### 1NC

#### A. Interpretation: medicine refers to treatments and cures only. Affirmatives must not reduce other medical IP protections.

**B. Violation: vaccines are medical interventions, not medicines**

Elbe 10 [Stefan Elbe, director of the Centre for Global Health Policy and a professor of international relations at the University of Sussex. "Security and Global Health," ISBN 0745643744, accessed 8-10-2021, https://www.wiley.com/en-ee/Security+and+Global+Health-p-9780745643731] HWIC

Yet here too we must be careful not to overlook other types of medical intervention simultaneously pursued by the 'social' arm of modern medicine at the population level. Vaccines in particular continue to be particularly important medical interventions that repeatedly surface in a variety of different health security delib- erations. Strictly speaking, vaccines are not medicines because they consist of small concentrations of disease-causing microbes (or their derivatives) used to enhance a person's immuno-response to a future infection. As a public health measure, vaccines have therefore also been largely sidelined in the existing medicalization literature. Yet, generally speaking, vaccines too can be considered as medical inter- ventions. That is certainly how the World Health Organization views them, pointing out that 'vaccines are among the most important medical interventions for reducing illness and deaths' available today (WHO 2009a). Whereas pills and other therapies mark the tools of clinical medicine, vaccines play a crucial part in the arsenal of 'social' medicine and public health. Developing and rolling out of new vaccines against a range of current (and future) diseases therefore represents further evidence of how the rise of health security is also encouraging security to be practised through the introduction of new medical interventions in society.

**Vaccines are different from medicines in the context of intellectual property**

Garrison 04 [Christopher Garrison, Consultant Legal Advisor to WHO. "Intellectual Property Rights and Vaccines in Developing countries," 04-13-2004, accessed 9-2-2021, https://www.who.int/intellectualproperty/events/en/Background\_paper.pdf?ua=1] HWIC

In the last few years, there has been a substantial debate about how intellectual property impacts medicines and in particular how the TRIPS Agreement impacts access to medicines in the developing world. Vaccines are different from medicines in a number of important respects however (at least from the small molecule ‘pill’ medicines if not the newer ‘biotech’ medicines). The issues raised in the access to medicines debate may therefore apply to a greater or lesser extent for vaccines, depending on these differences. This section examines a few of the different forms of intellectual property rights that are relevant in the context of vaccines and outlines the impact of some of the differences between vaccines and medicines.

#### C. Reasons to prefer

#### 1. Limits -- allowing any patented medical intervention includes testing and screening methods, surgery, contact tracing software etc. which takes away generics like innovation bc that applies to pharmaceutical development not distribution of preventative measures which explodes neg prep burden

#### 2. Precision -- we cite the WHO which proves common usage -- they add a whole new caselist based on social medicine which kills predictability -- that's k2 pre-tournament prep and deep clash around the core topic controversy. Reject counter-interps without a positive vision of the topic -- otherwise they can always shift the goalposts

#### D. Paradigm issues

#### 1. Drop the debater -- they skewed the debate from the 1AC and T indicts their advocacy

#### 2. Competing interps -- you can't be reasonably topical and reasonability invites judge intervention

#### 3. No RVIs -- forcing the 1NC to go all in kills substance education and discourages checking abuse

### Vaccine Diplomacy CP

#### Text: The People’s Republic of China should offer Chinese developed vaccines and medical technology related to COVID-19 to the world for free

#### The CP massively ramps up Chinese “vaccine diplomacy” which solves the case

Juecheng and Yuwei 8-13-21

(Zhao and Hu, https://www.globaltimes.cn/page/202108/1231387.shtml)

One of China’s most valued contributions to the global fair accessibility to COVID-19 vaccines is to enable more developing countries to hone their ability to produce vaccines by themselves, Zha Daojiong, professor of International Political Economy from Peking University, who closely studies the global vaccine equitable allocation framework, told the Global Times in a recent exclusive interview. Sharing his insights on widely discussed “vaccine nationalism,” “wavering vaccine intellectual property,” and “COVAX operation challenges,” Zha believes that China is advocating negotiations among countries on equitable global distribution of vaccines from a humanitarian, and global perspective. China has vowed to make efforts to provide the world with 2 billion doses of COVID-19 vaccines this year and donate $100 million to COVAX to promote global vaccine provision. This commitment comes amid the rampaging Delta variant, which is bringing more challenges for developing countries to access vaccines and combat the pandemic while the West continues to drag its heels in fulfilling its promises. The promise was made at the first meeting of a forum on international cooperation on COVID-19 vaccines held on August 5. Zha suggested that the forum, alongside the Initiative for Belt and Road Partnership on COVID-19 Vaccine Cooperation, reflect China’s efforts to support long-term cooperation in the vaccine industry globally. However, some Western media have labeled China and Russia as the pioneers of the global "vaccine diplomacy" campaign. The choice of vaccines by countries has become the epitome of global geopolitics.   Foreign comments on China using "vaccine diplomacy" in a narrow geopolitical sense reflect the real competition among COVID-19 vaccine providers, Zha told the Global Times. Due to China’s mature vaccine technologies, longer shelf life and lower requirement for storage and transportation, Chinese made vaccines are a more preferable choice for many developing countries with relatively weak vaccination infrastructure . This has been reflected in the approval of Chinese vaccines in more than 100 countries. But the phenomenon of “vaccine nationalism” was never absent in the decision by governments to choose vaccines, Zha suggested. “For example, some countries and regions would include geopolitical factors in choosing vaccines. These countries would reject certain vaccines. Moreover, some media outlets refuse to accept the fact that the professional assessment of vaccine efficacy is also a scientific process. Instead, they made comments on potential vaccines based on their geopolitical interests. This is also a kind of “vaccine nationalism”. Voices blaming “vaccine nationalism” have long been present in developed countries. For instance, Zha recalled how, during the H1N1 pandemic of 2009 which affected more than 200 countries and regions for more than a year, certain developed countries bought out entire stocks of vaccines against H1N1 once they were developed. Though some of those countries had promised to donate vaccines to others after they met their vaccination needs, the virus had long disappeared before their donations were made. Therefore, many in other nations lost the opportunity of a timely vaccination. Providing assistance from one country to another in the field of infectious or non-infectious diseases is often referred to as "health diplomacy." Some international public health research literature support "health diplomacy" because cooperation in this field is conducive to the improvement of political, economic and diplomatic relations, Zha said. China has taken important steps to close the global vaccine gap, including the acceleration of large-scale production, boosting fair distribution, and licensing local production in more countries.

