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### Intro

#### I affirm the resolution, resolved: The member states of the World Trade Organization ought to reduce intellectual property protections for medicines.

#### First, I would like to offer a couple of definitions:

The World Trade Organization describes its purpose as

WTO, , "Overview: WTO," World Trade Organization, https://www.wto.org/english/thewto\_e/whatis\_e/wto\_dg\_stat\_e.htm

The WTO provides a forum for negotiating agreements aimed at reducing obstacles to international trade and ensuring a level playing field for all, thus contributing to economic growth and development. The WTO also provides a legal and institutional framework for the implementation and monitoring of these agreements, as well as for settling disputes arising from their interpretation and application. The current body of trade agreements comprising the WTO consists of 16 different multilateral agreements (to which all WTO members are parties) and two different plurilateral agreements (to which only some WTO members are parties).

Trevor Brewer, a business lawyer specializing in regulations and transactions, writes in May 2019 that

Trevor Brewer, 5-16-2019, "What Are The 4 Types of Intellectual Property Rights?," BrewerLong, https://brewerlong.com/information/business-law/four-types-of-intellectual-property/SJKS

There are four types of intellectual property rights and protections (although multiple types of intellectual property itself). Securing the correct protection for your property is important, which is why consulting with a lawyer is a must. The four categories of intellectual property protections include: TRADE SECRETS Trade secrets refer to specific, private information that is important to a business because it gives the business a competitive advantage in its marketplace. If a trade secret is acquired by another company, it could harm the original holder. Examples of trade secrets include recipes for certain foods and beverages (like Mrs. Fields’ cookies or Sprite), new inventions, software, processes, and even different marketing strategies. When a person or business holds a trade secret protection, others cannot copy or steal the idea. In order to establish information as a “trade secret,” and to incur the legal protections associated with trade secrets, businesses must actively behave in a manner that demonstrates their desire to protect the information. [Trade secrets are protected *without* official registration](https://www.wipo.int/sme/en/ip_business/trade_secrets/protection.htm); however, an owner of a trade secret whose rights are breached–i.e. someone steals their trade secret–may ask a court to ask against that individual and prevent them from using the trade secret. PATENTS As defined by the [U.S. Patent and Trademark Office](https://www.uspto.gov/help/patent-help#patents) (USPTO), a patent is a type of limited-duration protection that can be used to protect inventions (or discoveries) that are new, non-obvious, and useful, such as a new process, machine, article of manufacture, or composition of matter. When a property owner holds a patent, others are prevented, under law, from offering for sale, making, or using the product. COPYRIGHTS Copyrights and patents are not the same things, although they are often confused. A copyright is a type of intellectual property protection that protects original works of authorship, which might include literary works, music, art, and more. Today, copyrights also protect computer software and architecture. Copyright protections are automatic; once you create something, it is yours. However, if your rights under copyright protections are infringed and you wish to file a lawsuit, then registration of your copyright will be necessary. TRADEMARKS Finally, the fourth type of intellectual property protection is a trademark protection. Remember, patents are used to protect inventions and discoveries and copyrights are used to protect expressions of ideas and creations, like art and writing. Trademarks, then, refer to phrases, words, or symbols that distinguish the source of a product or services of one party from another. For example, the Nike symbol–which nearly all could easily recognize and identify–is a type of trademark. While patents and copyrights can expire, trademark rights come from the use of the trademark, and therefore can be held indefinitely. Like a copyright, registration of a trademark is not required, but registering can offer additional advantages.

### Framework

#### I value morality because the word ought in the resolution implies a moral obligation.

#### Thus, the value criterion must be maximizing well-being for everyone.

#### There are two main reasons for this:

#### Everyone does not like painful or emotionally harmful experiences, so naturally we should try to replace these things with good experiences.

#### Things like death and oppression are intuitively bad, and effect everyone, so we should try to prevent them.

#### In summary, if I can prove to you that reducing IP protections would have a good impact on the world, then you should vote for the affirmative in today’s debate.

### Contention 1 is Covid 19 Vaccine Accessibility

#### There is a significant disparity between rich and poor nations on vaccination accessibility, rollout and rates. IP protections harm the ability to combat this gap in a short timeframe- sharing information is extremely important.

