### 1NC - CP

#### International donors should allocate 30% of vertical disease funding towards infrastructure in developing nations.

#### Disease specific funding causes budget imbalances and inequity in treatment. Using that funding to improve primary health care is key to non-HIV diseases and pandemics.

De Maeseneer et al. ’20 (Jan De Maeseneer is the Head of the Department of Family Medicine and Primary Health Care of Ghent University. He is also the Director of the International Centre for Primary Health Care and Family Medicine; Jan De Maeseneer, Donald Li, Bjorg Palsdottir, November 2020, “Universal health coverage and primary health care: the 30 by 2030 campaign,” Bulletin of the World Health Organization, <https://www.researchgate.net/publication/345938887_Universal_health_coverage_and_primary_health_care_the_30_by_2030_campaign>)

The World Health Organization (WHO) considers primary health care a cornerstone of universal health coverage (UHC) and describes it as an approach to health and well-being centred on the needs and circumstances of individuals, families and communities. Primary health care should address physical, mental and social health and well-being, and is about providing whole-person care for health needs throughout life, not just treating a set of specific diseases.1 We argue that implementing primary health care should focus on broadbased participatory action, including integrated and comprehensive personcentred care, community development and social determinants of health. The 30 by 2030 campaign To prevent most diseases and treat people in a holistic way, community-based primary health-care systems need to be strengthened. Therefore, organizations such as the World Organization of Family Doctors, European Forum for Primary Care, African Forum for Primary Care, Primary Health Care and Family Medicine, as well as The Network: Towards Unity for Health and Training for Health Equity Network are launching the 30 by 2030 campaign in November 2020. These organizations call for international donors to assign 30% of their vertical top-down, disease oriented budgets to strengthening integrated horizontal community-based primary health-care systems by 2030. The campaign seeks to put into practice Resolution WHA62.12, which urges Member States “to encourage the development, integration and implementation of vertical programmes, including disease-specific programmes, in the context of integrated primary health care.”2 This integration should also allow primary health-care services to become more responsive to the health needs of populations. The campaign has two components: (i) information, analysis and awareness on the impact of vertical programmes on health systems; (ii) encouraging the use of 30% of vertical donor investment to strengthen primary health-care services through coordination, increased human resources and improved infrastructure. The first component The average public expenditure in the WHO Africa Region on non-primary health care (hospitals and specialist care, mostly used by population groups with high incomes) is up to three times higher than the spending on primary health care and prevention.3 Only one third of total spending on primary health care comes from governments, and the lower the country’s income, the lower the share. The predominant source of financing for primary health-care services are private and external funds, including out-of-pocket expenses.3 Most of these funds are channelled through categorical programmes – that is, programmes that focus on the health problems of specific population subgroups or conditions – with little funding going through integrated primary health-care services, which address health conditions in a holistic manner. In the strategy to achieve UHC, WHO has put forward the target of adding 1% of gross domestic product (GDP) to the budget of primary health care. In low-income countries, adding 1% of GDP to current primary healthcare expenditures would increase annual spending in this sector, per capita, from 26 United States dollars (US$) to US$ 33.4 Such an increase could help, but new strategies should be explored to further strengthen primary health care. In 2006, the United States President’s Emergency Plan for AIDS Relief (PEPFAR) provided Zambia with a budget of US$ 150 million targeted for human immunodeficiency virus (HIV), whereas the entire budget of the health ministry was only US$ 136 million. This is an example of unbalanced distribution of health funding, and it continues to occur across sub-Saharan Africa.5 In many countries in the African continent, people living with HIV receive free care, food and educational grants for their children, whereas those with other diseases receive poor care and still have to pay out-of-pocket, leading to inequity by disease. Worldwide, the primary care facilities that address all diseases across the life-cycle, including common illnesses such as diarrhoea, malnutrition and respiratory tract infections, are largely underfunded. In addition, salaries of health-care providers working for donor-funded vertical programmes are often more than double those of equally trained government workers in the fragile public health sector, creating an internal brain drain. Interviews with 796 alumni from a medical school in Uganda found an influence of the PEPFAR projects on career choices of health professionals, with almost half working for an HIV-related nongovernmental organization and only over one third for government. We recommend that donor funds earmarked for HIV be channelled to primary health-care budgets through the 30 by 2030 mechanism, to attract health workers into other