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#### Apocalyptic pandemic reps lock in a neoliberal risk society of anxiety and health inequality that spreads disease. Independently, the aff masks health neoliberalism by spreading vaccine arms races horizontally instead of vertically.

Mannathukkaren 14

(Nissim Mannathukkaren, Dept. Chair and Associate Prof. of International Development Studies @ Dalhousie University, “Pandemics in the age of panic,” November 22, 2014, <http://www.thehindu.com/features/magazine/social-media-should-be-a-positive-force-and-public-health-systems-should-focus-on-prevention-of-epidemics/article6624674.ece>)

\*Evidence is edited to correct gendered language\*

If natural disasters induce panic, so do pandemics. In recent years, we have seen a series of pandemics: AIDS, avian influenza, SARS and H1N1. Now, we are in the midst of an epidemic, Ebola, which — according to experts — can acquire pandemic proportions. Natural disasters and pandemics have existed in the pre-modern era as well but what is remarkable is that, in the modern era, the attitudes towards hazards — both natural and man-made — have drastically changed. Panic is the order of the day, especially in sanitised spaces of the developed West. Medical scholars, Luc Bonneux and Wim Van Damme, term panic itself as a pandemic.

As they point out, in 1999, Belgium slaughtered seven million chicken and 60,000 pigs when dioxin, a cancer-causing chemical, entered animal feed. Not one person died from dioxin poisoning. In 2005, the chief avian flu coordinator of the UN predicted that 150 million people could be killed by the flu. However, in 10 years, it has killed less than 400 people. The same apocalyptic predictions were made about BSE/CJD, SARS, and H1N1 as well.

Media coverage and the responses of governments and people to Ebola and recent pandemics tell us an important and paradoxical truth: we might be living in an era that is the apogee of human scientific advancements but this has not necessarily mitigated our fears and panic about potential dangers. This has led theorists to argue that we live in a ‘risk society’, a society that generates a lot of risks precisely because it is obsessed with, as the sociologist Anthony Giddens puts it, “the aspiration to control and particularly with the idea of controlling the future.” Traditional cultures did not have a notion of risk as diseases and natural disasters were taken for granted and were attributed to God or fate.

Interestingly, many of the risks in the modern era, as Giddens elaborates, are manufactured by the “very progression in human development, especially by the progression of science and technology.” Diseases caused by industrial pollution, natural disasters caused by environmental destruction, man-made disasters like Bhopal gas tragedy, Chernobyl and Fukushima nuclear accidents, and latrogenesis — adverse effects caused by medical intervention and modern medicines — are examples of these manufactured risks. In the U.S., scholars estimate that 2,25,000 deaths annually are due to latrogenic causes, and is the third leading cause of death after heart disease and cancer! Thus, science and technology itself generates new uncertainties as it banishes old ones and fear of the unknown cannot be eliminated by further scientific progress.

We have to read the coverage of, and response to, Ebola in this wider context of a risk society. Politics of fear, panic, and scaremongering are inevitable outcomes of such a society. Look at the panic around Ebola in the U.S., where so far not one citizen has died of the disease. A nurse returning after treating Ebola patients in Sierra Leone has won a court order against a mandatory quarantine order imposed by the state. Australia and Canada have imposed visa ban on citizens travelling from the affected countries, violating WHO’s International Health Regulations.

Renowned journalist Simon Jenkins argues that “we have lost control of the language of proportion” in responding to Ebola and other pandemics. Similarly, other journalists have severely criticised the media’s coverage of Ebola. The scaremongering is seen in absurd and irresponsible statements like Ebola is ‘the ISIS of biological agents!’ One major responsibility of the mainstream media, other than providing detailed and proper information about the disease itself, is to enlighten the public about the socio-economic and political conditions that govern health and healthcare systems in various societies, which in turn impact the origin and spread of pandemics. Without educating the public about the root causes that condemn the poorer parts of the world to bear the brunt of global pandemics, the media becomes a handmaiden of the powers — developed countries and pharmaceutical corporations — that control global health.

This lack of knowledge about larger forces also adds to risks and the resultant panic. Thus, in the 2009 H1N1 pandemic, the media’s role in the investigation of allegations of whether it was a false pandemic was nothing to be proud of. The head of health at the Council of Europe had raised questions about the role of pharmaceutical corporations in the declaration of H1N1 as a pandemic. Later, an investigation by the British Medical Journal found that medical experts advising WHO on H1N1 had financial ties with pharmaceutical companies producing the vaccine for the pandemic. As all the developed countries stocked up on the vaccines, reportedly, the pharmaceutical companies made profits ranging from $ 7-10 billion.

In this context, the media’s role in the coverage of pandemics raises questions. Where are the stories in the media about the lack of vaccines for Ebola, 40 years after the disease emerged? Or about the drug firms now in the race to produce a vaccine (the share prices of one of the companies ahead in the race have shot up exponentially)?

While certain prominent Western media houses have definitely pushed the panic button with regard to Ebola, the hard data about the overall coverage as studied by the Foreign Policy magazine indicates that it is not the case. But this study is merely restricted to the English language coverage. Further, the mainstream media has failed miserably in countering the serious issue of the racialisation of Ebola (as with AIDS before) as an African disease caused and spread merely by its cultural practices.