#### Successful vaccine diplomacy is key to overall Chinese Soft Power

Huang, PhD, 3-11-21

(YANZHONG HUANG is Senior Fellow for Global Health at the Council on Foreign Relations, a Professor at Seton Hall University’s School of Diplomacy and International Relations, and Director of the school’s Center for Global Health Studies. https://www.foreignaffairs.com/articles/china/2021-03-11/vaccine-diplomacy-paying-china )

Vaccines have had a place in diplomacy since the Cold War era. The country that can manufacture and distribute lifesaving injections to others less fortunate sees a return on its investment in the form of soft power: prestige, goodwill, perhaps a degree of indebtedness, even awe. Today the country moving fastest toward consolidating these gains may be China, under President Xi Jinping, who proclaimed last May that Chinese-made vaccines against COVID-19 would become a “global public good.” Since that time, top officials have promised many developing countries priority access to Chinese vaccines, and the Chinese Foreign Ministry has announced that the country is providing free vaccines to 69 countries and commercially exporting them to 28 more. China’s competitors worry that where Beijing’s inoculations go, its influence will follow. But the field of COVID-19 vaccination is still a largely uncharted one and scattered with barriers, whether logistical, scientific, psychological, or geopolitical. China’s path through this labyrinth is neither obvious nor assured. The country faces stiffening competition from Russia and India. Now the United States, too, has entered the global stakes for equitable distribution of safe and effective vaccines. China has yet to prove that it can fulfill the role it has taken on or win the trust of those it has offered to aid. CHINA'S STAKE The Chinese government dislikes the term “vaccine diplomacy.” The implication that China would distribute vaccine doses in order to broaden its global political influence is a “sinister” one, according to the official Xinhua News Agency. Rather, the Chinese government contends that “in promoting cooperation in combating the pandemic, China does not seek any geopolitical goals or have any economic interest considerations, and it has never attached any political strings.” Xi has further stressed that by distributing necessary goods in a crisis, China is merely acting as a responsible great power should. In this regard, China may seek to succeed with vaccines where it failed with masks: last spring, quality-control issues and clumsy propaganda tarnished the country’s efforts to supply medical products to the developed world. Now China is looking to showcase its global health leadership to lower- and middle-income countries, where it is distributing vaccines. But Beijing surely has additional foreign policy objectives in mind. China began its vaccine development projects early last spring, and state media made quite clear that through them, China hoped to demonstrate its technological prowess and the superiority of its authoritarian model of governance. “We are not lagging behind the United States as far as the technology is concerned,” a Chinese virologist told the state-backed Global Times. Another scientist highlighted China’s “system advantages”: “The United States is no match for China in terms of concentrating power to accomplish big things.” Indeed, unlike in the United States, vaccine development in China was a highly state-driven process. The Chinese government simultaneously pushed several technological approaches, including inactivated vaccines, mRNA vaccines, and adenovirus vector vaccines. It mobilized at least 22 institutes and firms to work on 17 vaccine development projects. And until last summer, China was leading the global race in vaccine development. It developed a vaccine (Ad5-nCoV) as early as February 2020, started Phase 1 clinical trials on March 16, and published results of the trials in late May. General Chen Wei, the face of China’s vaccine development operation, celebrated such achievements as “an embodiment of our country’s S&T progress, an embodiment of China’s great-power image and responsibility, and, even more, a contribution to humankind.” Behind such lofty goals lie commercial objectives, too. Health-related development assistance has long offered Chinese pharmaceutical companies a low-cost means of expanding their market share in the developing world. In March 2020, President Xi explicitly linked the shipment of medical supplies overseas to the “Health Silk Road,” now an important component of the Belt and Road Initiative. Xiaofeng Liang, a former deputy director of the Chinese Center for Disease Control and Prevention, has publicly called for prioritizing BRI countries for access to Chinese vaccines. But the opportunity hardly ends there. Prior to the COVID-19 pandemic, few Chinese pharmaceutical companies had received World Health Organization prequalification to supply medical products to international organizations and donor funds. In 2019, China’s share in the value of UN-procured medical products was only 1.9 percent, compared with 21.9 percent for India. Chinese media lamented that of the 155 WHO-prequalified vaccines, only four were from China, compared with 44 from India. Indeed, Indian pharmaceutical firms produced more than 60 percent of the vaccines sold worldwide. The huge global demand for COVID-19 vaccines and “vaccine nationalism” in wealthy nations have created a great opportunity for China to break into a market that Indian and Western pharmaceutical firms have long dominated. If the vaccine were priced at $10 per dose with a 40 percent net profit margin, even a 15 percent share of the vaccine market in lower- and middle-income countries would generate total sales of $10.8 billion and a profit of $4.32 billion for the Chinese economy. In reality, Chinese vaccines are often priced higher than $10.

