“Communism is when no iPhone.” –Das Kapital, volume 4

# Developing Countries/Third World – Word PIC

## \*\*1NC – Developing Countries

#### We will endorse the entirety of the 1AC - minus their usage of the term ‘developing’ countries, nations or otherwise.

#### (Several of their cards use this term, including: Pley 21, Lindsey 21, second Pley21, Tafese 20, and Carmondy 20)

#### The term is outdated, unnecessary, and Eurocentric, There is no consistent criteria to determine development, which means the aff has no reason to include it

**Abrahams ‘19**

(Jessica Abrahams, December 05, 2020, Abrahams received her grad degree in journalism from City University London and IR from Institut Barcelona d’Estudis Internacionals. She was a writer, researcher and editor for multiple news sources including Prospect magazine, The Telegraph and Bloomberg News, is now an editor of Devex Pro, “Is it time to retire the term “developing country”?”, [https://www.prospectmagazine.co.uk/world/is-it-time-to-retire-the-term-developing-country-wto-united-nations-global-inequality //](https://www.prospectmagazine.co.uk/world/is-it-time-to-retire-the-term-developing-country-wto-united-nations-global-inequality%20//) HM)

Is South Korea—[the 12th biggest economy in the world](https://data.worldbank.org/indicator/ny.gdp.mktp.cd?most_recent_value_desc=false)—a developing country? It is according to its status at the **W**orld **T**rade **O**rganisation, which entitles the country to certain benefits in trade negotiations. Under pressure from the US, it announced in late October that it will no longer seek to make use of those benefits, though it declined to give up its . Other economic powers that still identify as developing, including China, are so far refusing to budge. It might seem surprising that some of the **richest countries** in the world are still **classified as developing**. But then again, pinning down the details of this nebulous term can be a challenge. Although most intergovernmental organisations use it as an official classification, few define what it means. And without a clear definition, it is arguably a term that has outlived its purpose. It might seem odd that the WTO relies on countries to self-designate. But the UN, which identifies 159 countries as developing, explains that “there is [**no established convention**](https://unstats.un.org/unsd/methods/m49/m49regin.htm#ftnc) **for** [this] **designation**… in the United Nations system.” It is largely based on the regional designations adopted as part of the Millennium Development Goals in 2000, under which North America, Europe, Japan and Australia are considered “developed”—everyone else is developing. With a focus on the economic elements of developments, the International Monetary Fund is the most specific, [taking into account](https://www.imf.org/external/pubs/ft/weo/faq.htm#q4b) a country’s per capita income level, export diversification and degree of integration into the global financial system. But even then, it notes, its **classification system “is not based on strict criteria**, economic or otherwise” and offers only “a reasonably meaningful method of organising data.” Part of the issue is that most of these classifications were set decades ago, and much about **the world has changed.** If these categorisations were ever fit for purpose, it is not clear that they still are.

#### The global North argues that development leads to increased quality of life to exploit the global South. It ultimately leads to more disparity.

Irfan and Lamichhane 20

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Development is a multi-dimensional process involving reorganization and reorientation of entire economic as well as social system. So, development is not purely an economic phenomenon rather it is a process of improving the quality of all human lives. The dimension of development is very much diversified which includes economic, social, political, legal & institutional structures, technology in various forms, the environment, religion, the arts, and culture. There are mainly three distinct conceptualizations of development: Development as a long term process of structural societal transformation; Development as short-to-medium term outcomes and desirable targets; and Development as a dominant discourse of western modernity. There is no doubt that development itself is a western centric concept. The discourse of development made it possible for the European powers to continue the **colonial** domination by using the language of development. In colonial period, power was centralized and had their own agenda in social, economic and political matter and forms of capitalism were introduced and development were mainly concentrated in urban centers. Efforts at industrialization were uneven and sporadic. Natural resources were unilaterally exploited by artificially created controlled mechanism. Later on, in post-World War II period many countries freed from colonial rule. The goal of development was to raise income and give poor nations access to basic necessities. Institutional apparatus was established (e.g. World Bank, IMF) in order to channel material aid and the ideology associated with development to these countries. This ideology repeats the basic 'truth' of Enlightenment that progress is the achievement of characteristic features of the already rich societies in the West. Consequently, in the post-colonial era these institutional apparatus became the centers of power-knowledge production and also the source of channeling them to the societies outside the West. The activities of these international financial are blamed to have been mechanized to work as per the policy of limited developed countries and scholar such as Joseph Stiglitz potray severely criticizes these organizations. Various development theories were proposed by the western thinkers in post war period such as Modernization Theory, Dependency Theory, Statism, etc. Modernization Theory was argued for creating certain injustices (for developing countries) by market economies. Dependency theory argued that the first world guides third-world development through aid, investment. However, it was criticized for draining the colonies of their sources that could have been used for investment, and had killed off local capitalism through competition. That means, by siphoning surplus away from the third world, the first world had enriched itself and by keeping the third world underdeveloped the first world ensured a ready market for their finished goods and a cheap supply of raw materials for their factories. The conclusion drawn from dependency theory was that Third world countries had to sever their ties to the world economy and become more self-sufficient with autonomous national development strategies. Thus, the faith in the state as the motor for development came in light. Some argue that globalization is a western concept that has lead to the development of the economy but at the same time there is counter argument that it has lead to enhance the gap between poor and rich, means increasing disparity. There is harsh criticism that globalization has been galvanized by developed countries (North) in their own favor and has used by them as a weapon for expanding their imperialism and neo-colonialism to the developing countries (South). The concept of development has changed drastically with the change in time. At present world, development is not limited to the sphere of economic prosperity. It demands the greater dimension of social inclusion, equality, ecological conservation, human rights and sustainability. Developing countries need to stand rigidly in formation of their own indigenous policies. These countries need to be careful enough to commercialize their agriculture even through continuous government subsidy, develop rural infrastructure and build Industrial backbone and adopting globalization principles in selective manner. The most essential step for them is the real transformation of regionalism in practice. These countries can only improve their bargaining capability by standing together emphasizing on regional trade and development.