In a risk society, we have to confront new unknowns too, like social media and its impact. One media source called Ebola ‘the first major outbreak in the era of social media’. But, in the coverage of the outbreak, social media has reportedly been a negative force spreading misinformation and rumours that, in some cases, even led to deaths due to dangerous treatments administered.

#### The alternative is to adopt a social medicine approach to health.

Mohan J. DUTTA 15, Professor and Head of the Department of Communications and New Media at the National University of Singapore, Adjunct Professor of Communication at the Brian Lamb School of Communication at Purdue University [*Neoliberal Health Organizing*, 2015, p. 231-234]

Latin American social medicine depicts a distinct and long strand of theorizing of health systems that challenges the liberal capitalist organizing of health, grounded in the organizing principles of social medicine and noting [END PAGE 231] that changing the overarching structures is central to transforming the conditions of poor health (Waitzkin, 1991, 2011; Waitzkin & Modell, 1974). That health is constituted within broader social conditions is the basis for research, teaching, clinical practice, and activism in socialist medicine, with early roots in Latin America. Social medicine thus connects health, healing, and health care delivery to the politics of social change and structural transformation, clearly voicing an activist agenda directed at transforming the unequal social conditions.

One of the earliest influences of social medicine was evident in the work of the medical student activist Salvador Allende, who would later become the president of Chile. In his book The Chilean Medico-Social Reality, Allende (1939) outlined the social conditions in Chile that resulted in poor health outcomes, emphasizing the broader conditions of foreign debt dependence, underdevelopment, international dependence, and resource consolidation in the hands of the local elite. Proposing social rather than medical solutions to health, Allende emphasized “income redistribution, state regulation of food and clothing supplies, a national housing program, and industrial reforms to address occupational health problems” (Waitzkin, 2011, p. 160). In his political life, Allende sought reforms in the Chilean national health service, complemented by reforms in the housing and nutrition areas, efforts at national income redistribution, and minimizing the role of multinational corporations.

The individualized model of public health that sees health and illness as a dichotomy is interrogated by the framework of social medicine that suggests that health and illness exist in a dialectical relationship that is dynamic and is continually shifting on the basis of social conditions, structures, cultural practices, economic production, reproduction, marginalizing practices, and processes of political participation. Thus, interventions in social medicine point toward the necessity for transforming the underlying relationships of production and resource distribution, resisting the public health narrative of interventions as mechanisms for improving economic productivity. Taking a social-class-driven approach to health inequities, Latin American social medicine sees the problems with health being situated within means of economic production, patterns of ownership of means of production, and control over productive processes. Therefore, health is approached from the framework of transforming the processes of economic production and labor processes.

The dominant framework of health as integral to growth and economic productivity is questioned by the framework of social medicine that situates the relationship between health and illness amid the very processes of economic organization, distribution of economic resources, and the pervasive effects of social class on health services and health outcomes. [END PAGE 232] The innovations in organizing of health structures in Chile, Cuba, Mexico, Bolivia, and Venezuela offer invaluable insights about the possibilities of alternative organizing that seek to redo the entire structure of social organizing that constitute health. The strong health indicators in Cuba demonstrate the effectiveness of a health system that is committed to addressing the structural determinants of health, creating equitable contexts for the realization and delivery of health (Campion & Morrissey, 2013). Social medicine research has looked at the relations among work, reproduction, the environment, and health, describing in-depth the material conditions that constitute health. For instance, researchers studying health in Mexico within the context of unions and local communities have documented health problems that relate to work processes and the environment. Similarly, researchers in Chile have documented the relations between gender, work, and environmental conditions. A key strand of social medicine examines the relationship between violence and health, connecting violence to poverty, the structures of organizing, and the inequities in ownership of processes of economic production. Investigations of violence attached to the U.S.-supported dictatorship in Chile, the violence connected to narcotics traffic and paramilitary operations, and the violence within the broader structures of the state-imperial networks draw linkages to the broader political economic configurations of neoliberalism.

Emerging from the broader framework of social medicine, the Barrio Adentro movement in Venezuela, started by former president Hugo Chavez, offers insights into structures and processes of alternative organizing of health, connecting local community structures, community ownership, and community solutions with state infrastructures and state-driven public health resources and solutions (Briggs & Mantini-Briggs, 2009; Muntaner et al., 2006; Waitzkin, 2011). The state-driven referendum by the Chavez government to create public health infrastructures and structures of delivery of integrated family medicine, build preventive infrastructures, and develop community health resources in extremely marginalized communities is supported by massive mass-based participation in popular politics and widespread community participation in developing local community infrastructures, community-based resources of problem solving, and community decision-making capacities. The community health centers built within the barrios serve approximately 250 families and are staffed with one integrated family care doctor, one community health worker, and one health promoter. The community health centers are stocked with medical supplies. The health team not only provides health care but also conducts health surveys in the communities and makes home visits for patients that are too ill to travel to the health centers. The Barrio Adentro is integrated with other missiones addressing education, food insecurity, housing, and [END PAGE 233] unemployment, addressing health within a broader structural context (Muntaner et al., 2006). Local community participatory processes are connected with state-driven processes of building community health infrastructures at the local level.