#### Chinese leadership stops global secessionist conflict

Griffiths 16 **-** Senior Lecturer in the Department of Government and International Relations at the University of Sydney (Ryan, States, Nations, and Territorial Stability: Why Chinese Hegemony Would Be Better for International Order, Security Studies, 25:3, 519-545, DOI: 10.1080/09636412.2016.1195628)

I began the article by claiming that the Pax Sinica would be better for international order. In making this claim I define “better” in narrow terms emphasizing territorial stability, which can be assessed in several ways. How often do either external aggressors or internal separatists shift sovereign borders through violence? What is the frequency of secessionist civil war? How much international discord is there on the topic of secession and recognition? This is the ledger I use when comparing the Pax Sinica with the post-1945 American-led order. There are many other factors, to be sure, and critics might point to a number of ways in which Chinese hegemony would be worse. For example, they may question the support for human rights under Chinese leadership. I do not argue that Chinese hegemony would be better in all ways—there are pros and cons to any order—but I contend that there are net benefits where territorial stability is concerned. Analyzed under these terms the key differences between the American order and the imagined Chinese order have to do with the politics of secession and sovereign recognition. International order matters because it determines diplomatic practices and shapes behavior. It sets the rules of the game. The American-led order over the last seventy years has attempted to balance the norms of territorial integrity and self-determination by establishing rules for what nations are eligible for independence. But, as Fabry notes, that is an enormously challenging project because developing clear rules that separate the lucky from the unlucky requires that states derive agreed-upon criteria in a constitutive process.73 Given the politics and conflicting principles of international life (and the evolving nature of normative arguments), inconsistency, ambiguity, and accusations of hypocrisy are unavoidable. The resulting political space creates uncertainty for states and nationalist movements over when self-determination applies and when it should be subordinated to territorial integrity. Incidents like the Ukrainian crisis cast a shadow over separatist crises elsewhere. The leadership in Azerbaijan detects double standards in American policy, wondering why it “punishes Russia for annexing Crimea, but not Armenia for similar behavior in Karabakh.”74 Such uncertainly can makes states feel vulnerable, as it has in Azerbaijan, change the incentives for key actors, and increase the chance of conflict. Secessionist civil war is a common feature of contemporary times. Scholars estimate that at least half of the civil wars since 1945 have involved secessionism, and Barbara F. Walter argues that secessionism is the chief source of violence in the world today.75 Erica Chenowith and Maria Stephan find that secessionism is one of the few (if only) forms of political protest where violent tactics are more effective than nonviolent.76 Meanwhile, Tanisha Fazal and I identify fifty-five secessionist movements as of 2011 and record that many of these movements feel they have a reasonable chance of gaining independence in light of the somewhat flexible practices surrounding recognition.77 Given the strategic environment in which secessionists operate, where violence can be effective and where sovereignty is thought to be obtainable, it should come as no surprise that conflict is common. In regard to territorial stability, the concern of contemporary times is not traditional territorial conquest, but the threat posed by state fragmentation.78 This is where Chinese hegemony ought to improve international order.

#### The impact is great power nuclear war and a collapse of institutions---the Chinese model is preferable because the US will call for partitions

Fearon 4- Department of Political Science Stanford University (James, “Separatist Wars, Partition, and World Order” <https://web.stanford.edu/group/fearon-research/cgi-bin/wordpress/wp-content/uploads/2013/10/Separatist-Wars-Partition-and-World-Order.pdf>)

Civil wars of separatist nationalism raged around the globe in the 1990s, in the Balkans, India, Russia, Azerbaijan, Sudan, Indonesia, Britain (Northern Ireland), Turkey, Georgia, the Philippines, and Burma, to name only some of the more prominent examples. These wars have caused considerable loss of life, massive refugee crises, economic devastation, significant strains on great power relations and important international institutions like NATO and the United Nations, and a significant risk of nuclear war in South Asia. What should be done? Thus far, the western powers’ approach has been ad hoc, with little public discussion of the broader implications of particular cases and the problems for the international system posed by separatist nationalism.1 At least five sorts of ad hoc responses can be identified: 1. The imposition of weak international protectorates by stronger states through international organizations, as at Dayton, over Kosovo, Northern Iraq, and, earlier, Cyprus. 2. Disapproval but little or no direct action, either due to lack of interest (Kurds in Turkey, Tamils in Sri Lanka, Southerners in Sudan, Tuaregs in Mali, and many other such cases) or due to the power of the states involved (Russia/Chechnya, China/Tibet, India/Kashmir). 3. Weak international attempts to facilitate partition when this is by mutual consent of some sort (East Timor, Eritrea, the Czech Republic and Slovakia, the West Bank in a halting way). 4. Stable cease-fires and de facto partitions, as in Nagorno-Karabagh and Somaliland. 5. Some efforts to help negotiate power-sharing agreements, as in Northern Ireland and Angola (the latter with a largely ethnic but not separatist war). That international responses to wars of separatist nationalism have been ad hoc is not surprising. International relations is the realm of the ad hoc, and even if it were possible it is hard to imagine a general, one-size-fits-all approach that would make sense. But the lack of discussion about the broader implications of different possible policies in particular cases is surprising. Here is a possible explanation. For the western powers, separatist nationalism is so perplexing and fundamental a problem that it has to be ignored as a general phenomenon. The problem is that the overwhelmingly accepted diagnosis of the cause of separatist nationalism implies a policy remedy no major power can stomach. In brief, the standard diagnosis is Wilsonianism, the theory that separatist nationalism stems from bad borders and incompatible cultures. Wilsonianism holds that violent separatism arises when state borders are not properly aligned with national groups, which are fixed, preexisting entities. Separatism is due to the injustice of depriving proper nations of proper states. If one accepts this, then the remedy for nationalist wars is obvious. Just redraw the borders. Impose partitions. And indeed with each nationalist war foreign policy analysts in the U.S. and elsewhere have called for partition as the obvious and proper solution.2 In the wake of the intense killing and brutality in Bosnia and Kosovo, partition has often seemed, reasonably, “inevitable.” Even if these people lived together once, analysts say, how can they live together now? If one accepts the general diagnosis, the argument for partition seems inescapably strong. So why not do it? Why aren’t the major powers leaping on partition as the obvious solution, rather than setting up costly and ineffectual protectorates? Are there any good reasons to oppose partition, or are the western powers just misguided, cowardly, or transfixed by a naive and dangerous commitment to multiculturalism (Mearsheimer and Van Evera 1995; Mearsheimer and Pape 1993)? I argue in this paper that there are indeed good reasons to be skeptical of partition as a general solution to nationalist wars. The most important of these, and the least explored, are two types of incentive effects. First, ad hoc partition applied to one trouble spot may help produce more violent separatist nationalist movements elsewhere, in addition to making existing nationalist wars more difficult to resolve. The Wilsonian diagnosis is wrong. The world is not composed of a fixed number of true nations, so that peace can be had by properly sorting them into states. Rather, there is literally no end of cultural difference in the world suitable for politicization in the form of nationalist insurgencies. As long as controlling a recognized state apparatus is a desirable thing and “nationhood” is understood to ground claims to a state, ambitious individuals will try to put together nationalist movements to claim statehood. A (de facto) policy of partition that says, in effect, “You may get a state if you can get a bloody enough nationalist insurgency going” provides the wrong incentives. The more general point is that whether partition is good idea depends in part on one’s theory of what causes separatist nationalism. I will argue that the dominant theory of Wilsonianism is misleading, and implies ad hoc “solutions” that states are right to shy away from.