disease areas and broaden health-care capacity.6 A review on the impact of global health initiatives on recipient country health systems in low- and middleincome countries selected three initiatives that accounted for an estimated two thirds of external funding earmarked for HIV/AIDS: the Global Fund to Fight AIDS, Tuberculosis and Malaria; the World Bank Multi-country AIDS Program; and PEPFAR. The review found the following effects of global health initiatives: distortion of recipient countries’ national health policies, notably through distracting governments from coordinated efforts to strengthen health systems and forcing health systems to adopt vertical, disease-specific projects.7 In the second decade of this century, a group of new vertical disease-oriented programmes focusing on noncommunicable diseases were developed by governments and major health actors. Evidence suggests that, the same as for infectious diseases, the best approach to tackle noncommunicable diseases is rather strengthening integrated primary health care. The long-term management of noncommunicable diseases requires much more than the implementation of standardized protocols and access to affordable essential drugs. Such management requires empowering people, reducing barriers to healthy lifestyles and providing care that reflects the values and goals of the individual patient. Evidence of the effectiveness of primary health care in reducing hospital admissions related to noncommunicable diseases is well documented, and multimorbidity among those with such diseases has been shown to be better tackled in primary health care.8 Evidence suggests that vertical disease-oriented programmes do not contribute to UHC. For example, in Mozambique, after nearly 15 years of significant foreign aid for health, 65% of the government’s health budget was funded by external donors in 2014. However, the health system coverage has barely changed: in 2014 the health workforce per population ratio was still among the five lowest in the world at 71/10 000, and the number of health facilities per capita was only 1/16 795 in 2015.9 The proportion of total governmental health expenditure allocated to health declined from 13.4% (US$ 109 million) in 2006 to 11.9% (US$ 138 million) in 2009 and 7.8% (US$ 481 million) in 2014, moving away from the Abuja target of 15%9 (whereby the increase in absolute numbers is due to the increase of GDP and of global government expenditure). Second component The first strategy of this campaign is direct investments to strengthen primary health care. Moreover, the 30 by 2030 campaign advocates for diagonal investments.10 Ethiopia offers an example, where the Global Fund, Gavi, the Vaccine Alliance and PEPFAR have collaborated with other donors to increase their financial support, therefore strengthening the primary health-care system. For example, 18.4% of the total Gavi support (US$ 173 million) between 2007 and 2018 was largely focused on the construction of primary health-care facilities, strengthening of the supply chain, laboratory management and training of primary health-care staff.11 When major donors launch a call for project proposals focusing on specific health conditions such as HIV, diabetes, mental health conditions, tuberculosis, malaria, or more recently, coronavirus disease 2019 (COVID-19) in low- and middle-income countries, applicants should make clear how they are going to improve primary healthcare service delivery and channel 30% of the resources into strengthening such service. This strengthening can be done by financing the cost of integrating the project in the local primary health-care system. Achieving such integration requires contributing to capacity building for primary health care, supporting infrastructure upgrading, strengthening leadership and organization and improving the community’s involvement. However, characteristics of high-quality care such as accessibility, continuity, coordination and person-centredness are also needed. Investment should also be made in assessing the impact of projects on the health system. Those authorities responsible for primary health-care development at project level (national, regional, provincial, district, community) should be involved in implementation. Moreover, together with other agents, the 30 by 2030 campaign will develop action plans to improve the government’s spending and governance efficiency, participatory processes at the community level and monitoring and evaluation processes. The organizations involved in the campaign, in the spirit of resolution WHA62.12, reiterate the importance to “train and retain adequate numbers of health workers, with appropriate skill mix, including primary health care nurses, midwives, allied health professionals and family physicians, able to work in a multidisciplinary context, in cooperation with community health workers in order to respond effectively to people’s health needs.”2 Resources could also be used to improve sustainability through better pay for teams of primary health-care professionals, preventing brain drain. The COVID-19 pandemic has documented the role primary health-care teams play in preparedness to address the challenges of a new, rapidly spreading disease. Where primary health-care services (community screening and testing, case investigation with support for home-based isolation or quarantine, triage at primary-care facilities) were effective, there was less pressure on hospitals.12 Not all countries have been able to respond to the pandemic from an effective primary health-care system, which is why we advocate for the 30 by 2030 campaign ([www.30by2030.net](http://www.30by2030.net)).