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According to Duke Global Health Innovation Center, which monitors COVID-19 vaccine purchases, rich nations representing just 14 per cent of the world population have bought up to 53 per cent of the most promising vaccines so far. As of 4 July 2021, the high-income countries (HICs) purchased more than half (6.16 billion) vaccine doses sold globally. At the same time, the low-income countries (LICs) received only 0.3 per cent of the vaccines produced. The low and middle-income countries (LMICs), which account for 81 per cent of the global adult population, purchased 33 per cent, and COVAX (COVID-19 Vaccines Global Access) has received 13 per cent.10 Many HICs bought enough doses to vaccinate their populations several times over. For instance, Canada procured 10.45 doses per person, while the UK, EU and the US procured 8.18, 6.89, and 4.60 doses per inhabitant, respectively.11

Consequently, there is a significant disparity between HICs and LICs in vaccine administration as well. As of 8 July 2021, 3.32 billion vaccine doses had been administered globally.12 Nonetheless, only one per cent of people in LICs have been given at least one dose. While in HICs almost one in four people have received the vaccine, in LICs, it is one in more than 500. The World Health Organization (WHO) notes that about 90 per cent of African countries will miss the September target to vaccinate at least 10 per cent of their populations as a third wave looms on the continent.13 South Africa, the most affected African country, for instance, has vaccinated less than two per cent of its population of about 59 million. This is in contrast with the US where almost 47.5 per cent of the population of more than 330 million has been fully vaccinated. In Sub-Saharan Africa, vaccine rollout remains the slowest in the world. According to the International Monetary Fund (IMF), at current rates, by the end of 2021, a massive global inequity will continue to exist, with Africa still experiencing meagre vaccination rates while other parts of the world move much closer to complete vaccination.14

This vaccine inequity is not only morally indefensible but also clinically counter-productive. If this situation prevails, LICs could be waiting until 2025 for vaccinating half of their people. Allowing most of the world’s population to go unvaccinated will also spawn new virus mutations, more contagious viruses leading to a steep rise in COVID-19 cases. Such a scenario could cause twice as many deaths as against distributing them globally, on a priority basis. Preventing this humanitarian catastrophe requires removing all barriers to the production and distribution of vaccines. TRIPS is one such barrier that prevents vaccine production in LMICs and hence its equitable distribution.

TRIPS: Barrier to Equitable Health Care Access

The opponents of the waiver proposal argue that IPR are not a significant barrier to equitable access to health care, and existing TRIPS flexibilities are sufficient to address the COVID-19 pandemic. However, history suggests the contrary. For instance, when South Africa passed the Medicines and Related Substances Act of 1997 to address the HIV/AIDS public health crisis, nearly 40 of world’s largest and influential pharma companies took the South African government to court over the violation of TRIPS. The Act, which invoked the compulsory licensing provision, allowed South Africa to produce affordable generic drugs.15 The Big Pharma also lobbied developed countries, particularly the US, to put bilateral trade sanctions against South Africa.16

Similarly, when Indian company Cipla decided to provide generic antiretrovirals (ARVs) to the African market at a lower cost, Big Pharma retaliated through patent litigations in Indian and international trade courts and branded Indian drug companies as thieves.17 Another instance was when Swiss company Roche initiated patent infringement proceedings against Cipla’s decision to launch a generic version of cancer drug, “erlotinib”. Though the Delhi High Court initially dismissed Roche's appeal by citing “public interest” and “affordability of medicines,” the continued to pressure the generic pharma companies over IPR. 18 Likewise, Pfizer’s aggressive patenting strategy prevented South Korea in developing pneumonia vaccines for children.19

A recent document by Médecins Sans Frontières (MSF), or Doctors Without Borders, highlights various instances of how IP hinders manufacturing and supply of diagnostics, medical equipment, treatments and vaccines during the COVID-19 pandemic. For instance, during the peak of the COVID-19 first wave in Europe, Roche rejected a request from the Netherlands to release the recipe of key chemical reagents needed to increase the production of diagnostic kits. Another example was patent holders threatening producers of 3D printing ventilators with patent infringement lawsuits in Italy.20 The MSF also found that patents pose a severe threat to access to affordable versions of newer vaccines.21

The opponents of the TRIPS waiver also argue that IP is the incentive for innovation and if it is undermined, future innovation will suffer. However, most of the COVID-19 medical innovations, particularly vaccines, are developed with public financing assistance. Governments spent billions of dollars for COVID-19 vaccine research. Notably, out of $6.1 billion in investment tracked up to July 2021, 98.12 per cent was public funding.22 The US and Germany are the largest investors in vaccine R&D with $2.2 billion and $1.5 billion funding.

