## 1AC – Nano Nagle

### Advantage

#### 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.

#### 1] The intellectual property system is fundamentally mismatched with emergency pandemic conditions. 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.

#### 2] COVID highlights just how vulnerable we are to both natural pandemics and human-made biological weapons—access is key

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.

#### 3] 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

#### 4] 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.

#### 5] 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.”

#### 6] Counterfeiting, innovation, donation, and manufacturing arguments are all wrong—strong domestic manufacturing is essential to pandemic containment

Gostin 9/27 — (Lawrence O Gostin, Lawrence O. Gostin is professor of global health law, Georgetown University, and directs the World Health Organization Center on Global Health Law. His book "Global Health Security: A Blueprint for the Future"will be published in Oct. 2021, “Biden’s plan to vaccinate the world won’t work. Here’s a better one. “, Washington Post, 9-27-2021, Available Online at https://www.washingtonpost.com/outlook/2021/09/27/biden-vaccines-globe-inequity-donations/, accessed 10-5-2021, HKR-AR)

Ramped up charitable donations are urgently needed but they will never be enough to meet global need. That’s why vastly increased manufacturing of vaccines abroad makes more sense than a donations-only approach. Donations — whether of personal protective equipment (PPE), oxygen or vaccines — always seem to come late and in insufficient quantities. Empowering regional hubs to manufacture their own vaccines, in contrast, would amplify supplies globally and enable countries to serve their own needs and that of their regions — whether Africa, Latin America or Asia.

The most likely vaccine candidates for regional production also happen to be the most technologically advanced. That’s because mRNA vaccines can be manufactured more rapidly, and at larger scale, more easily than traditional vaccine technologies, such as that used in the Johnson & Johnson vaccine. (MRNA vaccines are produced by small chemical reactions and don’t need living components, like the weakened or inactivated viruses used in traditional vaccines). They are also more easily adapted to target emerging variants, because it’s possible to replace one sequence of mRNA in the vaccine for another in a matter of weeks. But Pfizer-BioNTech and Moderna have thus far kept their intellectual property and trade secrets close to the chest. (Moderna has said it will not enforce its patents related to its coronavirus vaccine, but that doesn’t mean it will share its patented information with others, let alone its manufacturing know-how.)

The vaccines were hardly developed purely by the private sector: Moderna received $2.5 billion from Operation Warp Speed, both Moderna and Pfizer benefited from over a decade of National Institutes of Health basic research funding for mRNA technologies, and NIH holds several key mRNA patents.

That strengthens the case for forcing the companies — in the name of national defense — to share their technologies. Under the DPA, the government would compensate the companies both for the costs of any additional production and for the technology-sharing arrangements. The government would determine “reasonable” compensation, and the drug companies could challenge the sum in courts, but there is nothing outrageous about this: The Fifth Amendment to the Constitution requires “just compensation” for a “taking,” which is simply the fair market value for the property, including intellectual property.

Some observers might worry that sharing our cutting-edge technologies in this way would lead to its being co-opted by other countries, especially adversaries such as China or Russia. We could hedge against that threat by requiring that foreign producers keep innovative technologies confidential and secure. And these producers would have to pledge to exclusively serve low-income markets, and not usurp richer markets in the United States and Europe. We’ve used that model before to empower foreign manufacturers to make antiretroviral medications for HIV.

Many have argued that foreign manufacturers don’t have the technical competence to produce cutting-edge vaccines. But countries including India, Brazil and Vietnam have a proven track record in vaccine production. And South Africa is already establishing a major mRNA vaccine technology transfer hub, with the support of the World Health Organization. (All it’s waiting for is cooperation from the innovator drug companies.) Countries such as Australia, Singapore and South Korea have invested in advanced vaccine technology but they, too, require cooperation from Pfizer and Moderna.

#### 7] Only 0.9% of the developing world has the vaccine – capacity to produce it exists, but intellectual property restrictions are preventing production. Expanding access is key – it stops mutations and variants that take us back to square one on COVID

Erfani et al 21 [Parsa Erfani MD Candidate at Harvard Medical School. "Intellectual property waiver for covid-19 vaccines will advance global health equity." https://www.bmj.com/content/374/bmj.n1837]

By late June 2021, 46% of people in high income countries had received at least one dose of the covid-19 vaccine compared with 20% in middle income countries and only 0.9% in low income countries.1 This inequity has been driven by a global political economy that has permitted some countries to purchase more vaccine than they require while others have very limited supplies. Canada, for example, with a gross domestic product (GDP) of $46 000 (£32 000; €39 000) per head has vaccines for 434% of its population, whereas Jordan, which has twice the incidence of covid-19 and a GDP of $4400 per head, has secured doses for only 6% of its people.2 As covid-19 variants are already showing some ability to evade the current vaccines, it is evident that without global vaccine equity and immunity, our efforts against covid-19 are in jeopardy.

Equitable vaccine distribution to the world’s highest risk populations requires a multipronged approach that includes vaccine development and approval; scaling manufacturing; streamlining shipment, storage, and distribution; and building vaccine confidence. International collaborations have helped tackle several of these fundamentals. However, the global community remains deeply divided on how to overcome the scarcity of supply. Pharmaceutical trade associations claim that supply is not a problem as manufacturers can supposedly provide 10 billion doses by the end of 2021.3 But as suppliers consistently fall short in achieving manufacturing targets, production is clearly a bottleneck to global vaccination.3 Indeed, at the current global vaccination rate, it will take years to achieve the needed level of global immunity.4

The barrier to adequate vaccine supply today is not lack of vaccine options, nor even theoretical production capacity; the problem is the intellectual property (IP) protection governing production and access to vaccines—and ultimately, the political and moral will to waive these protections in a time of global crisis. Without such liberty, there will not be enough vaccine fast enough to prevent the spread of variants, the avoidable deaths, and the continued choking of low and middle income countries (LMICs) through poor health.

8] **Pharma would cut marketing not research**

**Light 17** — Donald W. Light, Professor of Psychiatry and Medical Sociology, Rowan University-School of Osteopathic Medicine Visiting Researcher, Division of Medical Ethics, NYU School of Medicine, 6-2-2017, Date Accessed: 11-11-2017, "Debunking The Pharmaceutical Research ‘Free Rider’ Myth: A response To Yu, Helms, And Bach" Health Affairs, <http://www.healthaffairs.org/do/10.1377/hblog20170602.060376/full/>

ECONOMIC BLACKMAIL

When pharmaceutical companies threaten that they will cut back on research if Americans pay European or Canadian prices, it’s a kind of economic blackmail: Pay our excess US prices, or your families will suffer from cutbacks on research for new cures. President Donald Trump and his team should call this bluff, because no research-based industry will cut back on the source of their own future revenues. The drug industry could much more easily cut back on marketing costs, which are two to three times greater than reported research costs before taxpayers’ subsidies. The $76 billion in research and development that pharmaceutical companies claim overlooks the ways that US employers and taxpayers pay for at least 44 percent of total corporate research and development through tax subsidies and credits. If one adds the taxes not paid when companies park tens of billions in foreign tax havens, most of the high risk and cost of pharmaceutical research is actually borne by taxpayers, not the companies. And this does not take into account the billions in research conducted by the National Institutes of Health, other government agencies, foundations, and charities. Finally, most corporate research and development is directed at minimally innovative new drugs. Independent teams of physicians and pharmacists conclude that 85--90 percent of new drugs offer few or no clinical advantages over existing drugs. But all of them give companies another 20 years of patent protection for charging monopoly prices. The pharmaceutical lobby convinced then-President Barack Obama to prohibit major forms of national and international free-market price competition. Will they be equally effective getting Trump to protect high prices by promoting the myth that lower prices will reduce research and innovation?

#### 9] Vaccine dependency results in imperialist exploitation of the Global South

Osborn 8/6 [Catherine Osborn is the writer of Foreign Policy’s weekly Latin America Brief. She is a print and radio journalist based in Rio de Janeiro. August 6, 2021, “COVAX Is Not Working,” Foreign Policy, https://foreignpolicy.com/2021/08/06/latin-america-covid-pandemic-who-wto-covax-vaccine-delay-delta-variant//lhs-ap]

It’s Big Pharma’s World

Last week, Paraguayan President Mario Abdo Benítez spoke with unusual candor about the problems plaguing the world’s only multilateral mechanism for equitable COVID-19 vaccine distribution, COVAX. “COVAX did not work,” he said of the initiative, operated jointly by the World Health Organization (WHO) and two nonprofits.

