and forging new partnerships to promote sustainable, long-term access to medicines.

Global health issues hit lower-income countries the hardest

The growth in development aid for health has fallen in recent years as donor government budgets have tightened. This is particularly concerning for low-income countries that rely heavily on aid to provide health services to their populations. Low-income countries are being hit the hardest: in these countries, government health expenditure as a percentage of GDP has been in decline in recent years, resulting in more needing to be done with less. In 2015, the UN agreed the Sustainable Development Goals, including global health targets such as the elimination of major disease epidemics and the reduction in the burden of childhood obesity. To ramp up progress towards these goals, in September 2019, the UN Secretary General called for a Decade of Action to deliver the Global Goals by 2030.

Progress in global health is not inevitable. Non-communicable diseases (NCDs) such as diabetes, cancer and heart disease are a growing challenge due to rapid urbanisation, worsening diets and increasingly sedentary lifestyles, they account for 71% of deaths globally each year, including 15 million people aged between 30 and 69 years, with more than 85% of these so-called premature deaths occurring in low- and middle-income countries. Access to prevention, detection, screening, treatment for NCDs is essential.

In addition, new public health crises have posed further challenges to global health and have put more pressure on already strained health systems and families paying out of pocket for health services. For instance, in 2019 the resurgence of measles was a threat with 6,000 deaths recorded in the Democratic Republic of the Congo by January 2020. Antimicrobial resistance, which already causes more than 700,000 deaths each year worldwide, is growing. The newly emergent coronavirus (SARS-CoV-2) which causes a severe acute respiratory disease, COVID-19, was identified in Wuhan, China in December 2019 and has been declared a global health pandemic by the World Health Organization since March 2020. To help address current and future global health issues, governments and regulators – as well as stakeholders from the public and private sectors – need to develop, support and implement innovative practices to reach more people in need.

#### Distributed manufacturing capacity is key – donations are insufficient for COVID and future pandemics because of capacity, speed, and supply

Maxmen 9/15/21 [Amy Maxmen is an American science writer and journalist who is a senior reporter at Nature. She covers evolution, medicine, science policy and scientists. She was awarded the Victor Kohn Prize for Excellence in Medical Science Reporting for her coverage of the COVID-19 pandemic. "The fight to manufacture COVID vaccines in lower-income countries." https://www.nature.com/articles/d41586-021-02383-z]

Vaccines against COVID-19 are not reaching many people in the global south, despite donations from wealthy nations. Less than 1% of people in low-income countries are fully vaccinated, and just 10% are in lower-middle-income countries, compared with more than half in high-income countries.

Many researchers say the best way to ensure equitable access to COVID-19 vaccines is to enable countries in the global south to make their own. “Charity is good, but we can’t rely on charity alone,” says Peter Singer, an adviser to the director-general of the World Health Organization (WHO).

Since last year, health-advocacy organizations have been pressing pharmaceutical companies and governments that developed highly effective vaccines to share their patented knowledge and technology with drug manufacturers that could produce them for poorer countries. These vaccines include the messenger-RNA jabs created by Moderna in Cambridge, Massachusetts, and Pfizer in New York City and BioNTech in Mainz, Germany, and a viral-vector vaccine developed by Johnson & Johnson (J&J) in New Brunswick, New Jersey.

Calls to manufacture more vaccines in the global south have grown louder in advance of high-level pandemic discussions at the United Nations General Assembly, which began this week, and a US-led, Global COVID-19 Summit on 22 September. Advocates are clamouring for a variety of approaches. Some had pointed to the deployment of the Sputnik V vaccine as a model of pandemic diplomacy. Russia broadly licensed the jab to 34 drug companies outside its borders, including several in India and Brazil. But manufacturers are now saying that the second dose of the vaccine — which has a different composition than the first — is difficult to produce in large quantities.

In a letter signed by several Indian civil society groups — shared with Nature — advocates are urging US President Joe Biden to compel J&J to partner with drug companies in the global south, arguing that those making Sputnik V could easily pivot to the J&J vaccine because they rely on similar technologies. They estimate that the transition would take less than six months.