Private companies received 94.6 per cent of this funding; Moderna received the highest $956.3 million and Janssen $910.6 million. Moreover, governments also invested $50.9 billion for advance purchase agreements (APAs) as an incentive for vaccine development. A recent IMF working paper also notes that public research institutions were a key driver of the COVID-19 R&D effort—accounting for 70 per cent of all COVID-19 clinical trials globally.23 The argument is that vaccines are developed with the support of substantial public financing, hence there is a public right to the scientific achievements. Moreover, private companies reaped billions in profits from COVID-19 vaccines.

One could argue that since the US, Germany and other HICs are spending money, their citizens are entitled to get vaccines first, hence vaccine nationalism is morally defensible. Nonetheless, it is not the case. The TRIPS Agreement includes several provisions which mandates promotion of technology transfer from developed countries to LDCs. For instance, Article 7 states that "the protection and enforcement of IP rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."24 Similarly, Article 66.2 also mandates the developed countries to transfer technologies to LDCs to enable them to create a sound and viable technological base. The LMICs opened their markets and amended domestic patent laws favouring developing countries’ products against this promise of technology transfer.

Another argument against the proposed TRIPS waiver is that a waiver would not increase the manufacturing of COVID-19 vaccines. Indeed, one of the significant factors contributing to vaccine inequity is the lack of manufacturing capacity in the global south. Further, a TRIPS waiver will not automatically translate into improved manufacturing capacity. However, a waiver would be the first but essential step to increase manufacturing capacity worldwide. For instance, to export COVID-19 vaccine-related products, countries need to ensure that there are no IP restrictions at both ends – exporting and importing. The market for vaccine materials includes consumables, single-use reactors bags, filters, culture media, and vaccine ingredients. Export blockages on raw materials, equipment and finished products harm the overall output of the vaccine supply chain. If there is no TRIPS restriction, more governments and companies will invest in repurposing their facilities.

Similarly, the arguments such as that no other manufacturers can carry out the complex manufacturing process of COVID-19 vaccines and generic manufacturing as that would jeopardise quality, have also been proven wrong in the past. For instance, in the early 1990s, when Indian company Shantha Biotechnics approached a Western firm for a technology transfer of Hepatitis B vaccine, the firm responded that “India cannot afford such high technology vaccines… And even if you can afford to buy the technology, your scientists cannot understand recombinant technology in the least.”25 Later, Shantha Biotechnics developed its own vaccine at $1 per dose, and the UNICEF (United Nations Children’s Emergency Fund) mass inoculation programme uses this vaccine against Hepatitis B. In 2009, Shantha sold over 120 million doses of vaccines globally.

India also produces high-quality generic drugs for HIV/AIDS and cancer treatment and markets them across the globe. Now, a couple of Indian companies are in the last stage of producing mRNA (Messenger RNA) vaccines.26 Similarly, Bangladesh and Indonesia claimed that they could manufacture millions of COVID-19 vaccine doses a year if pharmaceutical companies share the know-how.27 Recently, Vietnam also said that the country could satisfy COVID-19 vaccine production requirements once it obtains vaccine patents.28 Countries like the United Arab Emirates (UAE), Turkey, Cuba, Brazil, Argentina and South Korea have the capacity to produce high-quality vaccines but lack technologies and know-how. However, Africa, Egypt, Morocco, Senegal, South Africa and Tunisia have limited manufacturing capacities, which could also produce COVID-19 vaccines after repurposing.

Moreover, COVID-19 vaccine IPR runs across the entire value chain – vaccine development, production, use, etc. A mere patent waiver may not be enough to address the issues related to its production and distribution. What is more important here is to share the technical know-how and information such as trade secrets. Therefore, the existing TRIPS flexibilities, such as compulsory and voluntary licensing, are insufficient to address this crisis. Further, compulsory licensing and the domestic legal procedures it requires is cumbersome and not expedient in a public health crisis like the COVID-19 pandemic.