Last October, Paraguay made its first payment for an order of 4.3 million vaccine doses from COVAX, which was designed to get countries better prices than deals reached directly with manufacturers. But COVAX had only delivered the country 340,800 doses by the end of July. As of the most recent official data on July 25, just 4 percent of Paraguayans had been fully vaccinated.

“We bet on the COVAX mechanism to generate equity,” Abdo Benítez said. “I have to say it with pain. I cannot stay quiet.”

Globally, COVAX is running half a billion doses short of its delivery goals. Though one of its architects said COVAX aimed to “ensure that ability to pay does not become a barrier to accessing [vaccines],” the opposite appears to have occurred. Vaccine-makers have been reluctant to sell to COVAX, and wealthy countries bypassed the initiative to scoop up much of manufacturers’ available supply in direct deals. And there has been little technology transfer to expand global vaccine production, meaning that a delay at one plant can cause huge backups that ripple around the world.

Global vaccine distribution has overwhelmingly functioned according to the preferences of pharmaceutical companies and wealthy countries, rather than through an equity-based system. Though the United States, the largest vaccine donor to date, says it allocates doses based on criteria aimed at saving lives, it is doing so at a scale that is a mere one-hundredth of what the WHO says is necessary to get the pandemic under control globally.

Now, as the delta variant takes hold, several Latin American policymakers are scrambling to redefine their vaccine strategies and boost local production.

Seeking new supply. With its COVAX shots delayed, Paraguay has secured new contracts with Pfizer and Moderna. The Dominican Republic, which also complained about COVAX delays, increased its orders from China’s Sinovac.

These moves have come with their own challenges. An official from Paraguay, which diplomatically recognizes Taiwan, said a subsidiary of Chinese manufacturer Sinopharm canceled a vaccine contract for “geopolitical reasons,” while Pfizer reportedly pressured Latin American governments to sign over unprecedented sovereign assets as guarantees against the cost of potential lawsuits.

#### 10] Causes nuclear terrorism -- extinction

Namayanja 6/10 [Rose Namayanja is a Ugandan lawyer and author. She is the former Uganda information minister and current Deputy Secretary General of the National Resistance Movement, the ruling party. She is a graduate of the Defence Academy of the United Kingdom. June 10, 2021, “ Lack of Vaccines Fuels Terrorism in Africa,” Foreign Policy, https://foreignpolicy.com/2021/06/10/vaccines-africa-terrorism-covid-19//lhs-ap]

Meanwhile, under the fog of COVID-19, the specter of conflict is rising. With African governments and their limited resources occupied by the pandemic, terrorist groups across the continent have become emboldened. We are already seeing a resurgence in attacks. Around Lake Chad, Boko Haram has revived itself, even though it had been largely defeated just a few years ago thanks to combined military efforts of the countries in the area. In northern Mozambique, Islamist militants’ attacks have sharply increased. And across the Sahel, a plethora of al Qaeda- and Islamic State-affiliated groups are terrorizing communities. These groups thrive on economic instability, profiting from poverty to turn desperate, starving people into recruits.

Without sufficient access to vaccines, instability can only worsen. Governments across Africa are reduced to blunt instruments, such as economically damaging lockdowns, to protect citizens. Subsequently, businesses and livelihoods are still stalled, severely impacting the economies of what are already some of the poorest countries in the world.

These nations risk becoming breeding grounds for militant and terrorist groups. And as groups with international affiliates strengthen their footholds on the continent, what were once localized problems become sources of sustenance to global networks of terror. All this will only make bad economic problems worse. The observation that conflict is bad for business is banal. But it could also rupture global supply chains. Costs for many extractives could rise, and given high tech’s reliance on minerals under the continent, this is worrying.

Even without factoring in conflict, the cost to the global economy if poor countries remain unvaccinated is vast. A recent study commissioned by the International Chamber of Commerce predicts the world could suffer losses exceeding $9 trillion, at least half of which would be absorbed by wealthy, vaccinated nations.

In short, if the vaccine dearth in Africa and low-income countries elsewhere is not urgently addressed, the cost for Western nations—both in terms of finance and security—will be considerably higher than sharing hoarded vaccines or investing in accelerated production. Frugality now only defers costs later. When conflict rears its head, as is the case in Africa, it is not only those directly involved that suffer the consequences. And as the president of Africa’s largest economy, Nigeria, wrote recently, “around the world, conflict and the coronavirus have never been far apart.”

#### 11] Preventing pandemics should be our main priority – climate change and a host of other factors make them more common and more dangerous, so ensuring we are as ready as possible is key

**CNA 17,** California Nurses Association, January 2017, “SARS, EBOLA, AND ZIKA: What Registered Nurses Need to Know About Emerging Infectious Diseases,” accessed via Google Cache