#### Development discourse forced by the West imposes ecocentrism, leading to over-exploitation of resources.

Irfan and Lamichhane 20

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In a retrospective look at the construction of Third World, it is explicit to understand how the language of Development has been used by the West for legitimizing its interventions over the Third World. Further these countries have been referred to in a variety of forms. Before they gained independence, they were called Backward countries and upon the gaining of independence, they became Emergent or New States. Afterwards they became Developing Countries in order to fit into the Western notion of universal development or alternatively as Underdeveloped countries in the terminology of dependency critiques. Accordingly, the concepts Third Word and Development are inventions of the economically rich nations of the West and thus, Escobar (1995) argued development has become a discourse; a particular mode of thinking and a source of practice designed to instill in underdeveloped countries the desire to strive towards industrial and economic growth. Even though the broad meaning of development is the promotion of the creativity of humans, economic growth is the primary criterion by which development is determined. That is why economics has become the master discipline of theory-building and policy formulation. In his retrospective look at development anthropology at the World Bank, Michael Cernea referred to the econocentric and technocentric conceptual biases of development strategies as profoundly damaging. These paradigmatic biases largely neglect history of civilization and the associated values. The latter were the essential elements of social harmony and the balance between man and nature. Econocentrism does not tolerate the equivalence of nature with man. Therefore, it attempts to surrender nature by means of destruction and over-exploitation. Material accumulation has been the primary goal of the econocentric and techno centric development approaches.

#### Multispecies exploitation heightens extinction pathways and rushes the inevitable extinction timer.

Thurner et. al 8-15-21

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Although extinction itself may ultimately be inevitable, the rate at which it is occurring has been exacerbated by human activity (Bascompte, 2003). Compelling evidence shows that Earth's biota is amid its sixth mass extinction, and recent extinction rates are both unparalleled in human history and highly unusual in Earth's history (Baillie et al., 2004; Ceballos et al., 2015). Many major processes driving an increase in extinction rates are anthropogenic, including direct human exploitation, habitat loss, climate change, and introduced species (Diamond et al., 1989; Ichii et al., 2019; Keith et al., 2008; Purvis et al., 2000; Thomas et al., 2004). The Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services identifies direct exploitation as the second most important driver of change in the global state of nature (Ichii et al., 2019), and biological resource use is listed as a threat for all 189 species listed as “extinct” or “extinct in the wild” on the IUCN Red List (IUCN, 2020). When exploitation is directly targeted on a single species, extinction is expected to be relatively uncommon (e.g. Grafton et al., 2007). This is because as population size decreases, search costs nearly always begin to outweigh revenue, except in obvious cases where species are extraordinarily valuable or can be easily exploited (e.g., dodos). Nevertheless, extinction and serious depletion have been reported for many exploited species, resulting in a variety of hypotheses that provide explanations for high extinction risks under single-species exploitation, including tragedy of the commons (Feeny et al., 1990, 1996; Hardin, 1968; Ostrom, 1999; Ostrom et al., 1999), economics of overexploitation (Clark, 1973; Grafton et al., 2007), the Allee effect (Allee, 1931; Stephens et al., 1999), and the anthropogenic Allee effect (Courchamp et al., 2006). Intrinsic biological factors that decrease mean individual fitness at low population sizes can also increase extinction risk, collectively termed the Allee effect (Allee, 1931; Stephens et al., 1999). Reproduction and survival can be diminished in small populations through numerous mechanisms, which include mate shortage, lack of cooperation, and genetic Allee effects such as inbreeding depression. In such cases, species can suffer reproductive failure at low densities, resulting in rapid extinction once the population falls below a minimum population size. This phenomenon has been blamed for the demise of passenger pigeons (e.g., Stephens and Sutherland, 1999). An allied hypothesis is the anthropogenic Allee effect, where instead of lower survival at low numbers, income from exploitation increases markedly at low numbers (Courchamp et al., 2006). The classic case is when rare products such as beluga sturgeon caviar become disproportionately valuable because of their rarity, allowing for profitable overexploitation. Examples of species experiencing anthropogenic Allee effects include spectacular butterflies sought by collectors, goat-antelopes (family Caprinae) sought by trophy hunters, geckos (Goniurosaurus luii) captured to be exotic pets, large game birds (Tetrao urogallus) impacted by ecotourism, and the Chinese bahaba exploited for its perceived medicinal value (Courchamp et al., 2006; Holden and McDonald-Madden, 2017). In short, sometimes people are prepared to pay exorbitant prices to hunt, collect, or own specimens of the rarest species. All preceding explanations assume single-species exploitation, but when exploitation directly targets more than one species, the number of extinction pathways expands. For example, when many species are exploited together (e.g., through fisheries trawling gear), attempting to maximize overall revenue causes some species to decline to low levels (e.g., Hilborn et al., 2012; Ricker, 1958). Three modes of exploitation can be distinguished depending on the relative value of the various species: accidental exploitation, where there is accidental by-catch while targeting a species with economic value (Hall et al., 2000; Rasmussen et al., 2011); incidental exploitation, in which a less-desirable species with lower economic value is exploited while pursuing a higher-value target species (Megalofonou, 2005); and opportunistic exploitation, where a rare species with high monetary value is stumbled upon during targeted exploitation of a more abundant, less valuable target species (Branch et al., 2013). Opportunistic exploitation allows for valuable, yet scarce, species (hereafter, rare species) to be exploited while profitably targeting another more common species, because there are reduced (or zero) search costs associated with exploitation of the rare species. Thus, in multispecies exploitation scenarios there is a continuum of extinction pathways from accidental exploitation to incidental exploitation to opportunistic exploitation as value of the vulnerable species increases relative to other targeted species. Of these three pathways, opportunistic exploitation is most problematic since this mode involves the greatest economic incentive to continue exploitation of the species most at risk (Branch et al., 2013). Consider the case where black rhinoceroses (Diceros bicornis) were hunted to extinction in the Luangwa Valley, Zambia, even though illegally poaching rhino alone was not profitable due to their rarity (Milner-Gulland and Leader-Williams, 1992). Hypotheses assuming only single-species systems cannot fully explain this extinction event. In this case, illegal poaching was profitable when elephants and rhinos were hunted together, and as rhinos became rare, elephants became the main target (Milner-Gulland and Leader-Williams, 1992). Thus, opportunistic exploitation contributed to the extinction of black rhinoceros in Zambia in the 1990s (Chomba and Matandiko, 2011).