India’s Role in Ensuring Vaccine Equity India's response to COVID-19 at the global level was primarily two-fold. First, its proactive engagements in the regional and international platforms. Second, its policies and programmes to provide therapeutics and vaccines to the world. Since the beginning of the COVID-19 pandemic, India has been advocating international cooperation and policy coordination in fighting it. For instance, in April 2020, India co-sponsored a UN resolution that called for fair and equitable access to essential medical supplies and future vaccines to COVID-19. Later, in October 2020, India also put pressure on developed countries with a joint WTO proposal for TRIPS waiver. India’s Vaccine Maitri initiative also aims vaccine equity. As of 29 May 2021, India has supplied 663.698 lakh doses of COVID-19 vaccines to 95 countries. It includes 107.15 lakh doses as a gift to more than 45 countries, 357.92 lakh doses by commercial sales, and 198.628 lakh doses to the COVAX facility.29 The COVAX initiative aims to ensure rapid and equitable access to COVID-19 vaccines for all countries, regardless of their income level. India has decided to supply 10 million doses of the vaccine to Africa and one million to the UN health workers under the COVAX facility. India has also removed the IPR of Covaxin that would help platforms like C-TAP once WHO and developed countries’ regulatory bodies approve the vaccine. If agreed, the waiver would benefit India in many ways. First, more vaccines will help the country to control the pandemic and its recurring waves. Second, it will be a boost to India's pharma industry, particularly the generic medicine industry. According to the Biotechnology Innovation Organization, 834 unique active compounds are involved in the current R&D of COVID-19 therapeutics, vaccines, and diagnostics. It means that thousands of new patents are awaited, and that will hinder India's ability to produce COVID-19 related medical products. Only through a waiver, this challenge can be addressed. Similarly, scientists note that mRNA is the future of vaccine technology. However, manufacturing mRNA vaccines involves complex processes and procedures. Only a very few Indian manufacturers have access to this technology; however, that too is limited. Once Indian companies have access to mRNA technology, it will help country’s generic medicine industry and boost India’s economy. Therefore, even if the WTO agrees on a waiver for a period shorter than proposed, India should accept it. In addition, mRNA vaccines can be produced in lesser time compared to the traditional vaccines. While traditional vaccines’ production takes four to five months, mRNA needs only six to eight weeks. Access to this technology will be vital for India in expediting the fight against COVID-19 and future pandemics. Finally, a waiver may strengthen India's diplomatic soft power. At present, what hinders India's Vaccine Maitri initiative is the scarcity of vaccines at home. On the other hand, China is increasing its standing in Africa, South America and the Pacific through vaccine diplomacy. The WHO approval of the Chinese vaccines and lack of access to vaccines by most developing countries, opens up huge space for China to do its vaccine diplomacy. Here, India should convince its Quad partners, particularly Australia and Japan, who oppose the waiver that vaccine production in developing countries through TRIPS waiver will enable the grouping to deliver its pledged billion doses of COVID-19 vaccine in the Indo-Pacific region. In short, the proposed waiver, if agreed, will help India in addressing the public health crisis by producing more vaccines and distributing them at home; economically, by boosting its generic pharmaceutical industry, and diplomatically, providing vaccines to the developing and least-developed countries. Therefore, India should use all available means and methods, from trade-offs to pressurising, to make the waiver happen.

#### Intellectual Property is the barrier stalling vaccines from scaling up- only the affirmative can resolve such a problem

Parsa Erfiani, a Fogarty Global Health Scholar at Harvard Medical School, writes in May 2021

[Parsa; Lawrence Gostin; Vanessa Kerry; Parsa Erfani is a Fogarty Global Health Scholar at Harvard Medical School and the University of Global Health Equity. Lawrence Gostin is a professor at Georgetown University Law Center, director of the school’s O’Neill Institute for National and Global Health Law, and director of the World Health Organization Center on National and Global Health Law. Vanessa Kerry is a critical care physician at Massachusetts General Hospital, director of the Program for Global Public Policy at Harvard Medical School, and CEO of Seed Global Health, a nonprofit that trains health workers in countries with critical shortages; “Beyond a symbolic gesture: What’s needed to turn the IP waiver into Covid-19 vaccines,” STAT; 5/19/21; <https://www.statnews.com/2021/05/19/beyond-a-symbolic-gesture-whats-needed-to-turn-the-ip-waiver-into-covid-19-vaccines/>] Justin