[ INTRODUCTION ] Infectious diseases are a part of life, from the bubonic plague of the 15th century that decimat- ed populations in Europe to the Ebola outbreak of 2015 that has killed over 10,000 people in West Africa. Science and technology have allowed us to escape the effects of many diseases like yellow fever and rubella through vaccines. Since 1975, however, over 30 new diseases have appeared, including AIDS, Ebola, Lyme disease, Legionnaires’ disease, and antibiotic-resistant organisms. Most of these new infections are caused by pathogens present in the environment but infecting a new host or different population. Rarely, new pathogens may evolve to cause a new disease. New or newly noticed diseases are not the only concern. Old diseases, like malaria and cholera, have made comebacks. Underfunded, declining public health programs and crowded poor urban environments foster the transmission of diseases that spread through social contact between peo- ple, like tuberculosis and diphtheria. Vector-borne infections have also reappeared due to climate change and human disruption of ecosystems. Arboviruses, which are viruses spread by mosqui- toes and ticks, are responsible for more than 130 human diseases and the ranges of the vectors are rapidly expanding. Nurses are at the forefront of healthcare and are in a position to recognize new and re-emerging infectious diseases. Nurses are often the first to be exposed to infectious diseases. During an ongoing epidemic, little may be known about the disease, how it is transmitted, or what kinds of protections healthcare workers need. In these situations, it is vital — literally — that hospitals and other healthcare employers adhere to the precautionary principle — even in the face of scientific uncertainty, protective measures should be taken. In this home study, you will read about three recently emerged or re-emerged infectious dis- eases. Primary and secondary sources are used to demonstrate the kinds of literature that emerge surrounding infectious disease outbreaks. The conditions that led to the rise and/or spread of the outbreak into an epidemic are discussed. I. SEVERE ACUTE RESPIRATORY SYNDROME (SARS) The first major epidemic of the 21st century, the SARS epidemic of 2003 began in China and spread globally. The progression of the epidemic is described and the forces of urbanization and globalization on the emergence of the novel disease are discussed. II. ZIKA VIRUS DISEASE The current Zika epidemic began in Brazil in 2015 and has rapidly expanded to other Latin American and Caribbean countries in late 2015 and early 2016. The status of the epidemic is described. The impact of climate change and fragmented public health infrastructure on the emergence of the epidemic are discussed. III. EBOLA VIRUS DISEASE The origin and progression of the 2014 Ebola epidemic originating in West Africa is described. The spread of Ebola to the United States is dis- cussed in detail. The contributions of inadequate protections for healthcare workers and the frag- mented public health infrastructure of the United States are discussed. Page 3 3 [ SECTION I ] SEVERE ACUTE RESPIRATORY SYNDROME (SARS): FROM CHINA TO TORONTO A previously unknown respiratory disease began ailing people in the southern Chinese province Guangdong in late 2002. It spread rapidly across Asia and around the world, causing severe acute respiratory syndrome (SARS). This epidemic was the first major infectious disease epidemic of the 21st century and forced the need to reshape understanding of public health as global instead of national. The story of SARS clearly demonstrates the impact of urbanization and globalization on emerging infectious diseases. It also demonstrates how unprepared public health infrastructure can prolong an epidemic. By the end of 2003, all cases worldwide had been treated and the epidemic was over. Probable SARS cases were identified in 8,096 people worldwide and infection resulted in 774 deaths. On May 20, 2003, the World Health Organization (WHO) published a status report on the epidemic. This excerpt describes how the epidemic was started, which was an important discovery for breaking the transmission cycle. Excerpt below from: Severe acute respiratory syndrome (SARS): Status of the outbreak and lessons for the immediate future SARS: a puzzling and difficult new disease SARS is the first severe and readily trans- missible new disease to emerge in the 21st century. Though much about the disease remains poorly understood and frankly puzzling, SARS has shown a clear capacity for spread along the routes of internation- al air travel. At present, the outbreaks of greatest concern are concentrated in trans- portation hubs or spreading in densely populated areas. WHO regards every coun- try with an international airport, or border- ing an area having recent local transmis- sion, as at potential risk of an outbreak. The first cases of SARS are now known to have emerged in mid-November 2002 in Guangdong Province, China. The first official report of an outbreak of atypical pneumonia in the province, said to have affected 305 persons and caused 5 deaths, was received by WHO on 11 February. Around 30% of cases were reported to occur in health care workers. Confirmation that cases were consistent with the defi- nition of SARS was made after permission was granted, on 2 April, for a WHO team to visit the province. In the meantime, SARS was carried out of Guangdong Province on 21 February by an infected medical doctor who had treated patients in his home town. He brought the virus to the ninth floor of a four-star hotel in Hong Kong. Days later, guests and visi- tors to the hotel’s ninth floor had seeded outbreaks of cases in the hospital systems of Hong Kong, Viet Nam, and Singapore. Simultaneously, the disease began spread- ing around the world along international air travel routes as guests at the hotel flew home to Toronto and elsewhere, and as other medical doctors who had treated the earliest cases in Viet Nam and Singapore travelled internationally for medical or other reasons. When the disease moved out of southern China, the outbreaks it seeded — in Hanoi, Hong Kong, Singapore, and Toronto — became the initial “hot zones” of SARS, characterized by rapid increases in the number of cases, especially in health care workers and their close contacts. In these areas, SARS first took root in hospital settings, where staff, unaware that a new disease had surfaced and fighting to save the lives of patients, exposed themselves to the infectious agent without barrier pro- tection. All of these initial outbreaks were subsequently characterized by chains of secondary transmission outside the health care environment. By 15 March, WHO had received reports of more than 150 cases of a new disease, which it named severe acute respiratory syndrome. Epidemiological analysis indi- cated that the new disease was spreading along the routes of international air travel. WHO immediately issued emergency travel recommendations to alert health authori- ties, physicians, and the travelling public to what was now perceived to be a worldwide threat to health. The global alert achieved its purpose. After the recommendations, all countries with imported cases, with the exception of provinces in China, were able, through prompt detection of cases, imme- diate isolation, strict infection control, and vigorous contact tracing, to either prevent Page 4 4 further transmission or keep the number of additional cases very low. During the last week of April, the out- breaks in Hanoi, Hong Kong, Singapore, and Toronto showed some signs of peak- ing. On 28 April, Viet Nam became the first country to stop local transmission of SARS. However, new probable cases, including cases in hospital staff, additional deaths, and first cases imported to new areas continued to be reported from several countries. The cumulative total number of cases surpassed 5,000 on 28 April, 6,000 on 2 May, and 7,000 on 8 May, when cases were reported from 30 countries on six continents. At present, most new cases are being reported from Beijing and, increas- ingly, other parts of mainland China. Of the cumulative global total of 7761 probable cases and 623 deaths reported on 17 May, 5209 cases and 282 deaths had occurred in mainland China. Also of concern is a rapidly growing outbreak in Taiwan, China, with a cumulative total, on 18 May, of 344 cases, including many in hospital staff, and 40 deaths. [End excerpt] Later, it was discovered that the virus arose from exposure to and between wild animals in wet markets in Guangdong. China has experienced rapid urbanization and industrialization in recent decades, leading to the formation of a young, wealthy class. The new class seeks to eat exotic wild animals, which has encouraged the growth of wet markets where live animals are kept and sold. China has less wild expanse close to the city in which to hunt so many people hunt animals in Thailand and other countries. Many different animals who would stay far away from each other in the wild are kept in very close contact in transit and at these markets. It is hypothesized that SARS originated in horseshoe bats and jumped to other animals nearby, particularly palm civets, a type of wild cat. Because people who sell their catches at the wet markets also live there, the virus has the opportunity to jump from animal to animal to humans. SARS spread to Toronto in late February 2003, prompting the WHO to issue a global alert on March 12 and elevate the alert on March 15. The events in Toronto clearly demonstrate issues regarding protections for healthcare workers and isolation precautions in an emerging disease event. Excerpt below from: Learning from SARS: Preparing for the Next Disease Outbreak Phase I of the Toronto SARS Outbreak The index case and her husband had vacationed in Hong Kong and had stayed at a hotel in Kowloon from February 18 to 21, 2003. The index case began to experience symptoms after her return on February 23 and died at home on March 5. During her illness, family members, including her son (case A), provided care at home. Case A became ill on February 27 and presented to the index hospital on March 7 (Varia et al., 2003). Nosocomial transmission in the hospital began when case A presented to the emer- gency department on March 7 with severe respiratory symptoms. He was placed in a general observation area of the emergency department and received nebulized salbu- tamol. During this time, SARS was trans- mitted to two other patients in the emer- gency department (cases B and C). Case B, who had presented with rapid atrial fibrillation, was in the bed adjacent to case A, about 1.5 meters away and separated by a curtain, and was discharged home after 9 hours in the emergency department. Case C, who had presented with shortness of breath secondary to a pleural effusion, was three beds (about 5 meters) away from case A and was transferred to a hos- pital ward and later discharged home on March 10. The three patients were cared for by the same nurse. Case A was transferred briefly to a medical unit, then to the intensive care unit (ICU) 18 hours after his presentation to the emer- gency department. Three hours later, he was placed in airborne isolation because tuberculosis was included in his differential diagnosis. Contact and droplet precau- tions were implemented on March 10 by ICU staff caring for case A, and the patient remained in isolation until his death, on March 13. Case A’s family visited him in the ICU on March 8, 9, and 10. During this time, some family members were febrile, and two were experiencing respiratory symp- toms. Chest radiographs were taken of the family members on March 9 and again on March 11. Four members had abnormal radiographs and were instructed to wear masks at all times, wash their hands upon entering and leaving the ICU, and limit their visits to the ICU. Page 5 5 On March 12, the WHO alerted the global community to a severe respiratory syn- drome that was spreading among HCWs in Hanoi, Vietnam, and Hong Kong. The