Achal Prabhala, an author on the letter and a coordinator at AccessIBSA, a medicines-access initiative in Bengaluru, India, thinks this switch would help to quickly protect people in places lacking vaccines (see ‘Protection divide’). He adds that partnerships with the companies that developed mRNA vaccines will also be crucial because of the shots’ effectiveness and adaptability. India, in particular, could help to tame the pandemic if the country was enabled to make more shots, he says, illustrated by its role in providing the majority of vaccines against other diseases to low- and lower-middle-income countries. “For 3.9 billion people, we are the bulwark of vaccine manufacturing. So, if there aren’t contracts here, the world suffers.”

Such calls have not yet gained traction. Outside of deals to bottle and package their vaccines, J&J has only one partnership with an Indian company, and Pfizer, BioNTech and Moderna have none in India, South America or Africa. Pharmaceutical companies have cited reasons including quality concerns and the time required to get new companies up to speed. Instead, they say they’re ramping up their own production, and they ask wealthy nations to increase vaccine donations to poorer ones. Prabhala calls their arguments “a useful canard that obscures the real barrier — an unwillingness on the part of western pharmaceutical companies to relinquish control over their patents and technology, even at the cost of millions of lives”.

Although the Biden administration supported a waiver on intellectual property surrounding COVID-19 vaccines that was proposed by India and South Africa at a World Trade Organization meeting last October, action has stalled. And the administration has not pushed US companies to partner with those in the global south. Germany, which funded the development of BioNTech’s mRNA vaccine, later licensed to Pfizer, remains opposed to patent waivers.

As months pass, some researchers have stopped hoping for partnerships to come to fruition. A group in South Africa has decided to try and re-create existing vaccines. Others argue that funds would be best spent on getting manufacturers in the global south prepared to pump out the next generation of vaccines currently in clinical trials. Most global health researchers agree that regional manufacturing is the only way to ensure worldwide vaccination in a crisis. Shahid Jameel, a virologist at the Trivedi School of Biosciences at Ashoka University in New Delhi, says, “We can’t fix vaccine inequalities until vaccine manufacturing is distributed.”

#### Resistance causes extinction---microbiome collapse and superbugs.

Garrett 16. (Laurie Garrett is a Pulitzer prize-winning science journalist and writer of two bestselling books. She was awarded the Pulitzer Prize for Explanatory Journalism in 1996 for a series of works published in Newsday, chronicling the Ebola virus outbreak in Zaire. Antibiotic-Resistant Bacteria and the World's Peril. September 19, 2016. https://blogs.scientificamerican.com/guest-blog/antibiotic-resistant-bacteria-and-the-world-s-peril/)

Welcome to the Anthropocene, the era in which one species—human beings—so utterly dominates the planet that all of the driving forces of climate, oceans, geology, air and every other life form on Earth are controlled by the activities of humanity. Most of the damage is thoughtless. Humans don’t decide to pollute, they just do so. People don’t make a choice to lower the numbers of oxygen-producing trees on the planet, they just chop them down without thinking about it. Among the most dangerous of these thoughtless actions executed by our species is wild misuse of antibiotics. On September 21, the United Nations General Assembly is convening a special session to look at ways to curb use of precious medicinal drugs that are swiftly being outwitted by drug-resistant bacteria, making everything from a scraped knee to a bout of pneumonia far more dangerous and difficult to treat. But that focus, important as it is, remains limited to human use of chemicals and concern about their misuse to our species’ health. Genuine governance and stewardship in the Anthropocene requires a far broader look at what our activities mean for the planet, writ large. At the most basic levels of life every single system on Earth is controlled, or influenced, by microbes—microscopic creatures ranging from nano-sized viruses to enormous colonies of bacteria; from populations of microbes in the depths of the oceans to the inside of the human gut. A human being is made up of about 30 trillion cells and 39 trillion microbes, most of which are indispensable to our mental and physical health. If all the viruses and parasites swarming inside and on the skin of a human being are tallied the microbe-to-cell ratio is about ten-to-one. The microbes—collectively known as the Human Microbiome—digest our food, help us do battle with invading pathogens, clean our skin and provide us fuel. Life without microbes is no life at all. Antibiotics kill bacteria, and as anybody who has been on a long course of the drugs to treat an ailment knows, the medicine is indiscriminate, knocking off not only invaders like the bugs that cause pneumonia and ear infections, but also those that prevent stomach aches and constipation in response to ingestion of food. Human overuse or misuse of antibiotics has bred the emergence of Superbugs that are not only resistant to the drugs, but may be able to surge in numbers within a person’s gut, for example, leading to dangerous imbalances in bacterial populations that then cause diabetes, some types of heart disease, depression and an enormous range of common diseases. The Earth has its own microbiome, representing about a third of the weight of all biological material and life forms on the planet. And it is every bit as indispensable to the planet as your microbiome is to your personal health. Microbes living on the surface of the oceans, for example, aerosolize and end up in the atmosphere, where water droplets collect on their surfaces, forming clouds . Eliminating those microbes would directly affect rainfall. More oxygen that humans breathe is made by microbes than plants. And even the plants rely upon the microbiome of soil to transfer nutrients into their roots, allowing trees and forests to make more oxygen for humans to breathe. So it should be with some considerable alarm that we consider the killing potential manmade antibiotics have for Earth’s microbiome.