Currently many idle suppliers can’t begin vaccine production until they upgrade and repurpose existing manufacturing capacity for new technology. Opponents often argue that this step is the true barrier to rapid scale-up. One high-profile detractor, BIO President and CEO Michelle McMurry-Heath, argues that “handing [needy countries] the blueprint to construct a kitchen that — in optimal conditions — can take a year to build will not help us stop the emergence of dangerous new Covid variants.”

This argument ignores two core truths: In many cases, manufacturing capacity needs only repurposing which can take mere months. And Covid-19, at the current global response and vaccination rates, will be a threat for years.

Both truths suggest that we pass the blueprint and build the kitchen.

Facilitating structures to transfer technology and capacity are already in place. The WHO launched the mRNA technology transfer hub model last month to provide manufacturers in low- and middle-income countries with the financial, training, and logistical support needed to scale up vaccine manufacturing capacity. Scores of manufacturers in these countries have already expressed interest. This initiative, however, requires recipient manufacturers to acquire the IP necessary for mRNA technologies— which is currently missing.

#### Equitable vaccine distribution solves COVID- this study takes into account mutations and vaccine nationalism. The affirmative is saving millions of lives.

**Princeton University writes in August 2021**

Princeton University. "Vaccine stockpiling by nations could lead to increase in COVID-19 cases, novel variant emergence, study finds." ScienceDaily. ScienceDaily, 17 August 2021. <www.sciencedaily.com/releases/2021/08/210817152552.htm>. //Nato

The allocation of COVID-19 vaccine between countries has thus far tended toward vaccine nationalism, wherein countries stockpile vaccines to prioritize access for their citizenry over equitable vaccine sharing. The extent of vaccine nationalism, however, may strongly impact global trajectories of COVID-19 case numbers and increase the potential emergence of novel variants, according to a Princeton University and McGill University study published Aug. 17 in the journal Science. "Certain countries such as Peru and South Africa that have had severe COVID-19 outbreaks have received few vaccines, while many doses have gone to countries experiencing comparatively milder pandemic impacts, either in terms of mortality or economic dislocation," said co-first author Caroline Wagner, an assistant professor of bioengineering at McGill University who previously served as a postdoctoral research associate in Princeton's High Meadows Environmental Institute (HMEI). "As expected, we have seen large decreases in case numbers in many regions with high vaccine access, yet infections are resurging in areas with low availability," said co-first author Chadi Saad-Roy, a Princeton graduate student in ecology and evolutionary biology and the Lewis-Sigler Institute for Integrative Genomics. "Our goal was to explore the effects of different vaccine-sharing schemes on the global persistence of COVID-19 infections -- as well as the possibility for the evolution of novel variants -- using mathematical models," Saad-Roy said. The researchers projected forward the incidence of COVID-19 cases under a range of vaccine dosing regimes, vaccination rates, and assumptions related to immune responses. They did so in two model regions: One with high access to vaccines -- a high-access region (HAR) -- and a low-access region (LAR). The models also allowed for the regions to be coupled either through case importation, or the evolution of a novel variant in one of the regions. "In this way, we could assess the dependence of our epidemiological projections on different immunological parameters, regional characteristics such as population size and local transmission rate, and our assumptions related to vaccine allocation," Wagner said. Overall, the study found that increased vaccine-sharing resulted in reduced case numbers in LARs. "Because it appears that vaccines are highly effective at reducing the clinical severity of infections, the public health implications of these reductions are very significant," said co-author Michael Mina, an assistant professor at the Harvard T. H. Chan School of Public Health. Senior author C. Jessica E. Metcalf, a Princeton associate professor of ecology and evolutionary biology and public affairs and associated faculty in HMEI, added: "High case numbers in unvaccinated populations will likely be associated with higher numbers of hospitalizations and larger clinical burdens compared to highly vaccinated populations." The authors also drew on a framework developed in their prior work to begin trying to quantify the potential for viral evolution under different vaccine sharing schemes. In their model, repeat infections in individuals with partial immunity -- either from an earlier infection or a vaccine -- may result in the evolution of novel variants. "Overall, the models predict that sustained elevated case numbers in LARs with limited vaccine availability will result in a high potential for viral evolution," said senior author Bryan Grenfell, Princeton's Kathryn Briger and Sarah Fenton Professor of Ecology and Evolutionary Biology and Public Affairs and an associated faculty member in HMEI. "As with our earlier work, the current study strongly underlines how important rapid, equitable global vaccine distribution is," Grenfell said. "In a plausible scenario where secondary infections in individuals who have previously been infected strongly contribute to viral evolution, unequal vaccine allocation appears particularly problematic." As the pandemic progresses, viral evolution may play an increasingly large role in sustaining transmission, said senior author Simon Levin, Princeton's James S. McDonnell Distinguished University Professor in Ecology and Evolutionary Biology and an associated faculty member in HMEI. "In particular, antigenically novel variants have the potential to threaten immunization efforts globally through several mechanisms," he said," including higher transmissibility, reduced vaccine efficacy, or immune escape." Saad-Roy added: "In this way, global vaccine coverage will reduce the clinical burden from novel variants, while also decreasing the likelihood that these variants emerge." There are additional considerations for vaccine equity beyond epidemiological and evolutionary ones, said co-author Ezekiel Emanuel, the Diane v.S. Levy and Robert M. Levy University Professor and co-director of the Healthcare Transformation Institute at the University of Pennsylvania. "Ethics also argues against countries stockpiling vaccines or allocating doses for boosters," Emanuel said. "This study strongly supports that ethical position showing that stockpiling will undermine global health."