alert was forwarded to infectious disease and emergency department physicians in Toronto. The following day, case A died and it became clear that several other family members had worsening illness. The clinicians involved and the local public health unit suspected the family’s illness- es might be linked to cases of atypical pneumonia reported in Hong Kong. Four family members were admitted to three different hospitals on March 13, and anoth- er family member was admitted to hospi- tal on March 14. All were managed using airborne, droplet, and contact precautions. No further transmission from these cases occurred after admission to hospital. Case B became febrile on March 10, 3 days after exposure to case A in the emergency department and discharge home. Respi- ratory symptoms evolved over the next 5 days. He was brought to the index hospital on March 16 by two Emergency Medical Services paramedics, who did not immedi- ately use contact and droplet precautions. After 9 hours in the emergency depart- ment, where airborne, contact and droplet precautions were used, case B was trans- ferred to an isolation room in the ICU. His wife became ill on March 16. She was in the emergency department with case B on March 16 (no precautions used) and visited him in the ICU on March 21 (precautions used); he died later that day. The infection also spread to three other members of case B’s family. SARS developed in a num- ber of people who were in contact with case B and his wife on March 16, including the 2 paramedics who brought him to the hospital, a firefighter, 5 emergency department staff, 1 other hospital staff, 2 patients in the emergency department, 1 housekeeper who worked in the emergency department while case B was there, and 7 visitors who were also in the emergency department at the same time as case B (symptom onset March 19 to 26). The 16 hospital staff, visitors, and patients trans- mitted the infection to 8 household mem- bers and 8 other family contacts. In the ICU, intubation for mechanical ventilation of case B was performed by a physician wearing a surgical mask, gown and gloves. He subsequently acquired SARS and transmitted the infection to a member of his family. Three ICU nurses who were present at the intubation and who used droplet and contact precautions had onset of early symptoms between March 18 and 20. One transmitted the infection to a household member. Case C became ill on March 13 with symptoms of a myocardial infarction and was brought to the index hospital by paramedics. It was unknown that he had been in contact with case A on March 7, and thus it was not recognized that he had SARS. As a result, he was not isolated, and other precautions were not used. He was admitted to the coronary care unit (CCU) for 3 days and then trans- ferred to another hospital for renal dialysis. He remained in the other hospital until his death, on March 29. Subsequent transmis- sion of SARS occurred within that hospital (Dwosh et al., 2003). Case C’s wife became ill on March 26. At the index hospital, case C transmitted SARS to 1 patient in the emergency department, 3 emergency department staff, 1 housekeeper who worked in the emergency department while case C was there, 1 physician, 2 hos- pital technologists, 2 CCU, patients, and 7 CCU staff. One of the paramedics who transported case C to the index hospital also became ill. Further transmission then occurred from ill staff at the index hospital to 6 of their family members, 1 patient, 1 medical clinic staff, and 1 other nurse in the emergency department. On March 23, 2003, officials recognized that the number of available negative pres- sure rooms in Toronto was being exhaust- ed. In a 4-hour period on the afternoon of March 23, staff at West Park Hospital, a chronic care facility in the city, recom- missioned 25 beds in an unused building formerly used to house patients with tuberculosis. Despite the efforts of West Park physicians and nurses, and assistance from staff at the Scarborough Grace and Mount Sinai Hospitals, qualified staff could be found to care for only 14 patients. Faced with increasing transmission, the Ontario government designated SARS as Page 6 a reportable, communicable, and virulent disease under the Health Protection and Promotion Act on March 25, 2003. This move gave public health officials the authority to track infected people, and issue orders preventing them from engag- ing in activities that might transmit the new disease. Provincial public health activated its emergency operations center. By the evening of March 26, 2003, the West Park unit and all available negative pressure rooms in Toronto hospitals were full; however, 10 ill Scarborough Hospital staff needing admissions were waiting in the emergency department, and others who were ill were waiting at home to be seen. Overnight, with the declaration of a provincial emergency, the Ontario govern- ment required all hospitals to create units to care for SARS patients. By March 25, 2003, Health Canada was reporting 19 cases of SARS in Canada — 18 in Ontario and the single case in Van- couver. But 48 patients with a presumptive diagnosis of SARS had in fact been admitted to hospital by the end of that day. Many more individuals were starting to feel symptoms, and would subsequently be identified as SARS patients. Epidem- ic curves later showed that this period was the peak of the outbreak. On March 19, nine Canadians developed “probable” SARS, the highest single-day total. Taking “suspect” and “probable” cases together, the peak was March 26, and the 3 days, March 25 to 27 are the highest 3-day period in the outbreak. The Ontario government declared SARS a provincial emergency on March 26, 2003. Under the Emergency Management Act, the government has the power to direct and control local governments and facili- ties to ensure that necessary services are provided. All hospitals in the Greater Toronto Area (GTA) and Simcoe County were ordered to activate their “Code Orange” emergency plans by the government. “Code Orange” meant that the involved hospitals suspend- ed nonessential services. They were also required to limit visitors, create isolation units for potential SARS patients, and implement protective clothing for exposed staff (i.e., gowns, masks, and goggles). Four days later, provincial officials extended access restrictions to all Ontario hospitals. On May 14, 2003, WHO removed Toron- to from the list of areas with recent local transmission. This was widely understood to mean that the outbreak had come to an end. Consistent with the notion that the disease was contained, the government of Ontario lifted the emergency on May 17. Directives continued to reinforce the need for enhanced infection control practices in health care settings. Code Orange status for hospitals was revoked. It appeared that the total number of cases had reached a plateau — 140 probable and 178 suspect infections. Twenty-four Cana- dians had died, all in Ontario. [End of excerpt] In mid-May of 2003, after hospitals had discontin- ued SARS precautions, five patients in a Toronto rehabilitation hospital reported with febrile illness. Two of these patients were found to have been hospitalized at North York General Hospital, where a subsequent investigation of pneumonia cases identified eight previously unrecognized SARS cases. The first patient in this second transmis- sion apparently had no history of contact with a SARS patient or healthcare worker with SARS. The hospital was closed to new admissions on May 23, and infection control directives increased required protections. The second transmission of SARS in Toronto came to an end in June with 79 new SARS cases. Guangdong Province, China NOV. 2002 Toronto, Canada FEB. 2003 Page 7 7 [Excerpt continued] Transmission The SCoV has been isolated in sputum, nasal secretions, serum, feces, and bronchi- al washings (Drosten et al., 2003; Peiris et al., 2003b). Evidence suggests that SCoV is transmitted via contact and/or droplets (Peiris et al., 2003a; Poutanen et al., 2003) and that the use of any mask (surgical or N95) significantly decreases the risk of infection (Seto et al., 2003). However, there are cases that defy explanation based on these modes of transmission suggesting that alternative modes of transmission may also occur (Varia et al., 2003). SCoV remains viable in feces for days and the outbreak at the Amoy Gardens apartments highlights the possibility of an oral-fecal or fecal-droplet mode of transmission (WHO, 2003m,n). A number of cases occurred in HCWs wearing protective equipment following exposure to high risk aerosol- and drop- let-generating procedures such as airway manipulation, administration of aerosolized medications, noninvasive positive pressure ventilation, and bronchoscopy or intuba- tion (Lee et al., 2003; Ofner et al., 2003). When intubation is necessary, measures should be taken to reduce unnecessary exposure to health care workers, includ- ing reducing the number of health care workers present and adequately sedating or paralyzing the patient to reduce cough. Updated interim infection control pre- cautions for patients who have SARS are under development and will be available from CDC at http://www.cdc.gov/ncidod/ sars/index.htm. Currently, epidemiological evidence sug- gests that transmission does not occur prior to the onset of symptoms or after symptom resolution. Despite this, shedding of SCoV in stool has been documented by reverse-transcription polymerase chain reaction (RT-PCR) for up to 64 days fol- lowing the resolution of symptoms (Ren et al., 2003). A small group of patients appear to be highly infectious and have been referred to as superspreaders (CDC, 2003a). Such superspreaders appear to have played an important role early in the epidemic but the reason for their enhanced infectivity remains unclear. Possible explanations for their enhanced infectivity include the lack of early implementation of infection control precautions, higher load of SCoV, or larger amounts of respiratory secretions. [End of excerpt] The spread of SARS in Toronto was exacerbated due to delayed public health authority action in recognizing the outbreak, declaring an emergency, and tracing and isolating contacts. The complete lack of protections provided to healthcare work- ers and the late use of precautionary isolation of potential cases presenting with respiratory illness meant that many healthcare workers became infected and continued to infect others before they sickened. Note in the section discussing transmission, no description is given of the type of personal protective equipment (PPE) that healthcare workers wore during the high risk aerosol-generating procedures. Clearly, it was not protective enough. The outbreak was successfully contained after measures were taken to isolate cases and provide protection for healthcare workers. The outbreak in Toronto extended into the second phase because of the lack of integration of new information about SARS. Eight pneumonia cases were later identified as SARS cases, only after patients had had contact with others. Page 8 8 URBANIZATION AND SARS The pace of urbanization has increased significantly in the last century. Only 20% of the world’s pop- ulation lived in cities about 100 years ago. Trends towards urbanization are expected to increase in all countries from 45% in 1995 to 61% in 2030. Urban infrastructure has lagged behind and many cities host dense regions of people living in crowd- ed slums, with limited fresh water, sanitation, and healthcare access. The United Nations (UN) pre- dicts that “slums will become the dominant urban form within the next 15 years.” People living in these slums do and will continue to be dispropor- tionately affected by infectious diseases through more exposure to pathogens and vectors and less availability of healthcare and prophylaxis than their wealthier counterparts. The destruction of environment to create cities and even in rural areas increases the contact between humans and animals. This can accelerate the introduction of new zoonotic diseases, like