# Pharma DA

**Pharma profits are up from COVID vaccines, patent waivers threaten this**

**Buchholz 5-17-21**

(Katharina, https://www.statista.com/chart/24829/net-income-profit-pharma-companies/)

The profitability of coronavirus vaccines has been in the spotlight since U.S. President Joe Biden come out in support of temporarily lifting vaccine patents to make the production of the life-saving inoculations more financially feasible for poorer countries. EU leaders meanwhile remain divided over such a move. Company financial reports show that COVID-19 vaccine makers and developers like Johnson & Johnson, Pfizer, Moderna, AstraZeneca and BioNTech have seen their profits increase since the vaccine rollout, at times majorly. In early May, stocks of several companies that benefit from COVID-19 vaccine sales **took a nosedive on the news of Biden’s reversal**. Moderna stocks, for example, were still down more than 6 percent at close on May 5, the day of the announcement. Stocks recovered somewhat as German chancellor Angela Merkel came out against patent waivers the following day. While fluctuations in the stock market price have hurt drug makers in the **short term**, patent waivers would diminish the bottom line of companies involved with the development and production of COVID-19 **vaccines in the long term**. Pharma giants like Johnson & Johnson and Pfizer bring in billions of dollars of income every quarter from diverse sources, so the COVID bump was smaller for them. In the case of Pfizer, which has been a bigger producer than J&J, the year-over-year profit increase was a handsome 44 percent, however. For smaller AstraZeneca, the COVID year meant that its profits doubled. In the case of Moderna, the past year has turned a Q1 loss into a profit. The case is similar for German company BioNTech, which collaborated with Pfizer on its COVID vaccine. While Q1 2021 brought in a profit of $1.1 billion, the company ran a deficit since its founding in 2008 up until Q4 2020, when it posted a profit for the first time. The $446 million earned stood in contrast to losses of almost $428 million accrued in the first nine months of the year.

**Strong IP protection spurs innovation by encouraging risk-taking and incentivizing knowledge sharing -- prefer statistical analysis of multiple studies**

**Ezell and Cory 19** [Stephen Ezell, vice president & global innovation policy @ ITIF, BS Georgetown School of Foreign Service. Nigel Cory, associate director covering trade policy @ ITIF, MA public policy @ Georgetown. "The Way Forward for Intellectual Property Internationally," Information Technology & Innovation Foundation, 4-25-2019, accessed 8-25-2021, https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally] HWIC

IPRs Strengthen Innovation

Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that countries with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.46

IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47 In contrast, IPR reform has been associated with increased innovative activity, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts.

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The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that R&D to GDP ratios are positively related to the strength of patent rights, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56

**Biopharmaceutical innovation is key to prevent future pandemics and bioterror**

**Marjanovic and Feijao 20** [Sonja Marjanovic Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon. "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, accessed 8-8-2021, https://www.rand.org/pubs/perspectives/PEA407-1.html] HWIC

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences 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 context.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 competition 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 pharmaceutical 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 sector. 2 It is therefore unsurprising that we are seeing industry-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 compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials 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 accelerate 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 relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure 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 combination product that is being tested for therapeutic potential 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, bioterrorism 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 immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious 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 contributions 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 innovation conditions.

**That causes extinction, which outweighs.**

**Millett & Snyder-Beattie ‘17**. Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **Historically, disease events have been responsible for the greatest death tolls** on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to **remote populations**, overcome **rare genetic resistances**, and **evade detection**, cures, and **countermeasures**. Even evolution itself may work in humanity's favor: **Virulence and transmission is often a trade-off**, and so **evolutionary pressures** could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they **do not rule** the possibility **out** entirely. Although rare, there are recorded instances of **species going extinct due to disease**—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also **historical examples of large human populations being almost entirely wiped out** by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include **native American tribes** exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But **many diseases are proof** of principle that **each worst-case attribute can be realized independently**. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, **natural evolution** would be an **unlikely** source for pathogens with the **highest possible levels of transmissibility, virulence, and global reach**. But **advances in biotech**nology might allow the creation of diseases that **combine such traits**. Recent controversy has **already emerged** over a number of **scientific experiments** that resulted in viruses with enhanced **transmissibility**, **lethality**, and/or the ability to overcome **therapeutics**.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a **long historical track record** of**state-run bioweapon research** applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and **m**utually **a**ssured **d**estruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The **possibility of a war** between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

#### Climate change is causing catastrophic diseases to emerge from thawed permafrost. Some have been dormant for millennia—humans will have difficulty combatting them.

Goudarzi 16

Sara Goudarzi, 11-1-2016, "As Earth Warms, the Diseases That May Lie within Permafrost Become a Bigger Worry," Scientific American, <https://www.scientificamerican.com/article/as-earth-warms-the-diseases-that-may-lie-within-permafrost-become-a-bigger-worry/> (ML)