#### Current programs are inadequate in improving access; without strong infrastructure, HIV patients die from easily preventable infections, and ART drugs are leaked, creating resistant strains.

Buve et al. ’03 (Anne Buve, Sam Kalibala and James McIntyre from Institute of Tropical Medicine, Antwerp, Belgium; The Population Council, Nairobi, Kenya; and Perinatal HIV Research Unit, University of the Wltwatersrand, Johannesburg, South Africa; Anne Buve, Sam Kalibala, James McIntyre, 2003, “Stronger health systems for more effective HIV/AIDS prevention and care,” Int J Health Plann Mgmt, https://sci-hub.se/10.1002/hpm.725)

In some middle income countries with HIV epidemics of moderate severity, such as Brazil and Thailand, treatment with antiretroviral drugs has become a realistic option. The experiences from these countries, however, cannot readily be extrapolated to low income countries and middle income countries with high prevalence of HIV infection, such as Zambia, Zimbabwe, Botswana and South Africa (Table 1). In these countries ministries of health are faced with a double challenge: (1) how to ensure psychosocial support and management of opportunistic infections (treatment and prophylaxis) for all HIV-infected persons; and (2) how to meet the increasing demand for antiretroviral treatment. If, so far, public health services in developing countries have failed to provide appropriate care for the majority of HIV-infected patients, it is because they have been underfunded (lack of updating of skills and lack of supplies), rather than because the management of opportunistic infections requires sophisticated laboratory technology and special drugs that are not within the reach of public health services. The most common opportunistic infections in developing countries, including tuberculosis, community acquired pneumonia, chronic diarrhoea, candidiasis, can in principle be managed at the level of health centres and district hospitals. In many settings, however, this will require inputs to strengthen health services, including refresher training, motivation and regular supervision of health personnel, and regular supply of the necessary drugs and diagnostics. In many developing countries antiretroviral drugs have been circulating for some time in the private sector and even in the informal sector. Distribution or leakage of these drugs to an unregulated health sector constitutes a real danger for the development of drug resistance. The ultimate victims are the patients who may find themselves financially ruined and infected with a multi-drug resistant strain. This problem has several roots and requires solutions at several levels. At the central government level there needs to be the political will, as well as the technical capacity, to regulate the import, distribution and use of antiretroviral drugs within the private sector. But as long as the demand for antiretroviral treatment largely exceeds the supply and as long as health staff remains underpaid and demotivated, thefts and unsupervised use of drugs will remain a problem. While in Brazil and Thailand antiretroviral treatment is provided through a network of public health services that have a fair coverage (World Health Organization, 2000a), in most countries of sub-Saharan Africa only limited numbers of HIVinfected patients are on treatment. Outside the private for-profit sector antiretroviral treatment is available through UNAIDS and/or government supported initiatives in Senegal, Ivory Coast and Uganda. NGOs such as Me´decins sans Frontie`res have started pilot projects of access to antiretroviral treatment that are relatively small scale. Research projects, like randomised trials that compare different drug cocktails, cater for only a few hundred HIV-infected people each. Lastly, more and more employers in Africa are embarking on programmes of antiretroviral treatment for their workforce, including the diamond mines in Botswana, Goldfields in South Africa, Anglo-American in Zambia, the Kenya Ports Authority, the Bank of Uganda, the New Vision newspaper in Uganda and a multinational brewery in Central Africa. However, if the ultimate goals of programmes of access to antiretroviral treatment, are to put right an inequality, improve the overall life expectancy of HIVinfected people, decrease the transmission of HIV and mitigate the socio-economic impact, many more patients have to be reached than is currently the case. Scaling up of programmes of access to antiretroviral treatment is not only hampered by the drug prices and the lack of laboratory capacity to monitor HIV infection (Figure 1), but also by the lack of implementing capacity, in the first place skilled health care workers. Scaling up thus calls for massive investments in strengthening of health systems, including strengthening (or setting up) of a safe distribution system for antiretroviral drugs; training staff in prescribing antiretroviral treatment and in following-up patients; strengthening laboratories; and setting up systems to counsel patients and ensure compliance.