**1NC -- Disease**

**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 counties 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. Counties 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. 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

**COVID exceptions erode IP policies broadly.**

**PRMA 21** The Pharmaceutical Research and Manufacturers of America SPECIAL 301 SUBMISSION 2021 <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_2021-Special-301_Review_Comment-1.pdf> SM

Moreover, some countries are using the COVID-19 pandemic opportunistically to advance longstanding industrial policies to further erode intellectual property policies. India and South Africa are key sponsors of a proposal at the WTO TRIPS Council calling to eliminate for an indefinite term certain WTO obligations to grant IP on a wide range of technologies related to COVID-19. The proposal marks a significant escalation in anti-IP global activism and will further polarize legitimate conversations on countries’ engagement to combat the pandemic. The proposal will do nothing to address the production and distribution challenges for making COVID-19 vaccines globally available. If anything the proposals threaten to undermine the ability to respond to another pandemic, and will inevitably affect IP discussions in countries around the world.

**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

### Case:

#### No impact-we have had covid for over a year without escalating nuclear extinction. 1-proves the disad outweighs on risk and 2- denies escalation from covid

#### They need to win scale up to win covid. That not only means increasing production output but distribution and the aff doesn’t entail a plan for either but here are a bunch of reasons they wont

#### Their Boko Haram impacts ignores the fact that their leader died in may which was devastating to the terrorists

Nuke terror impossible

**Weiss 2/13/15**—visiting scholar at the Center for International Security and Cooperation at Stanford

(Leonard, “On fear and nuclear terrorism”, Bulletin of the Atomic Scientists March/April 2015 vol. 71 no. 2 75-87, dml)

If the fear of nuclear war has thus had some positive effects, the fear of nuclear terrorism has had mainly negative effects on the lives of millions of people around the world, including in the United States, and even affects negatively the prospects for a more peaceful world. Although there has been much commentary on the interest that Osama bin Laden, when he was alive, reportedly expressed in obtaining nuclear weapons (see Mowatt-Larssen, 2010), and some terrorists no doubt desire to obtain such weapons, evidence of any terrorist group working seriously toward the theft of nuclear weapons or the acquisition of such weapons by other means is virtually nonexistent. This may be due to a combination of reasons. Terrorists understand that it is not hard to terrorize a population without committing mass murder: In 2002, a single sniper in the Washington, DC area, operating within his own automobile and with one accomplice, killed 10 people and changed the behavior of virtually the entire populace of the city over a period of three weeks by instilling fear of being a randomly chosen shooting victim when out shopping.

Terrorists who believe the commission of violence helps their cause have access to many explosive materials and conventional weapons to ply their “trade.” If public sympathy is important to their cause, an apparent plan or commission of mass murder is not going to help them, and indeed will make their enemies even more implacable, reducing the prospects of achieving their goals. The acquisition of nuclear weapons by terrorists is not like the acquisition of conventional weapons; it requires significant time, planning, resources, and expertise, with no guarantees that an acquired device would work. It requires putting aside at least some aspects of a group’s more immediate activities and goals for an attempted operation that no terrorist group has previously accomplished. While absence of evidence does not mean evidence of absence (as then-Secretary of Defense Donald Rumsfeld kept reminding us during the search for Saddam’s nonexistent nuclear weapons), it is reasonable to conclude that the fear of nuclear terrorism has swamped realistic consideration of the threat. As Brian Jenkins, a longtime observer of terrorist groups, wrote in 2008:

Nuclear terrorism … turns out to be a world of truly worrisome particles of truth. Yet it is also a world of fantasies, nightmares, urban legends, fakes, hoaxes, scams, stings, mysterious substances, terrorist boasts, sensational claims, description of vast conspiracies, allegations of coverups, lurid headlines, layers of misinformation and disinformation. Much is inconclusive or contradictory. Only the terror is real. (Jenkins, 2008: 26)

The three ways terrorists might get a nuke

To illustrate in more detail how fear has distorted the threat of nuclear terrorism, consider the three possibilities for terrorists to obtain a nuclear weapon: steal one; be given one created by a nuclear weapon state; manufacture one. None of these possibilities has a high probability of occurring.

Stealing nukes. Nothing is better protected in a nuclear weapon state than the weapons themselves, which have multiple layers of safeguards that, in the United States, include intelligence and surveillance, electronic locks (including so-called “permissive action links” that prevent detonation unless a code is entered into the lock), gated and locked storage facilities, armed guards, and teams of elite responders if an attempt at theft were to occur. We know that most weapon states have such protections, and there is no reason to believe that such protections are missing in the remaining states, since no weapon state would want to put itself at risk of an unintended nuclear detonation of its own weapons by a malevolent agent. Thus, the likelihood of an unauthorized agent secretly planning a theft, without being discovered, and getting access to weapons with the intent and physical ability to carry them off in the face of such layers of protection is extremely low—but it isn’t impossible, especially in the case where the thief is an insider.

The insider threat helped give credibility to the stories, circulating about 20 years ago, that there were “loose nukes” in the USSR, based on some statements by a Soviet general who claimed the regime could not account for more than 40 “suitcase nukes” that had been built. The Russian government denied the claim, and at this point there is no evidence that any nukes were ever loose. Now, it is unclear if any such weapon would even work after 20 years of corrosion of both the nuclear and non-nuclear materials in the device and the radioactive decay of certain isotopes.