SARS, into humans. More than 60% of the 335 emerging infectious diseases identified between 1940 and 2004 have been zoonotic. Living in close contact with wild or domesticated animals, hunting, killing, or preparing food can be risk factors for an emerging disease to jump species to humans. Close contact between bats and primates in particular is thought to be a significant risk factor. This kind of new and close contact between different species was seen in China’s wet markets where SARS emerged. Food handlers at the wet market in Guangdong were found to be disproportionately affected by SARS early in the epidemic. Urbanization of China forced hunters to travel to new places, bringing different animals back to small areas in wet mar- kets waiting for sale. A key fact to dealing with the SARS epidemic was recognizing that a significant proportion of the initial illnesses occurred in food handlers catching, selling, and killing wild animals. Understanding how diseases are introduced into the population is critical to controlling ongoing epidemics and to preventing outbreaks from progressing to epidemics. GLOBALIZATION AND SARS The spread of SARS from Singapore and Hong Kong to Toronto served as a wake-up call for many about how connected the world had become. Historically, infectious disease outbreaks were geographically confined. International shipping transported some diseases like cholera and the technological developments of the Industrial Revolution like the steam engine and the railroad allowed diseases to be transported more quickly. International airplane travel significantly decreased the amount of time it takes to get from one place to another, allowing not-yet-symptom- atic people incubating a disease to travel to a new place before they even know they are sick. Inter- national tourist arrivals have exploded from 25 million in 1950 to more than one billion in 2013. Author Sonia Shah chronicles the development of several different infectious diseases over the past two centuries. In her book, Pandemic: Tracking Contagions, from Cholera to Ebola and Beyond, she describes the effect of increased global travel: [People] don’t just fly in and out of a hand- ful of prominent airports in major cities, but into and out of tens of thousands of airports in small towns and minor cities in even the most remote and far-flung nations. There are some fifteen thousand airports in the United States, but not only that: there are also more than two hundred in the Democratic Republic of Congo, one hundred in Thailand, and, as of 2013, nearly five hundred in China. New York City is no longer the center of today’s global trans- portation network, of course. The hub has shifted. Of the ten largest and busiest air- ports in the world, nine are in Asia, seven in China alone. And just as the United States’ gateway to the world was once New York City, China’s gateway to the world is Hong Kong, where more cargo — both visible and invisible — is loaded onto airplanes than anywhere else. Increased globalization enabled the spread of SARS to Toronto from China and later we will see how globalization contributes to other epidemics. A globalized, integrated public health system is needed to protect all people’s health in our inter- connected, modern world. Page 9 9 [ SECTION II ] ZIKA: AN EMERGING EPIDEMIC IN PROGRESS Note: The info on Zika is current as of the time of writing. As it is an ongoing epidemic, new informa- tion may emerge in the coming months. Zika virus is a positive sense, single-stranded RNA virus in the same family of mosquito-borne arbo- viruses as yellow fever, dengue, West Nile virus, and encephalitis. Zika virus was first isolated in 1947 during surveillance of diseases in macaques in Uganda. The first documented human infection was in 1954, and the virus spread slowly through sub-Saharan Africa to Asia by the 21st century. Outbreaks of Zika have been identified only in recent years: Yap Island in the Federated States of Micronesia in 2007, French Polynesia in 2013, and Brazil spreading to other parts of Latin America in 2015-16. Information about Zika virus is limited including symptoms, length of viremia, transmission, and potential neurological complications. A signifi- cant amount of data has become available during the 2013 and 2015-16 epidemics. Prior to the first recorded outbreak in 2009, only 25 papers were published in peer-reviewed literature compared to 225 in the first three months of 2016 alone. How- ever, few definitive answers have been reached. Zika virus has shown an extremely unusual propensity for multiple transmission pathways. Initially, it was thought that Zika was transmitted only by mosquitoes from human to human and possibly monkey to human. Now, there is evidence that Zika is sexually transmitted, transmitted through blood transfusions, and from a mother to her baby during pregnancy and birth. Additionally, there is one case where Zika was transmitted through bodily fluids from a patient with extreme- ly high levels of Zika virus in his body. Zika virus has been found in various bodily fluids, including saliva, urine, breast milk, the female genital tract, and semen. Viral particles appear to remain in semen for at least 90 days and the female genital tract for at least 14 days. Mosquito-borne transmission of Zika virus con- tinues to be the pathway of most concern in stopping the epidemic. Aedes mosquitoes have adapted to live near humans, requiring only the smallest amount of still water to reproduce. They are active and biting during the day, unlike other mosquito species that only feed at night. In the United States, the Aedes mosquitoes were nearly eradicated in the 1970’s through pesticide appli- cation, but they have made comebacks in some areas after pesticide use has declined or ceased. Urban poverty in Brazil has created “the perfect set of conditions for the transmission of such mosquito-borne viruses.” The lack of infrastructure and water security in conjunction with crowding and poor housing conditions has created a situ- ation where an abundance of breeding grounds exists in close proximity to living quarters where residents also have limited access to prevention like bug spray and air conditioning as well as limited healthcare access. These same conditions exist in many places in the United States that are vulnerable to mosquito-borne disease outbreaks, including Florida, Texas, and other Gulf Coast states. While the Aedes species is the confirmed Zika vector, some suspect other species may have adapted to carry Zika virus, which would help explain the sudden widespread nature of the Brazil outbreak as compared to previous progression of the disease. Global travel has also accelerated the spread of Zika virus. Symptoms of Zika virus infection are typically mild and self-limiting and include fever, itchy maculo- papular rash, joint paint, and conjunctivitis. The case definition of Zika virus disease has evolved during the 2015-16 epidemic from two symptoms with exposure to just one symptom with exposure. Symptoms last a few days to a week; severe illness and death are rare. The incubation period is esti- mated to be between three and twelve days. Up to 80% of people infected with the virus have no symptoms. When diagnostic assays are of limited availability as they have been in the Zika epidemic, establish- ing reliable and consistent case definition is crucial for treatment and prevention of further spread. Fever Conjunctivitis Rash Joint Pain Only 1 out of 5 people develop symptoms Page 10 10 ZIKA: INFORMATION EVOLVES DURING EPIDEMICS The most recent two outbreaks in French Poly- nesia and Brazil have brought to light potential neurological complications geographically and temporally associated with Zika virus infections. The 2013 outbreak in French Polynesia was accompanied by a “concomitant epidemic of 73 cases of Guillain-Barré syndrome and other neuro- logical conditions in a population of approximately 270,000.” Guillain-Barré Syndrome (GBS) is a rare auto-immune disorder that results in damaged nerve cells, weakened muscles, and paralysis. Most people recover from GBS, but some suffer perma- nent damage or death. The most recent outbreak that began in Brazil in 2015 has been accompanied by “an apparent 20-fold increase in incidence from 2014 to 2015” in microcephaly rates. Microceph- aly (head smaller than average) has been seen in infants born to women infected with Zika virus during pregnancy and is related to developmental delay, intellectual disability, vision problems, and other effects. CLIMATE CHANGE AND ARBOVIRUSES The rapid spread of Zika through Latin Ameri- can countries should serve as an exposition of the disastrous effects of climate change and the interactive effect with poverty on infectious disease. Climate change has been influencing weather patterns all over the globe, making them less predictable and weather more severe. The 2015 El Niño, “which is characterized by warming waters in the central and eastern Pacific Ocean,” has brought “warmer temperatures and shifting precipitation patterns to South America and can create conditions that help mosquito populations, and the diseases they can transmit, thrive.” Mas- sive flooding in parts of Uruguay, southern Brazil, and Paraguay in recent months has displaced 150,000 people and led to standing water, provid- ing breeding ground for mosquitoes and disrupted living situations and access to healthcare, water, and other vital services. On the other hand, north- ern Brazil, Venezuela, Guyana, and Suriname have had drier than usual weather. Because these areas lack a consistent water supply, many people have begun stockpiling water, creating mosquito breed- ing grounds near human dwellings. Additionally, 2015 was the hottest year on record; these warmer temperatures may mean mosquitoes are more active, reproducing more, and biting more there- fore infecting more people. Diseases carried by mosquitoes are particularly sensitive to meteorological conditions — warmer temperatures increase mosquito reproduction and biting activity and the rate at which pathogens mature inside them. Temperature also limits the range of mosquito vectors. Freezing kills Aedes larvae and eggs. As the earth warms, fewer plac- es will freeze over completely and Aedes vectors will increase their territory and spread infectious diseases to new places. Fossil evidence from the end of the last Ice Age “demonstrate[s] that rapid, poleward shifts of insects accompanied warming.” POVERTY AND INFECTIOUS DISEASES Many of the areas where Zika has been the biggest problem are also the poorest areas of Brazil. The low quality housing, lacking screens and air conditioning that help prevent exposure to mosquitoes, in addition to no reliable water or waste disposal systems creates situations where breeding grounds abound in urban, crowded areas. Brazil eradicated Aedes mosquitoes in 1958 through coordinated efforts and funding. However, over the years, the mosquitoes have returned and multiplied. Not only do residents in these areas have a higher risk for contracting Zika, they will also experience more challenges if they develop GBS or give birth to a baby with microcephaly. Lack of resources compounds the ramifications of disability. We see similar conditions in the United States in areas where Aedes mosquitoes are common, like Florida and Texas. These states have large impov- erished populations, a warm climate, and did not expand Medicaid. Not only are the mosquitoes present, which increases the risk for transmitting the disease from a returning infected traveler, the Page 11 11 housing stock in some areas is dilapidated, missing screens and air conditioning, and trash is abandoned to become breeding grounds for mosquitoes after rainfall. The mortgage foreclo- sure crisis hit Florida especially hard, where many houses remain empty, creating mosquito breeding territory. Further, if people begin to be infected locally and develop GBS or microcephaly, their access to healthcare is extremely limited due to their states’ limitations on Medicaid.