#### New diseases cause extinction – uniquely probable due to environmental changes.

Mooney 21 — (Tom Mooney, Senior Communications & Advocacy Manager for the Coalition for Epidemic Preparedness Innovations, “Preparing for the next “Disease X””, CEPI, 2-1-21, Available Online at <https://cepi.net/news_cepi/preparing-for-the-next-disease-x/>, accessed 9-10-21, HKR-AM)

Disease X represents the knowledge that a serious international pandemic could be caused by a pathogen currently unknown to cause human disease. It was first included in the WHO’s list of priority pathogens in 2018. COVID-19 represents the first occurrence of Disease X since its designation was established, emerging much sooner than anticipated.

While the world battles to control COVID-19, we know that future outbreaks of Disease X are **inevitable**. Our interconnected world has made us more vulnerable than ever to the rapid spread of new emerging infectious diseases. Rapid urbanisation, deforestation, intensive agriculture, livestock rearing practices, climate change and globalisation are increasing opportunities for animal-to-human contacts and for human-to-human transmission of disease on a global scale. **The threat of Disease X infecting the human population, and spreading quickly around the world, is greater than ever before.**

COVID-19: CEPI’s first Disease X

When CEPI was established in 2017 we classed Disease X as a serious risk to global health security, for which the world needed to prepare. Prior to the COVID-19 pandemic, CEPI had initiated a rapid response programme—including mRNA vaccines—against novel pathogens. Our goal was to be able to start safety testing of vaccines within months of a new pathogen being genetically sequenced.

In January 2020—within 2 weeks of the publication of the genome sequence of the COVID-19 virus, and with just 141 confirmed cases of COVID-19 globally—CEPI began work on developing vaccine candidates against the virus. CEPI was able to move with such agility because it had already identified coronaviruses as serious threats and invested over $140 million in the development of vaccines against MERS. Within a few weeks of the COVID-19 outbreak, most of CEPI’s MERS vaccine development partners had pivoted to work on the new virus.

Just one year later, two CEPI-supported vaccine candidates are amongst the first in the world to be approved by regulatory authorities and deployed to protect people from the virus; and potentially over one billion doses of vaccine enabled by CEPI investment will be available to the COVAX Facility in 2021.

The speed of the scientific progress has been astounding, compressing vaccine development—which typically takes a decade into the space of 12 months—yet over 2 million lives have been lost to COVID-19 already and economies the world over have been devastated.

So, could we move even faster next time?

What next for Disease X?

We don’t know where or when the next Disease X will emerge, only that it will. As COVID-19 has demonstrated, diseases do not respect borders so we need to be prepared on a global scale to respond to future outbreaks of Disease X, and we need to do it fast.

In many ways COVID-19 is a proof of concept for rapidly developing a vaccine against a new viral threat. Scientists were already working on vaccines against MERS and SARS—pathogens from the same virus family as COVID-19—which gave us a crucial head start this time around.

25 viral families are known to infect humans, and over 1.6 million yet-to-be-discovered viral species from these viral families are estimated to exist in mammal and bird hosts—the most important reservoirs for viral zoonoses.