Because of the large number of terrorist groups operating in its geographic vicinity, Pakistan is frequently suggested as a possible candidate for scenarios in which a terrorist group either seizes a weapon via collaboration with insiders sympathetic to its cause, or in which terrorists “inherit” nuclear weapons by taking over the arsenal of a failed nuclear state that has devolved into chaos. Attacks by a terrorist group on a Pakistani military base, at Kamra, which is believed to house nuclear weapons in some form, have been referenced in connection with such security concerns (Nelson and Hussain, 2012). However, the Kamra base contained US fighter planes, including F-16s, used to bomb Taliban bases in tribal areas bordering Afghanistan, so the planes, not nuclear weapons, were the likely target of the terrorists, and in any case the mission was a failure. Moreover, Pakistan is not about to collapse, and the Pakistanis are known to have received major international assistance in technologies for protecting their weapons from unauthorized use, store them in somewhat disassembled fashion at multiple locations, and have a sophisticated nuclear security structure in place (see Gregory, 2013; Khan, 2012).

However, the weapons are assembled at times of high tension in the region, and, to keep a degree of uncertainty in their location, they are moved from place to place, making them more vulnerable to seizure at such times (Goldberg and Ambinder, 2011). (It should be noted that US nuclear weapons were subject to such risks during various times when the weapons traveled US highways in disguised trucks and accompanying vehicles, but such travel and the possibility of terrorist seizure was never mentioned publicly.)

Such scenarios of seizure in Pakistan would require a major security breakdown within the army leading to a takeover of weapons by a nihilistic terrorist group with little warning, while army loyalists along with India and other interested parties (like the United States) stand by and do not intervene. This is not a particularly realistic scenario, but it’s also not a reason to conclude that Pakistan’s nuclear arsenal is of no concern. It is, not only because of an internal threat, but especially because it raises the possibility of nuclear war with India. For this and other reasons, intelligence agencies in multiple countries spend considerable resources tracking the Pakistani nuclear situation to reduce the likelihood of surprises. But any consideration of Pakistan’s nuclear arsenal does bring home (once again) the folly of US policy in the 1980s, when stopping the Pakistani nuclear program was put on a back burner in order to prosecute the Cold War against the Soviets in Afghanistan (which ultimately led to the establishment of Al Qaeda). Some of the loudest voices expressing concern about nuclear terrorism belong to former senior government officials who supported US assistance to the mujahideen and the accompanying diminution of US opposition to Pakistan’s nuclear activities.

Acquiring nukes as a gift. Following the shock of 9/11, government officials and the media imagined many scenarios in which terrorists obtain nuclear weapons; one of those scenarios involves a weapon state using a terrorist group for delivery of a nuclear weapon. There are at least two reasons why this scenario is unlikely: First, once a weapon state loses control of a weapon, it cannot be sure the weapon will be used by the terrorist group as intended. Second, the state cannot be sure that the transfer of the weapon has been undetected either before or after the fact of its detonation (see Lieber and Press, 2013). The use of the weapon by a terrorist group will ultimately result in the transferring nation becoming a nuclear target just as if it had itself detonated the device. This is a powerful deterrent to such a transfer, making the transfer a low-probability event.

Although these first two ways in which terrorists might obtain a nuclear weapon have very small probabilities of occurring (there is no available data suggesting that terrorist groups have produced plans for stealing a weapon, nor has there been any public information suggesting that any nuclear weapon state has seriously considered providing a nuclear weapon to a sub-national group), the probabilities cannot be said to be zero as long as nuclear weapons exist.

Manufacturing a nuclear weapon. To accomplish this, a terrorist group would have to obtain an appropriate amount of one of the two most popular materials for nuclear weapons, highly enriched uranium (HEU) or plutonium separated from fuel used in a production reactor or a power reactor. Weapon-grade plutonium is found in weapon manufacturing facilities in nuclear weapon states and is very highly protected until it is inserted in a weapon. Reactor-grade plutonium, although still capable of being weaponized, is less protected, and in that sense is a more attractive target for a terrorist, especially since it has been produced and stored in prodigious quantities in a number of nuclear weapon states and non-weapon states, particularly Japan.

But terrorist use of plutonium for a nuclear explosive device would require the construction of an implosion weapon, requiring the fashioning of an appropriate explosive lens of TNT, a notoriously difficult technical problem. And if a high nuclear yield (much greater than 1 kiloton) is desired, the use of reactor-grade plutonium would require a still more sophisticated design. Moreover, if the plutonium is only available through chemical separation from some (presumably stolen) spent fuel rods, additional technical complications present themselves. There is at least one study showing that a small team of people with the appropriate technical skills and equipment could, in principle, build a plutonium-based nuclear explosive device (Mark et al., 1986). But even if one discounts the high probability that the plan would be discovered at some stage (missing plutonium or spent fuel rods would put the authorities and intelligence operations under high alert), translating this into a real-world situation suggests an extremely low probability of technical success. More likely, according to one well-known weapon designer,4 would be the death of the person or persons in the attempt to build the device.

There is the possibility of an insider threat; in one example, a team of people working at a reactor or reprocessing site could conspire to steal some material and try to hide the diversion as MUF (materials unaccounted for) within the nuclear safeguards system. But this scenario would require intimate knowledge of the materials accounting system on which safeguards in that state are based and adds another layer of complexity to an operation with low probability of success.

The situation is different in the case of using highly enriched uranium, which presents fewer technical challenges. Here an implosion design is not necessary, and a “gun type” design is the more likely approach. Fear of this scenario has sometimes been promoted in the literature via the quotation of a famous statement by nuclear physicist Luis Alvarez that dropping a subcritical amount of HEU onto another subcritical amount from a distance of five feet could result in a nuclear yield. The probability of such a yield (and its size) would depend on the geometry of the HEU components and the amount of material. More likely than a substantial nuclear explosion from such a scenario would be a criticality accident that would release an intense burst of radiation, killing persons in the immediate vicinity, or (even less likely) a low-yield nuclear “fizzle” that could be quite damaging locally (like a large TNT explosion) but also carry a psychological effect because of its nuclear dimension.