### Contention 2 is Innovation

#### HIV/AIDs prove that an IP waiver is key to creating “global public goods” that create public incentives to innovate.

Hassan 21 [Fatima; South African social justice activist and human rights lawyer. She worked on HIV/AIDS medicine access advocacy and litigation for many years with the AIDS Law Project and for the Treatment Action Campaign, clerked at the Constitutional Court of South Africa, served as special advisor to South Africa’s former minister of health and public enterprises, and is the founder and current head of the Health Justice Initiative based in Cape Town; “Don’t Let Drug Companies Create a System of Vaccine Apartheid,” FP; 2/23/21; <https://foreignpolicy.com/2021/02/23/dont-let-drug-companies-create-a-system-of-vaccine-apartheid/>] Justin

The current TRIPS waiver request is rooted in what transpired 20 years ago during South Africa’s HIV/AIDS epidemic, when affordable generic drugs, made in countries where patents did not block production, began saving millions of people’s lives. At the time, many groups in the human rights and medical access community fought for that space to open up using antitrust measures, litigation, advocacy, and patent defiance campaigns. The eventual ability of generic manufacturers to enter low-income countries with high HIV burdens was a game-changer.

Without the temporary TRIPS waiver now, countries will be required to take individual domestic action and legal measures—while managing a pandemic. This is why the waiver is important, but also why all COVID-19 health tools and technologies should be regarded as global public goods, free from the barriers that patents and other intellectual property impose.

There will, of course, be resistance from companies and their lobbyists. The pharmaceutical industry is adept at evergreening and extending patent protections, and in some cases “gaming the patent system.” Moreover, it often creates the incorrect impression that all medical and public health innovation—supposedly for the broader public good—belongs to the industry alone. In fact, such innovation is dependent on co-funding, public investment, and public research. Without those contributions, the innovation needed to assist millions of vulnerable and sick people would be missing, and access to essential and life-saving diagnostics and therapeutics for many chronic conditions would be limited.

In a public health crisis such as COVID-19, patent and market exclusivity must be replaced with equitable access and the treatment of science as a public good. Otherwise, only the promise of patent protection will drive scientific innovation, continuing to benefit only the wealthy and powerful while millions die.

#### Pharmaceutical innovation is key to stop bioterrorism and antimicrobial resistance

Carolina Feijao, a Ph.D in biochemistry from the University of Cambridge, writes in 2020

Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism con-text.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation.

Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives.

This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic.