This past summer anthrax killed a 12-year-old boy in a remote part of Siberia. At least 20 other people, also from the Yamal Peninsula, were diagnosed with the potentially deadly disease after approximately 100 suspected cases were hospitalized. Additionally, more than 2,300 reindeer in the area died from the infection. The likely cause? Thawing permafrost. According to Russian officials, thawed permafrost—a permanently frozen layer of soil—released previously immobile spores of Bacillus anthracis into nearby water and soil and then into the food supply. The outbreak was the region's first in 75 years. Researchers have predicted for years that one of the effects of global warming could be that whatever is frozen in permafrost—such as ancient bacteria—might be released as temperatures climb. This could include infectious agents humans might not be prepared for, or have immunity to, the scientists said. Now they are witnessing the theoretical turning into reality: infectious microorganisms emerging from a deep freeze. Although anthrax occurs naturally in all soil and outbreaks unrelated to permafrost can occur, extensive permafrost thaw could increase the number of people exposed to anthrax bacteria. In a 2011 paper published in Global Health Action, co-authors Boris A. Revich and Marina A. Podolnaya wrote of their predictions: “As a consequence of permafrost melting, the vectors of deadly infections of the 18th and 19th centuries may come back, especially near the cemeteries where the victims of these infections were buried.” And permafrost is indeed thawing—at higher latitudes and to greater depths than ever before. In various parts of Siberia the active layer above permafrost can thaw to a depth of 50 centimeters every summer. This summer, however, there was a heat wave in the region, and temperatures hovered around 35 degrees Celsius—25 degrees warmer than usual. The difference possibly expanded or deepened the thaw and mobilized microorganisms usually stuck in rigid earth. Although scientists have yet to calculate the final depth, they postulate that it is a number that has not been seen in almost a century. Permafrost thaw overall could become widespread with temperatures only slightly higher than those at present, according to a 2013 study in Science. Heat waves in higher latitudes are becoming more frequent as well. What thawing permafrost could unleash depends on the heartiness of the infectious agent involved. A lot of microorganisms cannot survive in extreme cold, but some can withstand it for many years. “B. anthracis are special because they are sporulating bacteria,” says Jean-Michel Claverie, head of the Mediterranean Institute of Microbiology and a professor at Aix-Marseille University in France. “Spores are extremely resistant and, like seeds, can survive for longer than a century.” Viruses could also survive for lengthy periods. In 2014 and 2015 Claverie and his colleague Chantal Abergel published their findings on two still infectious viruses from a chunk of 30,000-year-old Siberian permafrost. Although Pithovirus sibericum and Mollivirus sibericum can infect only amoebas, the discovery is an indication that viruses that infect humans—such as smallpox and the Spanish flu—could potentially be preserved in permafrost. Human viruses from even further back could also make a showing. For instance, the microorganisms living on and within the early humans who populated the Arctic could still be frozen in the soil. “There are hints that Neandertals and Denisovans could have settled in northern Siberia [and] were plagued by various viral diseases, some of which we know, like smallpox, and some others that might have disappeared,” Claverie says. “The fact that there might be an infection continuity between us and ancient hominins is fascinating—and might be worrying.”

# Generics

## Impact Defense

### No extinction, surveillance solves

#### Surveillance efforts prevent extinction from future pandemics

Maureen **Miller**, Adjunct Associate Professor of Epidemiology, 8-1-20**21**, "The next pandemic is already happening – targeted disease surveillance can help prevent it," No Publication, https://www.yahoo.com/now/next-pandemic-already-happening-targeted-130202377.html?guccounter=1

As more and more people around the world are getting vaccinated, one can almost hear the collective sigh of relief. But the next pandemic threat is likely already making its way through the population right now. My research as an infectious disease epidemiologist has found that there is a simple strategy to mitigate emerging outbreaks: proactive, real-time surveillance in settings where animal-to-human disease spillover is most likely to occur. In other words, don’t wait for sick people to show up at a hospital. Instead, monitor populations where disease spillover actually happens. The current pandemic prevention strategy Global health professionals have long known that pandemics fueled by [zoonotic disease spillover](https://www.news-medical.net/health/What-is-a-Spillover-Event.aspx), or animal-to-human disease transmission, were a problem. In 1947, the World Health Organization established a global network of hospitals to [detect pandemic threats](https://www.who.int/influenza/gip-anniversary/en/) through a process called [syndromic surveillance](https://www.cdc.gov/nssp/overview.html). The process relies on standardized symptom checklists to look for signals of emerging or reemerging diseases of pandemic potential among patient populations with symptoms that can’t be easily diagnosed. This clinical strategy relies both on infected individuals coming to [sentinel hospitals](https://apps.who.int/iris/bitstream/handle/10665/259884/9789241513623-eng.pdf) and medical authorities who are [influential and persistent](https://www.bbc.com/news/world-asia-china-51364382) enough to raise the alarm. There’s only one hitch: By the time someone sick shows up at a hospital, an outbreak has already occurred. In the case of [SARS-CoV-2, the virus that causes COVID-19](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it), it was likely widespread long before it was detected. This time, the clinical strategy alone failed us. Zoonotic disease spillover is not one and done A more proactive approach is currently gaining prominence in the world of pandemic prevention: viral evolutionary theory. This theory suggests that [animal viruses become dangerous human viruses](https://doi.org/10.3390/v13040637) incrementally over time through frequent zoonotic spillover. It’s not a one-time deal: An “intermediary” animal such as a civet cat, pangolin or pig may be required to mutate the virus so it can make initial jumps to people. But the final host that allows a variant to become fully adapted to humans may be humans themselves. Viral evolutionary theory is playing out in real time with the rapid development of [COVID-19 variants](https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html). In fact, an international team of scientists have proposed that undetected human-to-human transmission after an animal-to-human jump is the likely [origin of SARS-CoV-2](https://doi.org/10.1038/s41591-020-0820-9). When novel zoonotic viral disease outbreaks like Ebola first came to the world’s attention in the 1970s, research on the extent of disease transmission relied on [antibody assays](https://www.cdc.gov/coronavirus/2019-ncov/testing/serology-overview.html), blood tests to identify people who have already been infected. Antibody surveillance, also called [serosurveys](https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/geographic-seroprevalence-surveys.html), test blood samples from target populations to identify how many people have been infected. Serosurveys help determine whether diseases like Ebola are circulating undetected. Turns out they were: Ebola antibodies were found in more than 5% of people tested in Liberia in 1982 decades before the West African epidemic in 2014. These results support viral evolutionary theory: It takes time – sometimes a lot of time – to make an animal virus dangerous and transmissible between humans. What this also means is that scientists have a chance to intervene. Measuring zoonotic disease spillover One way to take advantage of the lead time for animal viruses to fully adapt to humans is long-term, repeated surveillance. Setting up a [pandemic threats warning system](http://dx.doi.org/10.2471/BLT.16.175984) with this strategy in mind could help [detect pre-pandemic viruses](https://doi.org/10.3390/v13040637) before they become harmful to humans. And the best place to start is directly at the source. My team worked with [virologist Shi Zhengli](https://www.scientificamerican.com/article/how-chinas-bat-woman-hunted-down-viruses-from-sars-to-the-new-coronavirus1/) of the Wuhan Institute of Virology to develop a human antibody assay to test for a very distant cousin of SARS-CoV-2 found in bats. We established proof of zoonotic spillover in a small 2015 serosurvey in Yunnan, China: [3% of study participants living near bats](https://doi.org/10.1007/s12250-018-0012-7) carrying this SARS-like coronavirus tested antibody positive. But there was one unexpected result: None of the previously infected study participants reported any harmful health effects. Earlier spillovers of SARS coronaviruses – like the first SARS epidemic in 2003 and Middle Eastern Respiratory Syndrome (MERS) in 2012 – had caused high levels of illness and death. This one did no such thing. Researchers conducted a larger study in Southern China between 2015 and 2017. It’s a region home to bats known to carry SARS-like coronaviruses, including the one that caused the [original 2003 SARS pandemic](https://doi.org/10.1038/nature12711) and the one [most closely related to SARS-CoV-2](https://doi.org/10.1038/s41586-020-2012-7). Fewer than 1% of participants in this study tested antibody positive, meaning they had been previously infected with the SARS-like coronavirus. Again, none of them reported negative health effects. But syndromic surveillance – the same strategy used by sentinel hospitals – revealed something even more unexpected: An additional [5% of community participants](https://doi.org/10.1016/j.bsheal.2019.10.004) reported symptoms consistent with SARS in the past year. This study did more than just provide the biological evidence needed to establish proof of concept to measure zoonotic spillover. The pandemic threats warning system also picked up a signal for a SARS-like infection that couldn’t yet be detected through blood tests. It may even have detected early variants of SARS-CoV-2. Had surveillance protocols been in place, these results would have triggered a search for community members who may have been part of an undetected outbreak. But without an established plan, the signal was missed. From prediction to surveillance to genetic sequencing The lion’s share of pandemic prevention funding and effort over the past two decades has focused on discovering wildlife pathogens, and predicting pandemics before animal viruses can infect humans. But this approach has not predicted any major zoonotic disease outbreaks – including H1N1 influenza in 2009, MERS in 2012, the West African Ebola epidemic in 2014 or the current COVID-19 pandemic. Predictive modeling has, however, provided robust heat maps of the [global “hot spots”](https://doi.org/10.1038/s41467-017-00923-8) where zoonotic spillover is most likely to occur. Long-term, regular surveillance at these “hot spots” could detect spillover signals, as well as any changes that occur over time. These could include an uptick in antibody-positive individuals, increased levels of illness and demographic changes among infected people. As with any proactive disease surveillance, if a signal is detected, an outbreak investigation would follow. People identified with [symptoms that can’t be easily diagnosed](https://doi.org/10.1038/d41586-018-05373-w) can then be screened using genetic sequencing to characterize and identify new viruses. This is exactly what Greg Gray and his team from Duke University did in their search for [undiscovered coronaviruses](https://doi.org/10.1093/cid/ciaa347) in rural Sarawak, Malaysia, a known “hot spot” for zoonotic spillover. Eight of 301 specimens collected from pneumonia patients hospitalized in 2017-2018 were found to have a canine coronavirus never before seen in humans. Complete viral genome sequencing not only suggested that it had recently jumped from an animal host – it also harbored the same mutation that made both SARS and SARS-CoV-2 so deadly. [[The Conversation’s most important coronavirus headlines, weekly in a science newsletter](https://theconversation.com/us/newsletters/science-editors-picks-71/?utm_source=Yahoo&utm_medium=inline-link&utm_campaign=newsletter-text&utm_content=science-corona-important)] Let’s not miss the next pandemic warning signal The good news is that surveillance infrastructure in global “hot spots” already exists. The [Connecting Organisations for Regional Disease Surveillance](https://www.cordsnetwork.org/) program links six regional disease surveillance networks in 28 countries. They pioneered “participant surveillance,” partnering with communities at high risk for both initial zoonotic spillover and the gravest health outcomes to contribute to prevention efforts. For example, Cambodia, a country at risk of pandemic avian influenza spillover, established a free national hotline for community members to report animal illnesses directly to the Ministry of Health in real time. Boots-on-the-ground approaches like these are key to a timely and coordinated public health response to stop outbreaks before they become pandemics. It is easy to miss warning signals when global and local priorities are tentative. The same mistake need not happen again.