#### Independently, medical infrastructure is a prerequisite to the use of IP flexibilities like compulsory licensing in improving access.

Halaijan 13

Dina Halaijan (JD, Brooklyn Law School). “Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem.” Brooklyn Journal of International Law. Volume 38, Issue 3, Article 7 (2013). JDN. <https://brooklynworks.brooklaw.edu/cgi/viewcontent.cgi?article=1050&context=bjil>

4. Limitations Inherent in Developing Countries

Another impediment to the successful use of the TRIPS flexibilities and the successful achievement of its dual goals is the endemic and inherent characteristics of developing countries. Taking advantage of TRIPS flexibilities requires **technical expertise**, **intergovernmental coordination**, and **legal sophistication**, which are often lacking in developing governments.129 Thus, TRIPS flexibilities often do not benefit the least developed countries most in need of help, and rather help middle income countries such as India and Brazil.130 Developing countries also lack **proper disease diagnosis** capabilities, which hinders their ability to request proper quantities and types of medications in a compulsory license.131 Developing governments have been criticized for mass military spending when there are existing public health issues, and so they may need to reevaluate their priorities.132 Developing countries and their citizens may choose to spend funds on food rather than medication, even if costs are reduced, if insufficient funds exist to cover both costs.133 Additionally, some developing governments are corrupt and may resell medications at higher prices, rather than distributing the drugs to their citizens.134 A “scrupulous clean hands approach” must be practiced to ensure drugs are actually distributed at the lowest profitable prices, and unfortunately such practices have been questionable.135 Further, lobbying pressure and conflicting interests may create abusive overuse of compulsory licensing where, for example, “the chairman of a large generic drug manufacturer was also the Chairman of the Health Committee in Egypt’s upper house of Parliament at the time the [Viagra] compulsory license was issued [in Egypt].”13

### 1NC – Innovation

#### Pharmaceutical innovation is accelerating now – new medicines are substantially better than existing treatments.

Wills, MBA, and Lipkus, PhD, 20 – Todd J. Wills [Managing Director @ Chemical Abstracts Service, MBA from THE Ohio State University] and Alan H. Lipkus [Senior Data Analyst @ Chemical Abstracts Service, PhD Physical Chemistry from the University of Rochester], “Structural Approach to Assessing the Innovativeness of New Drugs Finds Accelerating Rate of Innovation,” ACS Medicinal Chemistry Letters, Vol. 11, 2020, <https://pubs.acs.org/doi/pdf/10.1021/acsmedchemlett.0c00319> C.VC

Despite recent concerns over an innovation crisis, this analysis shows pharmaceutical innovation has actually increased over the last several decades based on the structural novelty of approved NMEs. The higher proportion of Pioneers over the most recent decade is a sign that innovation within the industry is accelerating rather than slowing. It is also an encouraging sign for the state of innovation in drug discovery that these Pioneers are significantly more likely to be the source of promising new therapies that are expected to provide substantial clinical advantages over existing treatments. Drug hunters are discovering Pioneers in newer and less explored regions of chemical space as they are increasingly found on scaffolds first reported in the CAS REGISTRY five or less years prior to their IND year or on scaffolds populated with 50 or less other compounds at the time of IND.

As scale becomes less of a strategic advantage, Big Pharma’s share of Pioneers has decreased even though the number of Big Pharma originated Pioneers has increased. This has created a structural innovation gap between Big Pharma and the Rest of Ecosystem which has widened over the last two decades as the Rest of Ecosystem is now responsible for originating almost 3 out of every 4 Pioneers. Pioneers originated by the Rest of Ecosystem are increasingly on new scaffolds, while a majority of Big Pharma originated Pioneers have historically been on new scaffolds.