We cannot develop vaccines against all potential viral threats, but we could produce a library of prototype vaccines and other biological interventions against representative pathogens from each of these 25 viral families. Having such a library of prototype vaccines, which could be ‘pulled off the shelf’, and advanced into clinical testing as soon as a related threat emerges would dramatically accelerate the development of vaccines.

We also know that beta coronaviruses that cause SARS and MERS are associated with case fatality rates of 10-35% (25-88 times worse than COVID-19) and that coronaviruses circulate widely in animal reservoirs. The emergence of a coronavirus variant combining the transmissibility of COVID-19 with the lethality of SARS or MERS would be utterly devastating. We must minimise this threat as a matter of urgency. One way to do this in the long-term would be to develop a vaccine that provides broad protection against coronaviruses in general.

If we can produce vaccines against Disease X in a matter of months instead of a year or more, we could revolutionise the world’s ability to respond to epidemic and pandemic diseases. **Disease X and other emerging infectious diseases pose an existential threat to humanity**. But for the first time in history, with the right level of financial commitment and political will, we could credibly aim to eliminate the risk of epidemics and pandemics.

#### Lastly, disease structurally makes war more likely—populism, and decline in education, democracy, and inter-dependence.

Rohner 20 (Dominic Rohner is a professor of Political and Institutional Economics at HEC Lausanne, University of Lausanne and a research fellow in the Development Economics Programme at the Centre for Economic Policy Research (CEPR). August 24, 2020, accessed on 7-31-2021, Peace Economics, Peace Science and Public Policy, "COVID-19 and Conflict: Major Risks and Policy Responses", https://www.degruyter.com/document/doi/10.1515/peps-2020-0043/html)

The COVID-19 pandemic entails a medium- and long-run risk of heightened political conflict. In this short essay we distinguish four major consequences of COVID-19 that may fuel social tensions and political violence, namely i) spiking poverty, ii) education under stress, iii) potential for repression, and iv) reduced inter-dependence. After discussing them in turn, we will formulate policy recommendations on how to attenuate these risks.

1 The Shape of Things to Come: Conflict Risks Heightened by COVID-19

While in the very short-run some COVID-19 induced sanitary measures, such as lockdowns, may (mechanically) reduce the scope for political violence, in this essay we shall argue that in the medium- and long-run the COVID-19 pandemic entails the risk of heightening the likelihood of conflict. In particular, in what follows we shall outline through what main channels the current COVID-19 pandemic may result in higher conflict risk. We shall distinguish between four major dimensions, namely i) spiking poverty, ii) education under stress, iii) potential for repression, and iv) reduced inter-dependence. After discussing them in turn, policy recommendations on attenuating these risks will be formulated.

A typical feature of canonical conflict models is that poverty, low human capital and lack of economic perspectives and opportunities provide a fertile breeding ground for conflict (see Hirshleifer 2001; Konrad 2009). When lawful employment and integrating the labour force only yields dismal returns – barely enough to survive – the opportunity cost of leaving productive activities and becoming a combatant is low. A person who is poor, desperate and destitute may on average more easily be coaxed into leaving legal employment. Having large fringes of the population suffering from poverty may hence make it easier and cheaper to recruit a rebel army. Empirical results have by and large been in line with this standard prediction of conflict theory, as there is indeed a strong association between poverty and conflict. As surveyed by Dell, Jones, and Olken (2014), there is ample evidence of negative income shocks fuelling political violence, and as argued by Collier, Hoeffler, and Rohner (2009), poverty is empirically a key risk factor making an armed challenge to the state feasible.

COVID-19 entails a major risk of aggravating poverty and inequality. While in many countries parts of the labour force are barely affected economically by the pandemic – working remotely in secure jobs at full pay – those in temporary, informal or precarious employment are often hit hardest. Many of these jobs are gone for good and in many instances, there is not much of a social safety net allowing for the newly unemployed to maintain an income close to pre-pandemic levels. As highlighted by historical examples of major economic crises, those who have lost everything and lack perspectives for prosperity can be easy prey for political manipulation and radicalisation. This is powerfully illustrated by the expansion of fascist movements during the 1930s following the 1929 stock market crash and the subsequent great depression.[1] Today’s era is characterized by widespread populist movements and it is not far-fetched that COVID-19 induced poverty spikes could fuel electoral support of populists (see Guiso et al. 2020) and thereby aggravate the stirring of political hatred and inter-group tensions.