#### 12] 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.

#### 13] Pandemics increase the risk of regional and dyadic conflict—best case studies from COVID prove. Independently, negative examples are cherrypicked and solely analyze the beginnings of pandemics, continued transmission lays the groundwork for eventual instability and conflict

Ide 12/14 — (Tobias Ide, Tobias Ide’s research broadly focuses on the intersections of environmental change and environmental politics with peace, conflict, and security. In my current research, I assess the impact of disasters on conflict dynamics, the security implications of climate change, and environmental peacebuilding processes. Further academic interests of me include climate politics, peace and conflict studies, international politics, and the critical geopolitics of education. I employ various quantitative and qualitative research methods, including qualitative comparative analysis (QCA) and field research. My teaching is guided by three principles: (1) introduce the core theoretical foundations of a field, (2) explore their usefulness in the context of real word developments and practical examples, and (3) utilise interactive methods to increase learning success. I hold an MA in Political Science (Leipzig, 2012), a PhD in Earth Sciences (Hamburg, 2015) and an advanced PhD (Habilitation) in Political Science (Braunschweig, 2019). Previously, I worked at the Georg Eckert Institute and the University of Melbourne, and held visiting positions at the Hebrew University of Jerusalem and the American University in Washington DC. My research has attracted funding by various external bodies (see Awards and grants). I published in leading disciplinary and interdisciplinary journals, including Global Environmental Change, International Affairs, International Studies Review, Journal of Peace Research, Nature Climate Change, and World Development (see Publications). Furthermore, I am a director of the Environmental Peacebuilding Association (EnPAx) and have consulted several decision makers (see Professional and community service)., “COVID-19 and armed conflict“,Available Online at https://www.sciencedirect.com/science/article/abs/pii/S0305750X20304836?via%3Dihub, accessed 10-6-2021, HKR-AR)

The growing number of armed conflict events in India was not related to the Maoist insurgency. The presence of state security forces on the ground has been reduced due to fears of infectionand the Maoists’ supply lines were negatively affected by a comprehensive lockdown. There are concerns, however, that the rebels use the lack of state presence and economic deprivation caused by a heavy lockdown to **recruit** for future offensives (Bhardwaj, 2020;Kujur, 2020). Armed confrontations in the Kashmir region contested between India and Pakistan, by contrast, **increased significantly**. Clashes between both countries’ militaries were a result of longer-standing tensions and thus unrelated to the pandemic(Staniland, 2020). There is however evidence that Pakistan’s support for pro-Pakistani insurgents increased to put additional pressure on India during the COVID-19 crisis. At the same time, the Indian army capitalised on the comprehensive restrictions and the occupation of public attention with the pandemic to launch a heavy crackdown campaign against (presumed) insurgents in Kashmir (Basu & Philip, 2020; Islam & Uzair, 2020). Communal tensions in India also rose because of disputes related to permits for and infections linked to Hindu and Muslim religious gatherings during the pandemic. So far, these tensions rarely translated into larger violent confrontations (Kapur, 2020).

In Iraq, the capabilities of the government have been severely strained by the crisis, among others because oil prices collapsed and military forces were preoccupied with COVID-19 responses(e.g., enforcing curfews). Due to the pandemic, the international coalition supporting the government has also stopped training activities and some joint missions, and pulled out troops. The Islamic State (IS) was affected financially by the crisis as well due to its involvement in oil trade and the general economic decline. Nonetheless, the group sought to exploit the current weakness of the Iraqi state to expand its territorial control, thus launching additional attacks. The rise of violence in Iraq during the first months ofthe pandemic has been modest and non-linear (perhaps due to Ramadan in late April and May), but there was a clear upward trend of IS-initiated attacks (Hanna, 2020; Sattar, 2020).

The civil war in Libya between the Government of National Accord (GNA) and the Libyan National Army (LNA) has intensified since March 2020. Both parties aimed to launch decisive strikes and received significant logistical and material support from their international patrons. Therefore, an escalation of the war would have taken place irrespective of COVID-19. But the pandemic accelerated this escalation in two minor ways: It distracted the world’s attention from the fact that both sides ignored the peace agreement concluded in January 2020. Furthermore, the GNA and the LNA believed that the other side might collapse very soon under the combined pressure of military offensives and the virus(Allahoum, 2020; Mustasilta, 2020). Conflict intensity saw a rapid decline in June 2020, but this was due to the mutual acceptance of a military stand-off and renewed peace negotiations, **rather than related to the pandemic** (Gosh, 2020).

The military of Pakistan engaged in more battles with the Indian army and local Taliban groups from April 2020 onwards. The intensification of the India-Pakistani conflict is linked to other factors than COVID-19 (Staniland, 2020). It is plausible that groups like the Taliban have attempted to exploit a situation where the state is weakened, border controls with Afghanistan get more difficult, dissatisfaction with the government’s response is widespread (especially among religious groups), and a rise in poverty makes recruitment easier (Ahmed, 2020; Guz, 2020). Concrete evidence of this is currently lacking, however. A reason for the slight bump in violent events in May and early June could be that many senior Taliban leaders and commanders became infect with SARSCoV-2 (O’Donnell & Khan, 2020).

In the Philippines, the upwards trend in armed conflict events was mostly driven by a steep rise of clashes between the military and the Communist New People’s Army (NPA). Both sides declared unilateral ceasefires when the number of infections increase drapidly in late March to facilitate responses to COVID-19. Accusing each other of continuing attacks, the government and the NPA decided not to extend their respective ceasefires in late April. There have been reports that the government utilized the distraction caused by the pandemic as well as the increased control gained during a strict lockdown for harsher measures against its opponents, including the rebels. Others claim that the NPA sought to utilize the pre-occupation of security forces with health-related tasks to launch further attacks and raid food supplies (Chavez,2020; Lalu, 2020).

Besides its immediate health and economic effects, COVID-19 can also impact armed conflict risks, with these conflicts themselves being an important obstacle in dealing with the pandemic. This article provided an assessment of the impact of COVID-19 on armed conflict based on data from the first six months of 2020. Theoretically, the pandemic could affect conflict risks through increased grievances, possibilities to demonstrate solidarity, or modified opportunity structures for armed groups.

Results show that in four of the nine countries under study, the number of armed conflict events declined after the onset of the COVID-19 crisis. These declines are mostly related to strategic decisions and less favourable opportunity structures for armed groups, such as logistical difficulties and attempts to increase popular support. They offer few prospects for health diplomacy and sustainable peacebuilding. In places like Afghanistan, where the Taliban restrained their military activities to gain local support, the initial decline might even set the stage for a later escalation of the armed conflict. Similar concerns exist regarding recruitment in Colombia and India.