The work presented here was intended as a study of drug innovation at a macro level. As a result, it included substances of various sizes with different degrees of complexity belonging to a range of functional and drug classes. Even though it was outside the scope of the present work to study specific subsets, such focused studies could yield additional insights into how innovation at a more micro level has changed over time. Other interesting subsets of our data set are the shapes and scaffolds of the Settlers and Colonists. Many of these shapes and scaffolds are privileged in the sense that they are seemingly capable of serving as ligands for a diverse array of target proteins. A separate study of the Settlers and Colonists as well as their side chains could provide insights into possible target-specific innovation trends.

As it often takes more than 10 years after initial discovery for an experimental drug to gain FDA approval, any measure of drug innovation that relies on the time of approval incorporates a significant time lag between initial discovery and ultimate approval. However, characterizing drug innovation based on structural novelty provides a means to assess the forward-looking innovation potential of an experimental drug at the time of initial discovery by comparing its framework information (at the scaffold and shape level) with prior FDA-approved drugs. Therefore, a separate study of drug candidates with publically disclosed structures currently in clinical development could provide additional insights into innovation trends at an FDA regulatory review level and serve as a leading indicator of innovation trends at an FDA approval level.

Given the tremendous opportunity represented by the vast amount of chemical space yet to be explored, drug-hunters of all types will continue pushing the boundaries to find promising new therapies in previously unexplored areas of chemical space. The race to discover these new drugs will be fueled by further advancements in screening approaches and in-silico methods (including innovations related to machine learning algorithms and molecular representations). However, comprehensive data on known shapes and scaffolds can fast track the identification of meaningful open areas of chemical space (shapes or scaffolds that are potentially important but have never been used as the basis for a molecule) to further explore.

#### The biopharmaceutical industry is uniquely reliant on IP protections – undermining them would kill innovation by making an already expensive process completely unfeasible.

Kristina M. Lybecker, PhD, 17 [PhD Economics, Associate Professor of Economics @ Colorado College], “Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measures Up,” Fraser Institute, January 2017, <https://www.fraserinstitute.org/sites/default/files/intellectual-property-rights-protection-and-the%20biopharmaceutical-industry.pdf> C.VC

The unique structure of the innovative biopharmaceutical industry necessitates a variety of intellectual property protection mechanisms. In particular, the industry is characterized by a research and development (R&D) process that is lengthy, expensive, uncertain, and risky. According to DiMasi and colleagues, the estimated cost of developing a new medicine is US$2.6 billion (DiMasi, Grabowski, and Hansen, 2016).2 In addition, the time required to develop a new drug is also significant, averaging 10 to 15 years without any guarantee of success (PhRMA, n.d.). While these figures are highly controversial, biopharmaceutical innovation is unquestionably an expensive and lengthy undertaking.3 For the biopharmaceutical industry, innovation and its protection are essential and the source of both profits and growth. As such, patent protection is disproportionally more important for ensuring that the innovator appropriates the returns to R&D for the biopharmaceutical industry than virtually any other. Extending the findings of the 1987 “Yale Survey” (Levin, Klevorick, Nelson, and Winter, 1987), the “Carnegie Mellon Survey” established that while patents are again considered “unambiguously the least effective appropriability mechanisms,” the drug industry and other scholars regard them as strictly more effective than alternative mechanisms (Cohen, Nelson, and Walsh, 1996). The industry’s disproportionate reliance on patents and other forms of intellectual property protection is confirmed in numerous other studies.4

In essence, IPR protections provide innovative biopharmaceutical firms with an assurance of some return on their investment, thus creating incentives for the development of new technologies that could otherwise be easily replicated and sold by competitors. Due to the tremendous fixed costs required to develop new treatments and cures, a significant potential exists for free riding by follower firms, a market failure that would prevent investment in innovation were it not for the patents and other forms of intellectual property protections that provide a limited period of market exclusivity or other such incentives. Fundamentally, patents amount to an efficiency tradeoff. Society provides innovators with a limited period of market exclusivity to encourage innovation in exchange for public access to this knowledge. In exchange for the temporary static loss from market exclusivity, society gains complete knowledge of the innovation through disclosure, a permanent dynamic gain. Through this tradeoff, the existing patent system corrects the market failure that would stymie innovation. In its Apotex Inc. v. Wellcome Foundation Ltd. finding, Justice Binnie wrote for the Supreme Court of Canada, “A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the Patent Act” (para. 37).