## Case Turns

### \*\*Generic

**Overreliance on vaccines hurts pandemic response at large**

**Lovelace 1/13**

[Berkeley Lovelace Jr., health-care reporter for CNBC, mainly covering pharmaceuticals and the Food and Drug Administration. “WHO says Covid vaccines aren’t ‘silver bullets’ and relying entirely on them has hurt nations,” CNBC, 1-13-2021, accessed 8-11-2021, https://www.cnbc.com/2021/01/15/who-says-covid-vaccines-arent-silver-bullets-and-relying-entirely-on-them-has-hurt-nations.html] HWIC

The World Health Organization said Friday that coronavirus vaccines aren’t “silver bullets” and relying solely on them to fight the pandemic has hurt nations. Some countries in Europe, Africa and the Americas are seeing spikes in Covid-19 cases “because we are collectively not succeeding at breaking the chains of transmission at the community level or within households,” WHO Director-General Tedros Adhanom Ghebreyesus said during a news conference from the agency’s Geneva headquarters. With [global deaths reaching 2 million](https://www.cnbc.com/2021/01/15/coronavirus-live-updates.html) and new variants of the virus appearing in multiple countries, world leaders need to do all they can to curb infections “through tried and tested public health measures,” Tedros said. “There is only one way out of this storm and that is to share the tools we have and commit to using them together.” The [coronavirus](https://www.cnbc.com/coronavirus/) has infected more than 93.3 million people worldwide and killed at least 2 million since the pandemic began about a year ago, according to data compiled by Johns Hopkins University. The virus continues to accelerate in some regions, with nations reporting that their supply of oxygen for Covid-19 patients is running “dangerously low,” the WHO said. Some countries, including the U.S., have focused heavily on the use of vaccines to combat their outbreaks. While vaccines are a useful tool, they will not end the pandemic alone, Mike Ryan, executive director of the WHO’s health emergencies program, said at the news conference. “We warned in 2020 that if we were to rely entirely on vaccines as the only solution, we could lose the very controlled measures that we had at our disposal at the time. And I think to some extent that has come true,” Ryan said, adding the colder seasons and the recent holidays also may have also played a role in the spread of the virus. “A big portion of the transmission has occurred because we are reducing our physical distancing. ... We are not breaking the chains of transmission. The virus is exploiting our lack of tactical commitment,” he added. “We are not doing as well as we could.” Dr. Bruce Aylward, a senior advisor to the WHO’s director-general, echoed Ryan’s comments, saying, vaccines are not “silver bullets” “Things can get worse, numbers can go up,” he said. We have vaccines, yes. But we have limited supplies of vaccines that will be rolled out slowly across the world. And vaccines are not perfect. They don’t protect everyone against every situation.” In the U.S., the pace of vaccinations is going slower than officials had hoped. As of Friday at 6 a.m. ET, more than 31.1 million doses of vaccine had been distributed across the U.S., but just over 12.2 million shots have been administered, according to data compiled by the Centers for Disease Control and Prevention. Meanwhile, cases are rapidly growing, with the U.S. recording at least 238,800 new Covid-19 cases and at least 3,310 virus-related deaths each day, based on a seven-day average calculated by CNBC using Johns Hopkins data. On Thursday, President-elect Joe Biden [unveiled a sweeping plan](https://www.cnbc.com/2021/01/14/biden-unveils-sweeping-plan-to-combat-the-covid-pandemic-in-the-us.html) to combat the coronavirus pandemic in the United States. While his administration will invest billions in a vaccine campaign, it will also scale up testing, invest in new treatments and work to identify new strains, among other measures.