In five of the nine countries analysed, armed conflict prevalence increased in the face of the pandemic. This is further evidence that health diplomacy approaches demonstrating goodwill and reducing grievances have little impact during the pandemic (Polo,2020). COVID-19 did not change the root causes or principal dynamics of the armed conflicts in any of these five countries, but it accelerated existing trends and provided strategic opportunities for armed groups to exploit. Two factors are particularly relevant here: The weakening of state institutions (providing incentives for rebels to intensify military pressure) and a lack of(international) public attention (allowing to extend military operations without backlashes).

While short-term rises in armed conflict risks related to the pandemic are mostly driven by changed opportunity structures, grievances could play a more prominent role when longer time horizons are considered. The economic repercussions associated with the current global spike in infections could exceed the coping capacities of households that did relatively well during the first COVID-19 wave. In coincidence with ethnic or religious cleavages ,this could raise discontent to a level at which **armed conflicts erupt**. However, grievances usually take time to translate into organised armed activities. Declining levels of democracy as states claim emergency powers to combat COVID-19 are also a risk factor. Countries with a medium level of democracy and highly repressive regimes are empirically much more likely to experience civil wars than consolidated democracies (Cederman & Vogt, 2017).

#### 14] EUL

WHO ND — (World Health Organization, “Diagnostics laboratory emergency use listing“ , Available Online at https://www.who.int/teams/regulation-prequalification/eul, accessed 10-9-2021, HKR-AR)

The WHO Emergency Use Listing Procedure (EUL) is a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics with the ultimate aim of expediting the availability of these products to people affected by a public health emergency. This will assist interested UN procurement agencies and Member States in determining the acceptability of using specific products, based on an essential set of available quality, safety, and efficacy and performance data.

The procedure is a key tool for companies wishing to submit their products for use during health emergencies.

Eligibility of candidate products

The EUL concerns three product streams (vaccines, therapeutics and in vitro diagnostics), each of which has specific requirements for products to be eligible for evaluation under the EUL procedure.

The following criteria must be met:

The disease for which the product is intended is serious or immediately life threatening, has the potential of causing an outbreak, epidemic or pandemic and it is reasonable to consider the product for an EUL assessment, e.g., there are no licensed products for the indication or for a critical subpopulation (e.g., children);

Existing products have not been successful in eradicating the disease or preventing outbreaks (in the case of vaccines and medicines);

The product is manufactured in compliance with current Good Manufacturing Practices (GMP) in the case of medicines and vaccines and under a functional Quality Management System (QMS) in the case of IVDs; and

The applicant undertakes to complete the development of the product (validation and verification of the product in the case of IVDs) and apply for WHO prequalification once the product is licensed.

#### 15] Public health emergency of international concern

CFR 21 — ( “What Does the World Health Organization Do?“, Council on Foreign Relations, 1-29-2021, Available Online at https://www.cfr.org/backgrounder/what-does-world-health-organization-do, accessed 10-7-2021, HKR-AR)

In an extraordinary crisis, the WHO can declare a public health emergency of international concern (PHEIC, pronounced “fake”), which it has done six times: during the 2009 swine flu (H1N1) epidemic; in reaction to a reversal of progress in eradicating polio in 2014; amid the 2014 Ebola outbreak in West Africa; during the 2016 Zika virus outbreak in the Americas; once the ongoing Ebola epidemic reached the city of Goma in the Democratic Republic of Congo in 2019; and amid the global outbreak of the new coronavirus in 2020.

### Framework

#### the standard is maximizing expected wellbeing

#### Independently:

#### 1] Extinction o/ws – [a] trillions of people in future generations means the future holds a lot of value which extinction destroys – outweighs their offense under any framework, regardless of whether they are deontic or aretaic [b] Gateway issue - we need to be alive to assign value and debate competing moral theories- extinction literally ends the debate on “ought”. Use EM – Evaluate the framework debate as a sliding scale not true/false – weigh probability of framework being true times contention offense – framework serves to prioritize not preclude certain impacts, so only EM is logical – eg util agrees freedom matters, but wellbeing outweighs.

#### 2] All other frameworks fail

Mack 4 [(Peter, MBBS, FRCS(Ed), FRCS (Glasg), PhD, MBA, MHlthEcon) “Utilitarian Ethics in Healthcare.” International Journal of the Computer, the Internet, and Management Vol. 12, No.3. 2004. Department of Surgery. Singapore General Hospital.] SJDI

Medicine is a costly science, but of greater concern to the health economist is that it is also a limitless art. Every medical advance created new needs that did not exist until the means of meeting them came into existence. Physicians are reputed to have an infinite capacity to do ever more things, and perform ever more expensive interventions for their patients so long as any of their patients’ health needs remain unfulfilled. The traditional stance of the physician is that each patient is an isolated universe. When confronted with a situation in which his duty involves a competition for scarce medications or treatments, he would plead the patient’s cause by all methods, short of deceit. However, when the physician’s decision involves more than just his own patient, or has some commitment to public health, other issues have to be considered. He then has to recognise that the unbridled advocacy of the patient may not square with what the economist perceives to be the most advantageous policy to society as a whole. Medical professionals characteristically deplore scarcities. Many of them are simply not prepared to modify their intransigent principle of unwavering duty to their patients’ individual interest. However, in decisions involving multiple patients, making available more medication, labour or expenses for one patient will mean leaving less for another. The physician is then compelled by his competing loyalties to enter into a decision mode of one versus many, where the underlying constraint is one of finiteness of the commodities. Although the medical treatment may be simple and inexpensive in many instances, there are situations such as in renal dialysis, where prioritisation of treatment poses a moral dilemma because some patients will be denied the treatment and perish. Ethics and economics share areas of overlap. They both deal with how people should behave, what policies the state should pursue and what obligations citizens owe to their governments. The centrality of the human person in both normative economics and normative ethics is pertinent to this discussion. Economics is the study of human action in the marketplace whereas ethics deals with the “rightness” or “wrongness” of human action in general. Both disciplines are rooted in human reason and human nature and the two disciplines intersect at the human person and the analysis of human action. From the economist’s perspective, ethics is identified with the investigation of rationally justifiable bases for resolving conflict among persons with divergent aims and who share a common world. Because of the scarcity of resources, one’s success is another person’s failure. Therefore ethics search for rationally justifiable standards for the resolution of interpersonal conflict. While the realities of human life have given rise to the concepts of property, justice and scarcity, the management of scarcity requires the exercise of choice, since having more of some goods means having less of others. Exercising choice in turn involves comparisons, and comparisons are based on principles. As ethicists, the meaning of these principles must be sought in the moral basis that implementing them would require. For instance, if the implementation of distributive justice in healthcare is founded on the basis of welfare-based principles, as opposed to say resource-based principles, it means that the health system is motivated by the idea that what is of primary moral importance is the level of welfare of the people. This means that all distributive questions should be settled according to which distribution maximises welfare. Utilitarianism is fundamentally welfarist in its philosophy. Application of the principle to healthcare requires a prior understanding of the welfarist theory as expounded by the economist. Conceptually, welfarist theory is built on four tenets: utility maximisation, consumer sovereignty, consequentialism and welfarism. Utility maximisation embodies the behavioural proposition that individuals choose rationally, but it does not address the morality of rational choice. Consumer sovereignty is the maxim that individuals are the best judge of their own welfare. Consequentialism holds that any action or choice must be judged exclusively in terms of outcomes. Welfarism is the proposition that the “goodness” of the resource allocation be judged solely on the welfare or utility levels in that situation. Taken together these four tenets require that a policy be judged solely in terms of the resulting utilities achieved by individuals as assessed by the individuals themselves. Issues of who receives the utility, the source of the utility and any non-utility aspects of the situation are ignored.