The biopharmaceutical industry is characterized by a number of legal and economic issues that distinguish it from other research-intensive industries. Danzon (1999) describes three features that are particularly noteworthy. First, given that the biopharmaceutical industry is characterized by an unusually high rate of R&D, intellectual property protection provides for the potential for significant market power and monopoly pricing that raises numerous public health policy questions surrounding prices and profits. Second, virtually every aspect of the industry is heavily regulated, from safety and efficacy to promotion and advertising, to pricing and reimbursement. Danzon describes the impact of these regulations as “profound and multidimensional even within a single country, affecting consumption patterns, productivity, R&D and hence the supply of future technologies” (Danzon, 1999: 1056). Lastly, while research and development costs are borne solely by the innovator, the resulting product is a global public good. “Each country faces an incentive to adopt the regulatory policies that best control its pharmaceutical budget in the short run, free-riding on others to pay for the joint costs of R&D and ignoring cross-national spillovers of national regulatory policies through parallel trade and international price comparisons” (Danzon, 1999: 1056). The combination of these characteristics defines a set of unique economic and legal challenges for the innovation of new drugs and the public health policies that surround their production, marketing, and distribution.

Innovative companies make far greater investments in time, resources, and financial support than do generic firms. Notably, innovation-based companies spend more than 200 times that which generic companies spend on the development of a particular drug (CIPC, 2011: 10). In addition, the investment of time, from laboratory to market, is also close to double for innovative companies relative to generic producers. Table 1 highlights the differences in the drug development processes of innovative and generic companies. For innovative biopharmaceutical companies, the development process is expensive, risky, and time consuming, all of which points to the need for strong IP protection to encourage investment and ensure companies are able to recover their investments.

The risk involved in biopharmaceutical development is starkly illustrated in a recent report by Biotechnology Innovation Organization (BIO), which reports that less than one of every 10 drugs that enter clinical trials is ultimately approved by the Food and Drug Administration in the United States. The report finds a success rate of merely 9.6%, a calculation that is significantly smaller than the widely-cited 11.8% figure from a 2014 study by the Tufts University’s Center for the Study of Drug Development.5 The International Federation of Pharmaceutical Manufacturers and Associations (2012) estimates that more than 3,200 compounds were at different stages of development globally in 2011, but only 35 new medicines were launched (Dawson, 2015).

Fundamentally, research-based biopharmaceutical companies incur greater expenses and risk in the development of their products than do generic manufactures. These investments of time and financial resources should be recognized and the effective patent life should be sufficient to recoup these investments. Continued investment and innovation are contingent upon strong, effective intellectual property protection and the ability of innovative firms to recoup their investments. Patents and other forms of intellectual property protection are disproportionally important to the research-based biopharmaceutical industry. Consequently, the legal architecture necessary to foster a robust innovation-based industry is multifaceted and is a powerful force shaping the biopharmaceutical industry, its profitability, productivity, and innovative future.

**Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.**

**Marjanovic and Fejiao ‘20** 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.

#### Bioterrorism and future pandemics cause extinction.

Hamish De Bretton-Gordon, CBRN Expert @ British Army, 20 [Director @ DBG Defense, Consultant on CBRN and Biosecurity], “Biosecurity in the Wake of COVID-19: The Urgent Action Needed,” Combatting Terrorism Center Sentinel, November/December 2020, Volume 13, Issue 11, <https://ctc.usma.edu/biosecurity-in-the-wake-of-covid-19-the-urgent-action-needed/> C.VC

Policymakers around the world did not grasp just how large the impact of a bio threat could be. Beyond the enormous human and economic impact, the current pandemic has exposed the weakness, lack of preparedness, and poor responsiveness of healthcare systems of even highly developed countries like the United States and the United Kingdom. And the virus has inflicted carnage, even though SARS-CoV-2 (the virus that causes COVID-19) is not especially virulent. The world may be confronted with other viruses in the future whose combination of virulence (the harm a pathogen does to its host), transmissibility, and other characteristics pose much greater danger.