#### IP protections don’t cause disease spread because patent incidence is low and independently increases access- prefer empirics.

Stevens 04

[Philip Stevens, Director of Health Projects at the International Policy Network. “Diseases of poverty and the 10/90 Gap.” November 2004. <https://www.who.int/intellectualproperty/submissions/InternationalPolicyNetwork.pdf>] AL

Much debate on this issue of access has centred around the claim that patents held by pharmaceutical companies are a significant contributor to the dire health outcomes experienced by people in the poorest parts of the world. This claim is based on the premise that pharmaceutical companies use their patents to withhold drugs from poorer people in order to maximise their profits. However, **this premise is false.** A study by Amir Attaran has shown that in 65 low- and middleincome countries, where four billion people live, **patenting is rare for the 319 products** on the World Health Organisation’s Model List of Essential Medicines. Only seventeen essential medicines on the list are on patent in any of the countries, so that **overall patent incidence is low (1.4 percent)** and concentrated in larger markets. Those drugs on patent include 12 antiretrovirals and one antifungal, with most of those ARVs belonging to one company.30 Furthermore, **many companies choose not to enforce their patents** in certain lower-income countries. Of the 969 cases surveyed by Attaran where companies probably could have obtained and maintained patents for these essential medicines, they did so only 31 per cent of the time. However, intellectual property rights (IPR) are still important factor in ensuring access to essential medicines. Without IPR, it is **unlikely that sufficient incentives would have existed to develop many of the 319 products on the WHO’s essential medicines list in the first place.** This is substantiated by the fact that 90 per cent of the products on the list were originally discovered and/or developed by private companies.31

## Solvency Answers

**TL--Vaccines**

**No solvency and reject "empirical" claims -- vaccines require complex infrastructure to manufacture, not just patents**

**Hotez 5/10** [Peter J. Hotez, Maria Elena Bottazzi, and Prashant Yadav. "Producing a Vaccine Requires More Than a Patent," Foreign Affairs, 5-10-2021, accessed 8-8-2021, https://www.foreignaffairs.com/articles/united-states/2021-05-10/producing-vaccine-requires-more-patent] HWIC