In any case, since the critical mass of a bare metal perfect sphere of pure U-235 is approximately 56 kilograms, stealing that much highly enriched material (and getting away without detection, an armed fight, or a criticality accident) is a major problem for any thief and one significantly greater than the stealing of small amounts of HEU and lower-enriched material that has been reported from time to time over the past two decades, mostly from former Soviet sites that have since had their security greatly strengthened. Moreover, fashioning the material into a form more useful or convenient for explosive purposes could likely mean a need for still more material than suggested above, plus a means for machining it, as would be the case for HEU fuel assemblies from a research reactor. In a recent paper, physics professor B. C. Reed discusses the feasibility of terrorists building a low-yield, gun-type fission weapon, but admittedly avoids the issue of whether the terrorists would likely have the technical ability to carry feasibility to realization and whether the terrorists are likely to be successful in stealing the needed material and hiding their project as it proceeds (Reed, 2014). But this is the crux of the nuclear terrorism issue. There is no argument about feasibility, which has been accepted for decades, even for plutonium-based weapons, ever since Ted Taylor first raised it in the early 1970s5 and a Senate subcommittee held hearings in the late 1970s on a weapon design created by a Harvard dropout from information he obtained from the public section of the Los Alamos National Laboratory library (Fialka, 1978). Likewise, no one can deny the terrible consequences of a nuclear explosion. The question is the level of risk, and what steps are acceptable in a democracy for reducing it.

Although the attention in the literature given to nuclear terrorism scenarios involving HEU would suggest major attempts to obtain such material by terrorist groups, there is only one known case of a major theft of HEU. It involves a US government contractor processing HEU for the US Navy in Apollo, Pennsylvania in the 1970s at a time when security and materials accounting were extremely lax. The theft was almost surely carried out by agents of the Israeli government with the probable involvement of a person or persons working for the contractor, not a sub-national terrorist group intent on making its own weapons (Gilinsky and Mattson, 2010). The circumstances under which this theft occurred were unique, and there was significant information about the contractor’s relationship to Israel that should have rung alarm bells and would do so today. Although it involved a government and not a sub-national group, the theft underscores the importance of security and accounting of nuclear materials, especially because the technical requirements for making an HEU weapon are less daunting than for a plutonium weapon, and the probability of success by a terrorist group, though low, is certainly greater than zero. Over the past two decades, there has been a significant effort to increase protection of such materials, particularly in recent years through the efforts of nongovernmental organizations like the International Panel on Fissile Materials6 and advocates like Matthew Bunn working within the Obama administration (Bunn and Newman, 2008), though the administration has apparently not seen the need to make the materials as secure as the weapons themselves.

Are terrorists even interested in making their own nuclear weapons?

A recent paper (Friedman and Lewis, 2014) postulates a scenario by which terrorists might seize nuclear materials in Pakistan for fashioning a weapon. While jihadist sympathizers are known to have worked within the Pakistani nuclear establishment, there is little to no evidence that terrorist groups in or outside the region are seriously trying to obtain a nuclear capability. And Pakistan has been operating a uranium enrichment plant for its weapons program for nearly 30 years with no credible reports of diversion of HEU from the plant.

There is one stark example of a terrorist organization that actually started a nuclear effort: the Aum Shinrikyo group. At its peak, this religious cult had a membership estimated in the tens of thousands spread over a variety of countries, including Japan; its members had scientific expertise in many areas; and the group was well funded. Aum Shinrikyo obtained access to natural uranium supplies, but the nuclear weapon effort stalled and was abandoned. The group was also interested in chemical weapons and did produce sarin nerve gas with which they attacked the Tokyo subway system, killing 13 persons. Aum Shinrikyo is now a small organization under continuing close surveillance.

What about highly organized groups, designated appropriately as terrorist, that have acquired enough territory to enable them to operate in a quasi-governmental fashion, like the Islamic State (IS)? Such organizations are certainly dangerous, but how would nuclear terrorism fit in with a program for building and sustaining a new caliphate that would restore past glories of Islamic society, especially since, like any organized government, the Islamic State would itself be vulnerable to nuclear attack? Building a new Islamic state out of radioactive ashes is an unlikely ambition for such groups. However, now that it has become notorious, apocalyptic pronouncements in Western media may begin at any time, warning of the possible acquisition and use of nuclear weapons by IS.

Even if a terror group were to achieve technical nuclear proficiency, the time, money, and infrastructure needed to build nuclear weapons creates significant risks of discovery that would put the group at risk of attack. Given the ease of obtaining conventional explosives and the ability to deploy them, a terrorist group is unlikely to exchange a big part of its operational program to engage in a risky nuclear development effort with such doubtful prospects. And, of course, 9/11 has heightened sensitivity to the need for protection, lowering further the probability of a successful effort.

No materials—answers every warrant

Pyotr Topychkanov 1-28-2014; PhD in History, Associate in the Carnegie Moscow Center’s Nonproliferation Program "Nuclear Terrorism: Bogeyman or Real Threat?" http://russiancouncil.ru/en/inner/?id\_4=3045#top

Overall, acts of nuclear terrorism can be linked to attempts to build or acquire, first, a nuclear explosive device, and, secondly, radiological weapons (i.e. a ‘dirty bomb’), giving rise to nuclear or radiological terrorism, respectively. DIY Nuclear terrorism involves using fissile weapons-grade materials: Uranium-235 enriched to over 90% and plutonium-239 with an isotopic purity of at least 94%. According to current estimates, in the five countries that have nuclear weapons, building a nuclear device requires 8kg of plutonium or 25kg of highly-enriched uranium (HEU); although some specialists suggest 4kg to 5kg of plutonium or 16kg of HEU would be sufficient. With 20% enriched uranium, it would take 800kg of material to reach the critical mass needed for a nuclear explosion, which is believed to be technically implausible [3]. Obtaining fissile weapons grade materials is no easy matter for terrorists, chiefly for the following reasons. Enriching uranium or producing the necessary quantity of plutonium requires scientific and technological facilities that no terrorist organisation has. Acquiring the necessary quantities of fissile weapons-grade materials on the black market would require the relevant supply, which is not currently there (the IAEA receives about 150-200 reports from Member States each year of fissile materials that are lost, stolen or otherwise out of their control, but, first, most incidents are unrelated to weapons-grade uranium or plutonium and, secondly, in all reported incidents the fissile materials are returned under proper control).