While overwhelming evidence points to SARS-CoV-2 spontaneously spreading to humans, the advances in synthetic biology and the growth in the number of Level 3 and 4 biocontainment facilities around the world storing deadly viruses1 mean there is also the very real possibility that in the future, bad actors will try to engineer or steal/obtain a highly transmissible and highly virulent virus and unleash it onto the world. Another risk is accidental releases from such biocontainment facilities.

COVID-19, a highly transmissible but not very virulent pathogen, has had a devastating global impact, a fact that will not have gone unnoticed by rogue states and terror organizations. Advances in synthetic biology have created tools that could be put to malevolent use. In the last two decades, scientists synthesized the poliovirus from its genetic sequence,2 recreated the 1918 Spanish flu virus,3 and succeeded in modifying the H5N1 avian flu virus so that it resulted (in a research laboratory) in airborne transmission among mammals.4 In the future, we should think of weaponized biology as no less of an existential threat to the planet than weaponized atomic science. It should also be noted that the fear and panic that even a medium-scale bioterror attack could create could have dangerous implications that may rival or even surpass the immediate loss of life.

The Need to Rethink Likelihood

Given the fact that in late 2019 when, as far as is known, COVID-19 cases first started emerging in China, it had been more than a century since the previous catastrophic outbreak (the 1918-1919 “Spanish flu” pandemic),d it was unsurprising that many thought of such pandemics as a one-in-a-100-year event. Such assumptions should no longer hold. The encroachment of human settlements into areas that had previously been sanctuaries for wildlife5 and the popularity in some parts of the world of markets where people and wild animals are brought into proximity have made it more likely viruses will make the species leap to human beings.e And when they do, as the COVID-19 pandemic illustrated, the interconnectedness of a world in which millions of people fly each day6 means they can spread very rapidly.

There is also growing concern about engineered viruses. Not only have advances in synthetic biology (SynBio) created growing capacity for extremely dangerous viruses to be engineered in a laboratory, but the number of people with access to potentially dangerous ‘dual use’ technology has greatly expanded and continues to expand, making malevolent use of such technology ever more likely.

In the August 2020 issue of this publication, scientists at the U.S. Military Academy at West Point warned that:

The wide availability of the protocols, procedures, and techniques necessary to produce and modify living organisms combined with an exponential increase in the availability of genetic data is leading to a revolution in science affecting the threat landscape that can be rivaled only by the development of the atomic bomb. As the technology improves, the level of education and skills necessary to engineer biological agents decreases. Whereas only state actors historically had the resources to develop and employ biological weapons, SynBio is changing the threat paradigm.

The cost threshold of engineering viruses is also lowering, with the West Point scientists warning that synthetic biology has “placed the ability to recreate some of the deadliest infectious diseases known well within the grasp of the state-sponsored terrorist and the talented non-state actor.”7

As already noted, another source of vulnerability is that deadly viruses could be stolen from or escape from a research laboratory. There are now around 50 Biosafety Level 4f facilities around the world, where the deadliest pathogens are stored and worked on, and this figure is set to increase in the next few years.g This is a large increase over the last 30 years, creating bigger risk of a breach. Of equal, if not greater concern are the thousands of Biosafety Level 3 labs globally,8 which handle deadly pathogens like COVID-19.9

Given what has been outlined above, the risk of a future destructive biological attack or another devastating global pandemic should no longer be seen as low. From this point forward, there should no higher priority for the international community than biosecurity.

## case

### Plan already done

#### WTO already did the AFF – Doha Declaration nullifies medical patents for developing countries struggling with pricing

**World Trade Organization 17** (World Trade Organization – you should know who this is, “WTO IP rules amended to ease poor countries’ access to affordable medicines”, <https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm>, 23 January 2017, EmmieeM)

**An amendment to** the agreement on **intellectual property entered** into force today (23 January) **securing for developing countries a legal pathway to access affordable medicines under WTO rules**.

The amendment to the WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement marks the first time since the organization opened its doors in 1995 that WTO accords have been amended.