On May 5, President Joe Biden announced that the United States would support an international bid to waive intellectual property rights to vaccines for the duration of the coronavirus pandemic, thereby ostensibly allowing other countries to ramp up production even of the sophisticated technology behind the Pfizer-BioNTech and Moderna vaccines against COVID-19. Many in the global health community and developing world welcomed the decision as a victory for greater equity in vaccine distribution, in which middle- and low-income countries are lagging far behind wealthy ones. But the jubilation may be premature. The drive for intellectual property waivers originates in part from the world’s experience fighting the last war, against HIV/AIDS. Patent pools, intellectual property waivers, and other liberalizing mechanisms were urgent in assuring equity of access to lifesaving drugs during that epidemic. But these tools are better suited to medicines and other pharmaceuticals than to vaccines. Producing vaccines—particularly those as technologically complex as the messenger RNA (mRNA) inoculations against COVID-19—requires not only patents but an entire infrastructure that cannot be transferred overnight. The sharing of patents is an important and welcome development for the long term, but it may not even be the most pressing first step. JUST OPEN THE SPIGOT At the turn of the millennium, multinational pharmaceutical companies were charging $10,000 per patient for a daily drug regimen that could keep those infected with HIV/AIDS alive. Those in low- and middle-income countries in Africa and elsewhere could access this cocktail only under limited circumstances. Then, in 2001, the Indian drug manufacturer Cipla Limited began producing versions of a triple antiretroviral drug cocktail for a mere $350. Cipla, in collaboration with Médecins Sans Frontières (Doctors Without Borders), helped usher in a new era of global access to essential medicines—one that justified relaxing or even ignoring international patents and other property rights to produce and distribute an important and lifesaving drug as a generic. Since that time, global health advocacy organizations have found increasingly sophisticated ways to work with multinationals in ensuring access to essential medicines for low- and middle-income countries. In the 2010s, the global health initiative Unitaid helped create a Medicines Patent Pool, in which pharmaceutical companies from all over the world offered antiretroviral drug licenses, thereby creating a path for developing generic versions so long as the patent holders received royalties. The mechanism supplied voluntary licenses to new producers even while protecting the legal rights of the drugs’ original manufacturers. Companies such as Gilead, for example, have supplied voluntary licenses for their antivirals directly to generic manufacturers, allowing for tiered pricing across countries. Barely any COVID-19 vaccines have been administered in the African continent or in low- or middle-income countries in Asia and Latin America. Global health professionals have understandably sought to ascertain whether a similar approach could help make the distribution of COVID-19 vaccines less lopsided. More than one billion vaccine doses have now been administered—but overwhelmingly to people living in just a few countries. More than half have been administered in the United States (250 million) and China (290 million) alone, followed by India (160 million), the United Kingdom (51 million), and Germany (32 million). In contrast, for all practical purposes, barely any COVID-19 vaccines have been [administered](https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html) in the African continent or in low- or middle-income countries in Asia and Latin America. Global health advocates have responded to this inequity by seeking to apply the lessons they learned from antiretroviral drugs and demanding patent pools or other intellectual property waivers for COVID-19 vaccines. In March 2021, Médecins Sans Frontières organized protests at the World Trade Organization (WTO) headquarters in Geneva, unfurling a banner that read, “No COVID Monopolies—Wealthy Countries Stop Blocking TRIPS Waiver,” referring to the organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights. The assumption underlying such demands is that intellectual property is a crucial barrier blocking vaccine developers, especially in low- and middle-income countries, from producing COVID-19 vaccines to scale—particularly the high-performing mRNA vaccines that Pfizer-BioNTech and Moderna currently produce. These vaccines elicit more than 90 percent protective immunity against both symptomatic illness and documented infection, including asymptomatic infection, with COVID-19. They are successfully driving the recovery of the United States, Israel, and other nations. But so far, mRNA vaccines are mostly invisible to Africa, Latin America, and low- and middle-income countries in other regions. The hope of those pushing for TRIPS waivers and patent pools is that these will unleash the technology to make the recovery global. IT TAKES A WHOLE ECOSYSTEM Intellectual property sharing may be helpful in the long term. But producing complicated biologics, especially innovative ones such as mRNA or adenovirus-vectored vaccines, is not solely a matter of patent access. Small-molecule antiviral drugs are comparatively straightforward: the multistep chemical processes through which they are synthesized are often fully detailed in published patents or scientific papers. Chemists and formulation experts can often synthesize and scale up production just from knowing the drug structure. But vaccines are different. Producing and manufacturing lipid-encased mRNA molecules, recombinant adenoviruses, or even the proteins or whole inactivated viruses used in older-generation vaccines requires a far higher level of sophistication than is needed for producing small-molecule drugs. Moreover, vaccine production must meet stringent requirements for quality control, quality assurance, and regulatory oversight. The **effective transfer of such complex technology requires a receiving ecosystem that can take years, sometimes decades, to build**. Countries seeking to ramp up vaccine production will need to train staff scientists and technicians. They will also need scientific administrators versed not only in basic research and development but also in detailed record keeping, including specific documentation practices such as batch production records. Moreover, they will need strong quality control systems and regulatory guardrails. Building such an infrastructure requires intensive training and often considerable financial investment and risk. It also takes time—by some estimates, vaccine development requires at least 11 years, and even then the probability that such efforts will result in bringing a vaccine to market is less than ten percent. Consider that the COVID-19 vaccines were themselves the outcome of decades of research and development. Few nations are prepared to take such risks. Only a handful of low- or middle-income countries currently have the capacity to produce new vaccines. Only a handful of low- or middle-income countries currently have the capacity to produce new vaccines. The most notable and largest is India, which currently makes the adenovirus-vectored vaccines developed by Janssen and by Oxford and AstraZeneca, as well as an older-technology recombinant protein vaccine and a whole inactivated virus vaccine. Manufacturers in Brazil, Cuba, and some Southeast Asian countries have experience producing childhood vaccines and may be able to develop the capacity to make COVID-19 vaccines as well. Other possibilities may develop elsewhere, including in the Middle East and Africa. But in the near term, such manufacturers will require financing, access to very large amounts of raw materials and supplies (possibly including relaxation of export controls), and some technical expertise in manufacturing and quality control if they are to produce the existing vaccines against COVID-19. Vaccinating India alone will require almost two billion doses, and more than 12 billion doses will be required to vaccinate the world. The emergence of new variants and the need for booster doses may increase demand even further. Whether mRNA vaccine technology can be scaled to produce billions of doses in 2021, or even by early 2022, remains entirely unknown, but the goal is worth pursuing. To this end, some kind of patent relaxation may be necessary, but far from sufficient. Would-be producers will need technical know-how, regulatory controls, and components that are currently in very short supply, such as nucleotides and lipids.

#### Tech transfer is key and not included under IP

Smith 05/05

(Laura Smith-Spark; Newsdesk Editor, CNN Digital; (05-05-21) Rich nations urged to share vaccine knowledge while WTO debates waiving patents; CNN; <https://www.cnn.com/2021/05/05/world/covid-19-vaccine-patents-wto-intl/index.html>; CKD)

Thomas Bollyky, director of the Global Health Program at the Council on Foreign Relations, told CNN on Friday that what's really needed to scale up global manufacturing of vaccines is technology transfer. "It's not just a matter of intellectual property. It's also the transfer of know-how," he said. "I don't think there's clear evidence that a waiver of an intellectual property is going to be the best way for that technology transfer to occur." Waiving patents will not work in the same way for vaccines as it has for drugs, Bollyky said. For HIV drugs, for example, manufacturers were more or less able to reverse engineer them without much help from the original developer. "It's very different for vaccines, where it's really a biological process as much as a product. It's hard to scale up manufacturing in this process for the original company, let alone another manufacturer trying to figure this out without assistance," he said. "It requires a lot of knowledge that's not part of the IP." The deal between AstraZeneca and the Serum Institute of India is a successful example of such technology transfer, Bollyky said, where the licensing of IP happened voluntarily. "The question is what can we do to facilitate more deals like the one between AstraZeneca and the Serum Institute of India to have this transfer," he said. Michael Head, senior research fellow in global health at the University of Southampton, in England, told CNN that increasing regional manufacturing capacity, particularly in the global south, was key -- and should be a focus between pandemics. "Sharing intellectual property during the pandemic is something that should happen but that doesn't resolve the issues," he said. "Manufacturing vaccines is hard. It's hard to rapidly set up a new site with all the equipment, infrastructure, all the vaccine ingredients, with suitable staff to produce a large number of high quality vaccine products." Philanthropist Bill Gates, a major supporter of [global Covid-19 vaccine equity](https://www.cnn.com/2021/02/05/world/covax-explainer-intl/index.html) through the Bill & Melinda Gates Foundation, also [told Sky News](https://news.sky.com/story/covid-19-bill-gates-hopeful-world-completely-back-to-normal-by-end-of-2022-and-vaccine-sharing-to-ramp-up-12285840) last month that he did not believe overriding IP rules was the answer. "There's only so many vaccine factories in the world and people are very serious about the safety of vaccines," he said. "The thing that's holding things back in this case is not intellectual property. There's not, like, some idle vaccine factory with regulatory approval that makes magically safe vaccines. You've got to do the trials on these things and every manufacturing process has to be looked at in a very careful way."