#### 3] Non util ethics are impossible

Greene 10 – Joshua, Associate Professor of Social science in the Department of Psychology at Harvard University (The Secret Joke of Kant’s Soul published in Moral Psychology: Historical and Contemporary Readings, accessed: www.fed.cuhk.edu.hk/~lchang/material/Evolutionary/Developmental/Greene-KantSoul.pdf)

**What turn-of-the-millennium science** **is telling us is that human moral judgment is not a pristine rational enterprise**, that our **moral judgments are driven by a hodgepodge of emotional dispositions, which themselves were shaped by a hodgepodge of evolutionary forces, both biological and cultural**. **Because of this, it is exceedingly unlikely that there is any rationally coherent normative moral theory that can accommodate our moral intuitions**. Moreover, **anyone who claims to have such a theory**, or even part of one, **almost certainly doesn't**. Instead, what that person probably has is a moral rationalization. It seems then, that we have somehow crossed the infamous "is"-"ought" divide. How did this happen? Didn't Hume (Hume, 1978) and Moore (Moore, 1966) warn us against trying to derive an "ought" from and "is?" How did we go from descriptive scientific theories concerning moral psychology to skepticism about a whole class of normative moral theories? The answer is that we did not, as Hume and Moore anticipated, attempt to derive an "ought" from and "is." That is, our method has been inductive rather than deductive. We have inferred on the basis of the available evidence that the phenomenon of rationalist deontological philosophy is best explained as a rationalization of evolved emotional intuition (Harman, 1977). Missing the Deontological Point I suspect that **rationalist deontologists will remain unmoved by the arguments presented here**. Instead, I suspect, **they** **will insist that I have simply misunderstood what** Kant and like-minded **deontologists are all about**. **Deontology, they will say, isn't about this intuition or that intuition**. It's not defined by its normative differences with consequentialism. **Rather, deontology is about taking humanity seriously**. Above all else, it's about respect for persons. It's about treating others as fellow rational creatures rather than as mere objects, about acting for reasons rational beings can share. And so on (Korsgaard, 1996a; Korsgaard, 1996b). **This is, no doubt, how many deontologists see deontology. But this insider's view**, as I've suggested, **may be misleading**. **The problem**, more specifically, **is that it defines deontology in terms of values that are not distinctively deontological**, though they may appear to be from the inside. **Consider the following analogy with religion. When one asks a religious person to explain the essence of his religion, one often gets an answer like this: "It's about love**, really. It's about looking out for other people, looking beyond oneself. It's about community, being part of something larger than oneself." **This sort of answer accurately captures the phenomenology of many people's religion, but it's nevertheless inadequate for distinguishing religion from other things**. This is because many, if not most, non-religious people aspire to love deeply, look out for other people, avoid self-absorption, have a sense of a community, and be connected to things larger than themselves. In other words, secular humanists and atheists can assent to most of what many religious people think religion is all about. From a secular humanist's point of view, in contrast, what's distinctive about religion is its commitment to the existence of supernatural entities as well as formal religious institutions and doctrines. And they're right. These things really do distinguish religious from non-religious practices, though they may appear to be secondary to many people operating from within a religious point of view. In the same way, I believe that most of **the standard deontological/Kantian self-characterizatons fail to distinguish deontology from other approaches to ethics**. (See also Kagan (Kagan, 1997, pp. 70-78.) on the difficulty of defining deontology.) It seems to me that **consequentialists**, as much as anyone else, **have respect for persons**, **are against treating people as mere objects,** **wish to act for reasons that rational creatures can share, etc**. **A consequentialist respects other persons, and refrains from treating them as mere objects, by counting every person's well-being in the decision-making process**. **Likewise, a consequentialist attempts to act according to reasons that rational creatures can share by acting according to principles that give equal weight to everyone's interests, i.e. that are impartial**. This is not to say that consequentialists and deontologists don't differ. They do. It's just that the real differences may not be what deontologists often take them to be. What, then, distinguishes deontology from other kinds of moral thought? A good strategy for answering this question is to start with concrete disagreements between deontologists and others (such as consequentialists) and then work backward in search of deeper principles. This is what I've attempted to do with the trolley and footbridge cases, and other instances in which deontologists and consequentialists disagree. **If you ask a deontologically-minded person why it's wrong to push someone in front of speeding trolley in order to save five others, you will get** characteristically deontological **answers**. Some **will be tautological**: **"Because it's murder!"** **Others will be more sophisticated: "The ends don't justify the means**." "You have to respect people's rights." **But**, as we know, **these answers don't really explain anything**, because **if you give the same people** (on different occasions) **the trolley case** or the loop case (See above), **they'll make the opposite judgment**, even though their initial explanation concerning the footbridge case applies equally well to one or both of these cases. **Talk about rights, respect for persons, and reasons we can share are natural attempts to explain, in "cognitive" terms, what we feel when we find ourselves having emotionally driven intuitions that are odds with the cold calculus of consequentialism**. Although these explanations are inevitably incomplete, **there seems to be "something deeply right" about them because they give voice to powerful moral emotions**. **But, as with many religious people's accounts of what's essential to religion, they don't really explain what's distinctive about the philosophy in question**.

#### 4] That justifies util – it’s impartial, specific to public actors, and resolves infinite regress which explains all value.

Greene 15 — (Joshua Greene, Professor of Psychology @ Harvard, being interviewed by Russ Roberts, “Joshua Greene on Moral Tribes, Moral Dilemmas, and Utilitarianism”, The Library of Economics and Liberty, 1-5-15, Available Online at <https://www.econtalk.org/joshua-greene-on-moral-tribes-moral-dilemmas-and-utilitarianism/#audio-highlights>, accessed 5-17-20, HKR-AM) \*\*NB: Guest = Greene, and only his lines are highlighted/underlined

Guest: Okay. So, I think utilitarianism is very much misunderstood. And this is part of the reason why we shouldn't even call it utilitarianism at all. We should call it what I call 'deep pragmatism', which I think better captures what I think utilitarianism is really like, if you really apply it in real life, in light of an understanding of human nature. But, we can come back to that. The idea, going back to the tragedy of common-sense morality is you've got all these different tribes with all of these different values based on their different ways of life. What can they do to get along? And I think that the best answer that we have is--well, let's back up. In order to resolve any kind of tradeoff, you have to have some kind of common metric. You have to have some kind of common currency. And I think that what utilitarianism, whether it's the moral truth or not, is provide a kind of common currency. So, what is utilitarianism? It's basically the idea that--it's really two ideas put together. One is the idea of impartiality. That is, at least as social decision makers, we should regard everybody's interests as of equal worth. Everybody counts the same. And then you might say, 'Well, but okay, what does it mean to count everybody the same? What is it that really matters for you and for me and for everybody else?' And there the utilitarian's answer is what is sometimes called, somewhat accurately and somewhat misleadingly, happiness. But it's not really happiness in the sense of cherries on sundaes, things that make you smile. It's really the quality of conscious experience. So, the idea is that if you start with anything that you value, and say, 'Why do you care about that?' and keep asking, 'Why do you care about that?' or 'Why do you care about that?' you ultimately come down to the quality of someone's conscious experience. So if I were to say, 'Why did you go to work today?' you'd say, 'Well, I need to make money; and I also enjoy my work.' 'Well, what do you need your money for?' 'Well, I need to have a place to live; it costs money.' 'Well, why can't you just live outside?' 'Well, I need a place to sleep; it's cold at night.' 'Well, what's wrong with being cold?' 'Well, it's uncomfortable.' 'What's wrong with being uncomfortable?' 'It's just bad.' Right? At some point if you keep asking why, why, why, it's going to come down to the conscious experience--in Bentham's terms, again somewhat misleading, the pleasure and pain of either you or somebody else that you care about. So the utilitarian idea is to say, Okay, we all have our pleasures and pains, and as a moral philosophy we should all count equally. And so a good standard for resolving public disagreements is to say we should go with whatever option is going to produce the best overall experience for the people who are affected. Which you can think of as shorthand as maximizing happiness--although I think that that's somewhat misleading. And the solution has a lot of merit to it. But it also has endured a couple of centuries of legitimate criticism. And one of the biggest criticisms--and now we're getting back to the Trolley cases, is that utilitarianism doesn't adequately account for people's rights. So, take the footbridge case. It seems that it's wrong to push that guy off the footbridge. Even if you stipulate that you can save more people's lives. And so anyone who is going to defend utilitarianism as a meta-morality--that is, a solution to the tragedy of common sense morality, as a moral system to adjudicate among competing tribal moral systems--if you are going to defend it in that way, as I do, you have to face up to these philosophical challenges: is it okay to kill on person to save five people in this kind of situation? So I spend a lot of the book trying to understand the psychology of cases like the footbridge case. And you mention these being kind of unrealistic and weird cases. That's actually part of my defense.