The WTO Secretariat has received in recent days notifications from five members that they have ratified the protocol amending the WTO TRIPS Agreement. These notifications — from Burkina Faso, Nigeria, Liechtenstein, the United Arab Emirates and Viet Nam — brought to two-thirds the number of WTO members which have now ratified the amendment. The two-thirds threshold was needed to formally bring the amendment into the TRIPS Agreement.

Members took the decision to amend the TRIPS Agreement **specifically to adapt** the **rules** of the global trading system **to the public health needs of people in poor countries**. This action follows repeated calls from the multilateral system for acceptance of the amendment, most recently by the United Nations General Assembly High-Level Meeting on Ending AIDS in June 2016.

“This is an **extremely important amendment**. It **gives legal certainty that generic medicines can be exported at reasonable prices to satisfy the needs of countries with** no pharmaceutical production capacity, or those with **limited capacity**. By doing so, **it helps the most vulnerable** access the drugs that meet their needs, helping to deal with diseases such as HIV/AIDS, tuberculosis or malaria, as well as other epidemics. I am delighted that WTO members have now followed through on their commitment and brought this important measure into force,” said WTO Director-General Roberto Azevêdo. In video statements available here, some of the key players share their thoughts on the TRIPS amendment.

Unanimously adopted by WTO members in 2005, the protocol amending the TRIPS Agreement **makes permanent a mechanism to ease poorer WTO members’ access to affordable generic medicines produced in other countries**. The amendment **empowers** importing **developing and least-developed countries facing public health problems and lacking** the **capacity to produce drugs** generically to seek such medicines from third country producers under "compulsory licensing" arrangements. Normally, most medicines produced under compulsory licences can only be provided to the domestic market in the country where they are produced. This amendment allows exporting countries to grant compulsory licences to generic suppliers exclusively for the purpose of manufacturing and exporting needed medicines to countries lacking production capacity.

“As important as trade policy is, health and well-being must take precedence,” said Amina Mohamed, Kenya’s Foreign Minister who chaired the WTO General Council at the time when the amendment was approved in December 2005. “WTO members recognise this and have proven how seriously they take health issues by ratifying and putting into force an amendment to WTO rules which will facilitate access to essential medicines in low income countries.”

The amendment provides **a secure and sustained legal basis for** both potential exporters and importers to adopt legislation and establish the means needed to allow **countries** with limited or no production capacity **to import affordable generics from countries where pharmaceuticals are patented**. More and more WTO members are taking practical steps to implement the system in their laws. The bulk of global medicine exports is covered by laws enabling exports under this system, opening up new options for potential beneficiaries to access a wider range of potential suppliers and enabling new, innovative procurement strategies.

### AT Developing Countries

#### It doesn’t solve – there are tons of barriers to access to vaccines, especially in developing countries. Even if it’s legal to make generics, lack of raw materials, expertise, and production facilities mean the plan is a drop in the bucket for responding to global covid

Herper et al 21 [Matthew Herper Senior Writer, Medicine, Editorial Director of Events at STAT. "Waiver of patent rights on Covid-19 vaccines, in near term, may be more symbolic than substantive." https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/]

Prashant Yadav, a supply chain expert and senior fellow at the Center for Global Development, said the biggest barrier to increasing the global vaccine supply is a lack of raw materials and facilities that manufacture the billions of doses the world needs. Temporarily suspending some intellectual property, as the U.S. proposes to do, would have little effect on those problems, he said.

“My take is: By itself, it will not get us much benefit in increased manufacturing capacity,” Yadav said. “But as part of a larger package, it can.”

That larger package would include wealthy nations like the U.S. mounting an Operation Warp Speed-style effort to invest in manufacturing in low-income countries, he said, using their vast financial resources to actually produce vaccine doses rather than solely targeting patents.

Lawrence Gostin, director of the O’Neill Institute for National and Global Health Law at Georgetown Law, said the waiver is necessary but hardly sufficient. It will likely take months of international infighting before the proposal would take effect, he said, months during which would-be manufacturers would not have the right to start producing vaccines.

“We’re not talking about any immediate help for India or Latin America or other countries going through an enormous spread of the virus,” Gostin said. “While they’re going to be negotiating the text, the virus will be mutating.”