#### Equitable distribution of vaccines can’t combat disease spread because of other barriers like vaccine uptake, effectiveness, durability, eligibility factors, logistical problems, and mutations- ignore aff’s myopic promotions

MacLeod 2-10 [Iain MacLeod, co-founder and CEO of Aldatu Biosciences of Watertown, Massachusetts, which develops novel viral diagnostics, including those for pathogens such as SARS-CoV-2, and a research associate at the Harvard T.H. Chan School of Public Health. “Do the math: Vaccines alone won’t get us out of this pandemic.” February 10, 2021. <https://www.statnews.com/2021/02/10/vaccines-alone-wont-end-pandemic/>] AL

But it seems as if there is light at the end of the tunnel. As long as we maintain social distancing, keep wearing masks, and washing our hands, it feels to many as though we can hold on until we get vaccinated. I’m sorry to be writing the words that follow, but here they are: We can’t vaccinate our way out of this pandemic. And the myopic focus on achieving herd immunity through mass vaccination may even make it tougher for America — and the world — to defeat Covid-19. Don’t get me wrong: Mass vaccination is essential. But herd immunity is a numbers game. It is defined as the point at which community spread of a disease stops because unprotected individuals are surrounded by a “herd” of people who are immune to infection, making it difficult, if not impossible, for infected people to pass on the disease. Many experts have said we will achieve herd immunity when about 70% of the population is immune to SARS-CoV-2, the virus that causes Covid-19, either through vaccination or by having had Covid-19. How do we reach that number? It’s harder than it seems. For starters, while the Pfizer/BioNTech and Moderna vaccines showed about 95% efficacy in the clinical trials, **vaccine effectiveness** — how well a vaccine performs under real-world conditions — is likely to be lower for several reasons. One is that the people who participate in clinical trials are an imperfect representation of the whole population. They tend to be healthier, and younger. Real-world factors such as vaccine transportation and storage can also reduce vaccine effectiveness. Say the Moderna and Pfizer vaccines now being given across the country achieve 90% effectiveness. Vaccinating 70% of U.S. residents puts us at 63% immunity. So, we’ll need to vaccinate a full 80% of the population to reach the herd immunity threshold. **Additional vaccines are starting to be approved. Some of them have lower efficacy.** For instance, the AstraZeneca vaccine has about 70% efficacy, and Johnson & Johnson has reported that its one-dose vaccine has 66% efficacy. Their real-world performance could be lower still. If these vaccines become part of the mix in the U.S., actual protection will be lower than the estimated 90% we’d get from just the Moderna and Pfizer vaccines. There are other barriers to achieving herd immunity. Vaccine uptake — how many people actually get vaccinated — is far below the level we need, in part because Covid-19 beliefs have been politicized in the U.S. and a percentage of the population doesn’t even believe the disease is real. In a Kaiser Health News survey released near the end of January, 13% of Americans said they would “definitely not” get vaccinated, 7% would take the vaccine only if it was “required,” and another 31% would “wait and see how it’s working” before getting vaccinated. Not encouraging numbers for those hoping for a quick journey to herd immunity. Even when ample vaccine supplies are restored — perhaps by President Biden invoking the Defense Production Act — other factors will further drive down the number of people who get vaccinated. Eligibility factors currently exclude approximately 25% of U.S. residents from Covid-19 vaccination. The Pfizer vaccine can be administered only to those age 16 and up; for the Moderna vaccine, it’s those 18 and up. This represents approximately 20% of the population. Furthermore, although the CDC says that pregnant people may get vaccinated, it stops short of a clear recommendation. The decision is a “personal choice” left up to individuals and their health care providers. Excluding those currently ineligible for vaccination against SARS-CoV-2 due to age or other conditions leaves 75% of Americans with no restrictions on vaccination. Factoring in the 13% of Americans who definitely don’t want the vaccine and the 7% who would get it only if it was required means just 49.5% of Americans would have immunity in the near future. If half of those who are in a wait-and-see mode don’t get vaccinated — another 15% of the population — then we are looking at just 40% vaccine coverage of the currently eligible population, far below the 70% needed for herd immunity. And that’s even before considering that real-world vaccine effectiveness will be below clinical trial levels. The young people who aren’t cleared to get the Moderna and Pfizer vaccines have proven to be highly efficient asymptomatic spreaders of Covid-19. Leaving this population unprotected will enable the disease to continue to spread widely. Finally, we don’t yet know the durability of the immune response to the various vaccines. It may persist. Or it may wear off, leaving people vulnerable after they’ve been vaccinated and creating conditions for new outbreaks. If my years of global health work on the HIV/AIDS epidemic has taught me anything, it’s that even the best laid plans can’t anticipate every challenge. To vaccinate 75% of the U.S. population, approximately 248 million people — that’s nearly 500 million doses — are needed. And it means we need to be vaccinating nearly 2 million people a day so all of them are immune by the fall of 2021. As I write this, we’re vaccinating only about 1 million people a day. At that pace, Reuters estimates it would take until April 2022 for 75% of Americans to receive at least their first vaccine dose. And that’s only if everything goes well logistically (it won’t) and if there are no further mutations in SARS-CoV-2 that make combating it more difficult (there will be). It’s time to stop promoting the myopic belief that the unrealistic goal of herd immunity can be achieved in 2021 and start looking to reinforcing all aspects of the health care response as we start to concede that Covid-19 will become an endemic disease that will continue to lurk in the population. For the foreseeable future, that means continued physical distancing; occupancy limits in restaurants and other retail establishments; replacement of physical menus with smart phone-based menus to prevent surface spread of the virus, and more. We’ll also need to monitor people who have been vaccinated to gauge the durability of the immune system’s response and whether booster shots are necessary, as they are for tetanus and diphtheria. Finally, our nation’s public health infrastructure will need to be bolstered, putting in place new protocols to monitor for new variants of the virus as soon as they emerge. Can we defeat Covid-19? We can and we will. But setting sights on a near-term goal of achieving herd immunity ignores the math that governs the spread of disease. That approach is going to take a while. To get past Covid-19, we need to use all the tools available.