#### Their solvency flows aff: we read green

Lindsey, JD Harvard, 21

(Brink, <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/>, 6-3)

Waiving patent protections is certainly no panacea. What is needed most urgently is a massive drive of technology transfer, capacity expansion, and supply line coordination to bring vaccine supply in line with global demand. Dispensing with patents in no way obviates the need for governments to fund and oversee this effort. Although focusing on these immediate constraints is vital, we cannot confine our attention to the short term. First of all, the COVID-19 pandemic is far from over. Although Americans can now see the light at the end of the tunnel thanks to the rapid rollout of vaccines, most of the world isn’t so lucky. The virus is currently raging in India and throughout South America, overwhelming health care systems and inflicting suffering and loss on a horrific scale. And consider the fact that Australia, which has been successful in suppressing the virus, recently announced it was sticking to plans to keep its borders closed until mid-2022. Criticisms of the TRIPS waiver that focus only on the next few months are therefore short-sighted: this pandemic could well drag on long enough for elimination of patent restrictions to enable new vaccine producers to make a positive difference. Furthermore, and probably even more important, this is almost certainly not the last pandemic we will face. Urbanization, the spread of factory-farming methods, and globalization all combine to increase the odds that a new virus will make the jump from animals to humans and then spread rapidly around the world. Prior to the current pandemic, the 21st century already saw outbreaks of SARS, H1N1, MERS, and Ebola. Everything we do and learn in the current crisis should be viewed from the perspective of getting ready for next time. THE NATURE OF THE PATENT BARGAIN When we take the longer view, we can see a fundamental mismatch between the policy design of intellectual property protection and the policy requirements of effective pandemic response. Although patent law, properly restrained, constitutes one important element of a well-designed national innovation system, the way it goes about encouraging technological progress is singularly ill-suited to the emergency conditions of a pandemic or other public health crisis. Securing a TRIPS waiver for COVID-19 vaccines and treatments would thus establish a salutary precedent that, in emergencies of this kind, governments should employ other, more direct means to incentivize the development of new drugs. Here is the basic bargain offered by patent law: encourage the creation of useful new ideas for the long run by slowing the diffusion of useful new ideas in the short run. The second half of the bargain, the half that imposes costs on society, comes from the temporary exclusive rights, or monopoly privileges, that a patent holder enjoys. Under U.S. patent law, for a period of 20 years nobody else can manufacture or sell the patented product without the permission of the patent holder. This allows the patent holder to block competitors from the market, or extract licensing fees before allowing them to enter, and consequently charge above-market prices to its customers. Patent rights thus slow the diffusion of a new invention by restricting output and raising prices. The imposition of these short-run costs, however, can bring net long-term benefits by sharpening the incentives to invent new products. In the absence of patent protection, the prospect of easy imitation by later market entrants can deter would-be innovators from incurring the up-front fixed costs of research and development. But with a guaranteed period of market exclusivity, inventors can proceed with greater confidence that they will be able to recoup their investment. For the tradeoff between costs and benefits to come out positive on net, patent law must strike the right balance. Exclusive rights should be valuable enough to encourage greater innovation, but not so easily granted or extensive in scope or term that this encouragement is outweighed by output restrictions on the patented product and discouragement of downstream innovations dependent on access to the patented technology. Unfortunately, the U.S. patent system at present is out of balance. Over the past few decades, the expansion of patentability to include software and business methods as well as a general relaxation of patenting requirements have led to wildly excessive growth in these temporary monopolies: the number of patents granted annually has skyrocketed roughly fivefold since the early 1980s. One unfortunate result has been the rise of “non-practicing entities,” better known as patent trolls: firms that make nothing themselves but buy up patent portfolios and monetize them through aggressive litigation. As a result, a law that is supposed to encourage innovation has turned into a legal minefield for many would-be innovators. In the pharmaceutical industry, firms have abused the law by piling up patents for trivial, therapeutically irrelevant “innovations” that allow them to extend their monopolies and keep raising prices long beyond the statutorily contemplated 20 years. Patent law is creating these unintended consequences because policymakers have been caught in an ideological fog that conflates “intellectual property” with actual property rights over physical objects. Enveloped in that fog, they regard any attempts to put limits on patent monopolies as attacks on private property and view ongoing expansions of patent privileges as necessary to keep innovation from grinding to a halt. In fact, patent law is a tool of regulatory policy with the usual tradeoffs between costs and benefits; like all tools, it can be misused, and as with all tools there are some jobs for which other tools are better suited. A well-designed patent system, in which benefits are maximized and costs kept to a minimum, is just one of various policy options that governments can employ to stimulate technological advance—including tax credits for R&D, prizes for targeted inventions, and direct government support. PUBLIC HEALTH EMERGENCIES AND DIRECT GOVERNMENT SUPPORT For pandemics and other public health emergencies, patents’ mix of costs and benefits is misaligned with what is needed for an effective policy response. The basic patent bargain, even when well struck, is to pay for more innovation down the road with slower diffusion of innovation today. In the context of a pandemic, that bargain is a bad one and should be rejected entirely. Here the imperative is to accelerate the diffusion of vaccines and other treatments, not slow it down. Giving drug companies the power to hold things up by blocking competitors and raising prices pushes in the completely wrong direction

.**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."