In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6

The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10

Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterror-ism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

#### Bioterror and biotechnology are the largest medical threat—only generating innovative drugs can prevent millions from death

Bakerlee 21 Chris Bakerlee is a Ph.D. candidate studying evolutionary genetics at Harvard University and a fellow in the Council on Strategic Risks’s Fellowship for Ending Bioweapons Programs. "Mother Nature is not 'the ultimate bioterrorist' - STAT." STAT, 8 Jan. 2021, www.statnews.com/2021/01/08/mother-nature-is-not-the-ultimate-bioterrorist. [Quality Control]

Taken together, these examples show that this meme no longer serves us well. It is undoubtedly a mistake to underestimate the threats from natural pathogens. At the same time, it is equally unwise to wield this 19-year-old expression like a magic wand, intending to briskly banish concerns about people causing harm with biology. We can’t afford to blind ourselves or others to the uncomfortable truth that, with each passing day, humans grow more capable of outdoing nature and harnessing biotechnology to cause harm on a staggering scale, by either cruelty or carelessness.

Nature has no interests, motives, or political goals. To the extent it can be said to “want” anything, it is to perpetually enhance populations’ differential reproductive success, which only rarely aligns with causing greater harm to humans. Notably, the trillions of bacteria living in the average human’s colon appear to have adapted toward a peaceful and often mutually beneficial coexistence with their host. And even deadly pathogens may theoretically evolve toward making humans less sick if doing so opens up more opportunities for transmission between hosts.

The process of natural selection, for all its power, is highly constrained in its ability to generate “superbugs” possessing a diabolical suite of traits. Like human bioengineers, natural selection must work around stubborn physiological trade-offs between traits, such as genome replication rate and mutation rate. But natural selection is also handicapped by near-sightedness, driving improvements in traits that enhance a population’s fitness in its current environment with no attention to maintaining or improving traits that enhance fitness in other environments.

If creating an especially deadly pathogen were like winning a soccer match against a formidable opponent, natural selection would be competing with all the cunning of an especially persistent horde of 5-year-olds, glued to the ball and only ever capable of playing offense, defense, or goalie at any one time.

By contrast, modern biologists are gaining the ability to see the whole field, develop an intuition about where the ball will be next, and play multiple positions simultaneously. Through a combination of rational design, directed evolution, breeding, and brute force trial and error, they can increasingly engineer organisms that excel in multiple desired functions at once, such as the ability to grow quickly in a massive industrial fermenter while churning out commercially valuable biomolecules. This growing capability promises tremendous benefits for agriculture, industry, and human health, but its potential application to the creation of pathogens poses serious concerns.

It is worth emphasizing that trained biologists — let alone terrorists — still have difficulty one-upping natural selection’s creative output. Our understanding of biology is very much in its infancy. Yet our knowledge and capabilities are maturing rapidly, as evidenced by Twist’s prolific gene synthesis capabilities, along with recent feats in predicting protein structure, gene editing, and genome assembly. We are much closer to this exciting but frightening horizon today than we were in 2001, and this trend will likely persist.

It’s also worth noting that, when it comes to weapons-grade biotechnology, states likely pose a greater risk than non-state terrorists. States have vastly more resources to support the development of biological weapons, and about 23 are known or suspected to have maintained biological weapons programs in the 20th century. Some programs, like North Korea’s, likely persist to this day. As countries jockey for advantage, state biological weapons programs remain an ever-present danger, despite the treaties and export controls designed to rein them in. Covid-19, which has exposed countries’ vulnerability to biological threats, has done little to mitigate this danger.

Accidental releases pose an additional source of anthropogenic biorisk. Thanks to the U.S. government’s monitoring program, we know that dozens of agents and toxins with the potential to pose a severe threat to public health and agriculture are reported accidentally lost or released from U.S. labs every year. We also know that accidental releases around the world have already caused significant harm. Such risks increase as biotechnology expands across the world and gains in strength.

Biotechnology, with all its promise and peril, is moving fast. It’s irresponsible of us to shrug off current and emerging biotechnological threats by reciting “Nature is the ultimate bioterrorist” like some article of faith. As with global warming, the cost of willful ignorance and inaction is high — and increasing.

Our health security requires that we engage cautiously but honestly with the full spectrum of evolving biological risks, striving toward solutions with open eyes and moral courage.