A second, related risk is that universal schooling comes under strain during the pandemic. As found in recent research (Rohner and Saia 2020), education can constitute a powerful rampart against inter-group conflict. When compulsory public schooling gets now discontinued for sanitary reasons, this entails the risk of parts of the population being stuck with substantially reduced human capital and dismal job market perspectives. As argued above, this can reduce the opportunity cost of “swapping the plough for the rifle”. While the risks linked to acute poverty spikes described above may kick in very rapidly, the impact of the human capital gap may be resented only later – yet could have longer-lasting negative implications. Another notable feature of this risk is that it may hit different places and population groups very differently – those from a privileged background may be barely affected (with home-schooling by educated parents, privately hired educators or online schooling making up for face-to-face interaction in schools), while poor population groups in poor countries may be disproportionally hit. This may further aggravate inequalities both in terms of education and eventually in income, with such a rise in inequalities persisting potentially over time.

A third major political risk of the COVID-19 pandemic is mounting repression, strains on freedom of expression and hollowing out of democracy.[2] Already before the beginning of the COVID-19 pandemic, democracy worldwide has been under severe stress, with overall global democracy scores displaying negative trends for the last 10 years (see Laurent-Lucchetti, Rohner, and Thoenig 2020, for a discussion of democracy trends and a rationale and evidence of why democracy fosters peace). There is a very real and substantial risk that this negative tendency could be further aggravated by COVID-19. The reason is that legitimate sanitary concerns call for social distancing and for avoiding too large accumulations of people. This, however, provides a formidable pretext for (would-be) autocrats to restrain the freedom of assembly. In the same vein, contact tracing constitutes a powerful tool for limiting the spread of infections. Again, however, contact tracing can also help autocratic regimes extending their grip on society by building up water-tight surveillance. Finally, it is attractive for political leaders to carry out unpopular measures when “the world is not watching” (Durante and Zhuravskaya 2018). This is typically frequently the case during a situation of acute crisis, such as the current COVID-19 pandemic, where the main focus of many governments lies on putting in place the appropriate domestic sanitary measures.

Last, but not least, international cooperation, inter-dependence and trade may suffer from the COVID-19 pandemic. Drawing on the classic liberal argument of inter-dependence fostering peace, a series of articles (Martin, Mayer, and Thoenig 2008; Polachek 1980; Rohner, Mathias, and Thoenig 2013), have found in formal game-theoretic models and empirical analysis that inter-group business and bilateral trade can promote peace between two countries or groups. The rationale is that inter-dependence increases the opportunity costs of engaging in a conflict with the other party, as this would result in forgone economics gains. Beyond the existing econometric results, the creation of the European Coal and Steel Community (ECSC) – giving eventually birth to the European Union – is a telling example of how bottom-up economic interaction and growing inter-dependence and trust building can drive down the risk of renewed wars. Put bluntly, by making war costlier, trade can contribute to peace. The trouble with the current situation is that governments may – in reply to epidemiological considerations— choose to close borders and rely to a larger extent on domestic production (fearing the disruption of global supply chains). While the sanitary logic is understandable, this entails the negative side effect of making the world less integrated, and diminished inter-dependence and dropping trade flows reduce the conflict costs of forgone trade, and hence weaken the business ramparts against renewed domestic or international wars.

### Framing

#### the standard is maximizing expected wellbeing

#### 1 – Extinction o/ws under any framework, even under moral uncertainty – infinite future generations

#### 2 – Actor specificity:

#### [A] Governments must aggregate since every policy benefits some and harms others, which also means side constraints freeze action.

#### [B] No act- omission distinction— governments must vote on bills, so inaction is an explicit act taken, and governments are responsible for the public sphere so they must aggregate. Actor-specificity comes first since different agents have different ethical standings.

#### 3 - only it can explain degrees of wrongness- it is worse to kill thousands than to lie to a friend- either ethical theories cannot explain comparative badness, or it collapses