#### Reducing IP rights aren’t quick enough to help the pandemic – legal battles slow the process – experts agree

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)

But even as public pressure grows, some experts argue that handing over the IP rights for Covid-19 vaccines won't necessarily mean that more can be rapidly produced worldwide at large scale. US infectious diseases chief Anthony Fauci [told the UK's Financial Times](https://www.ft.com/content/2f41b122-5738-4707-a822-0d79276710c5) on Monday that he was not convinced that forcing companies to share their intellectual property was the most effective approach, warning that legal battles could slow the process. "Going back and forth, consuming time and lawyers in a legal argument about waivers -- that is not the endgame. People are dying around the world and we have to get vaccines into their arms in the fastest and most efficient way possible," he said.

#### The squo is goldilocks--COVAX and licensing agreements ensure vaccine access now, but patent waiver causes unsafe vaccines and decks innovation.

Crosby et al. 21 (Daniel Crosby [Lawyer specializing in international trade/law], Evan Diamond [Lawyer specializing in pharmaceutical and biotechnology patent litigation], Isabel Fernandez de la Cuesta [Lawyer specializing in international treaty arbitration], Jamieson Greer [Lawyer specializing in international trade], Jeffrey Telep [Lawyer specializing in international trade litigation], Brian White [Lawyer specializing in international arbitration], Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products, JD Supra, 3/5/2021, <https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/>) hwof

Efforts to develop, produce, and equitably distribute medical products. WTO Members recognize that unprecedented demand for medical products used in the fight against COVID-19 has far outstripped supply of required supplies. Several WTO Members have pointed out that intellectual property protections have not limited production of vaccines and other medical products. Rather, these Members have argued that intellectual property protection has incentivized the research, development and production of the necessary vaccines, treatments and products. Moreover, the international community is coordinating and funding equitable COVID-19 vaccine distribution globally through COVAX, which is organized by Gavi, the Vaccine Alliance, the World Health Organization and the Coalition for Epidemic Preparedness Innovations. Despite these facts, less developed countries continue to push for a waiver of all intellectual property protection for medical products related to the pandemic. Waiver risks uncontrolled use of patented technologies, without improving vaccine access. Pharmaceutical companies can provide, and have provided, licenses to distribute or scale-up production of COVID-19 vaccines and therapies at reduced cost. Such license agreements allow for expanded access in low- and middle-income countries, while also setting reasonable parameters so that patents and other IP rights are used to address the specific medical needs of the COVID-19 pandemic at hand, and not for other purposes. License agreements also allow for orderly technology transfer, including of unpatented “trade secret” information and other critical “know-how,” that may be essential to efficiently producing and scaling-up safe and effective versions of technologically complex vaccines and biologic drug products. Under the present TRIPS waiver proposal, however, member countries could try to exploit an extraordinarily broad scope of IP and copy patented technologies so long as they are “in relation to prevention, containment or treatment of COVID-19.” For example, under an expansive reading of the proposed waiver language, a member country could try to produce patented pharmaceutical compounds that have other indicated uses predating COVID-19, if such compounds had later been studied or experimentally used for potential symptomatic relief or antiviral activity in COVID-19 patients. The same risks may be faced by manufacturers of patented materials or devices that have multiple uses predating COVID-19, but also may be used as “personal protective equipment” or components thereof, or in other measures arguably relating to COVID-19 “prevention” or “containment.” At the same time, it is unclear how the proposed TRIPS waiver could provide the technology transfer and know-how critical for making the complex molecules and formulations constituting the various COVID-19 vaccines. Vaccine manufacture undertaken by an unauthorized party without the proper processes and controls could result in a different product that is potentially ineffective or results in unwanted health consequences. And even if an unauthorized manufacturer could overcome those substantial hurdles to reverse-engineer and scale up a safe and effective vaccine copy, it would likely take substantial time and a series of failures to do so. Notably, several of the original COVID-19 vaccine developers have recently faced low product yield and other manufacturing challenges during pre-commercial scale-up efforts and the initial months of commercial production.

#### The WTO has already published how to make COVID vaccines.

Taylor 8-5-21 (Nick Taylor [Journalist specializing in the biopharma industry], Biopharma Reporter, WTO lists critical inputs for COVID-19 vaccines to address gaps in global supply, 8/5/21, <https://www.biopharma-reporter.com/Article/2021/08/05/WTO-lists-critical-inputs-for-COVID-19-vaccines?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright>) hwof

The World Trade Organization (WTO) Secretariat has published a list of critical inputs for COVID-19 vaccines as part of an effort to address gaps in global production and distribution of the products. Officials at the WTO Secretariat prepared the list to inform talks at its COVID-19 Vaccine Supply Chain and Regulatory Transparency Symposium in late June. A version was released for consultation after the event. The document lists the wide range of products that are needed to make COVID-19 vaccines and get them to the public. On the manufacturing side, the list covers the active ingredients for vaccines from AstraZeneca, Johnson & Johnson, Moderna and Pfizer-BioNTech, noting that the latter two products use “nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2.”Consumables and equipment required for production A long list of inactive ingredients is also included by the WTO Secretariat, as is a breakdown of the other ingredients such as preservatives, adjuvants and stabilizers that are used in the four vaccines.The list features details of the consumables and equipment required to make the vaccines, too. For example, the list states that single-use bioreactor bags are needed for cell culture and fermentation and microfluid and nanofluid mixers are required to produce the lipid nanoparticles that are used in the delivery of mRNA vaccines. Dry ice, vials and stoppers Finally, the list covers the products needed to get vaccines from manufacturing plants and into the arms of people. The list ranges from vials and vulcanized rubber stoppers, to dry ice for storage and adhesive bandages to put on the injection site after administration of the vaccine. The list is the product of multiple organizations. The WTO Secretariat said the Asian Development Bank, the Organization for Economic Cooperation and Development, the World Customs Organization, some COVID-19 vaccine manufacturers, researchers Chad Bown and Chris Rogers, the Coalition for Epidemic Preparedness Innovations and DHL jointly produced the list.