The narrative of Barrio Adentro offers an alternative to the neoliberal narrative of the community in mainstream health communication and yet is marked by its absence from disciplinary discourses. Similarly, social medicine and its tradition of addressing the structural contexts of health is marked by its absence from the dominant discourses of health communication. A review of the two major collections of health communication scholarship, The Routledge Handbook of Health Communication and The Handbook of Global Health Communication, depicts the marked absence of the Latin American innovations of social medicine from the discursive space. Opportunities for resistance to neoliberal organizing of health structures and the invitation to imagine alternative possibilities is grounded in materially grounded concrete politics of popular participation in supporting state policies for building public health and health care infrastructures, complemented by local processes of participation in the creation of health solutions.

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#### CP: The People’s Republic of China should cede all patent rights over genomic medicines.

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#### CP: States except the United States and Saudi Arabia should adopt open licensing policy for genomic medicines.

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#### The US is concerned about Saudi IPR but trade relations are fine now

US Gov 21 [United States Government, Office of the US Trade Representative “2021 Special 301 Report” Published: 2021] [https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20(final).pdf] || SM

Saudi Arabia remains on the Priority Watch List in 2021.

Ongoing Challenges and Concerns

Saudi Arabia was placed on the Priority Watch List in 2019 for failing to take action against the rampant satellite and online piracy made available by illicit pirate service beoutQ, continued lack of effective protection of intellectual property (IP) for pharmaceutical products, and long-standing concerns regarding enforcement against counterfeit and pirated goods within the country. BeoutQ ceased operations in August 2019. The Saudi Authority for Intellectual Property (SAIP) continued to take steps to improve IP protection, enforcement, and awareness throughout Saudi Arabia in 2020. However, concerns remain over actions by the Saudi Arabia Food and Drug Authority (SFDA), which the Minister of Health oversees, that are contrary to Saudi Arabia’s public statements in paragraph 261 of the Report of the Working Party on the Accession of the Kingdom of Saudi Arabia to the World Trade Organization. Starting in 2016, SFDA has been granting marketing approval to domestic companies for subsequent versions of registered products, without requiring the submission of data that meets the same requirements applied to the initial applicant, despite the period of protection provided to the initial applicant by Saudi regulations. SFDA’s continued actions and the lack of redress for affected companies have intensified concerns. Furthermore, the National Unified Procurement Company for Medical Supplies, also overseen by the Minister of Health, reportedly awarded national tenders to some of these domestic companies for the affected products.

#### Wavering Saudi IPR sends investors scrambling and guts US-Saudi coop. Recent missteps in pharma IPR prove it’s uniquely key to perception.

Stevens 17 [Philip Stevens “Saudi missteps on intellectual property will hold back its economy” Published: The Hill, September 17, 2017] [https://thehill.com/opinion/international/351074-saudis-missteps-on-intellectual-property-will-hold-back-its-economy] [Stevens: Director of Geneva Network, a UK-based research organization focusing on trade and innovation issues.] || SM

Saudi Arabian policymakers know that increasing knowledge-based sectors is the key to sustainable growth as their economy transitions away from oil.

“You cannot be depending on oil in a world where the knowledge economy is the driver of economic development — manufacturing is 20th century,” Fahd Al-Rasheed, CEO of King Abdullah Economic City, said in June.

Vision 2030, the plan to diversify the Saudi economy, also sees a big role for knowledge-based industries.

This makes sense. In the U.S., knowledge-intensive goods and services from sectors including biotech, chemicals, entertainment and information technology now make up over half of all U.S. exports, reversing the situation of only 40 years ago when manufacturing dominated. Advanced Asian economies — Japan, the Republic of Korea,

Advanced Asian economies — Japan, the Republic of Korea, Singapore and Taiwan — have also taken this path, moving over recent decades from agriculture to manufacturing to knowledge-based economies.

Few countries have developed thriving knowledge-based industries purely from domestic resources. Scientific knowledge, technological know-how and the required research and development capital are dispersed globally.

Gone are the days when one R&D company, for example, the industrial behemoth General Electric or the biopharmaceutical major Merck, created products in-house from start to finish.

Today, innovation is a result of collaboration between multinational companies, small companies, start-ups, academia and the public sector at all stages of the R&D cycle, often across borders.

Saudi Arabia’s challenge is to become a meaningful participant in this new world of networked innovation. It must attract innovative companies to its shores, bringing with them the capital, skills and technological know-how the Kingdom may be missing.

The potential prize is enormous: China now captures more Foreign Direct Investment in R&D than the U.S. the pharmaceuticals sector leads the way with investments, totaling $1.6bn between 2010 and 2015, according to FDI Markets.

The Kingdom has some advantages that could direct it down the R&D path. It has a young population, a growing base of science graduates and relatively high investment in health care, internet and other forms of infrastructure.

Tax incentives, and investment in education and information technology will only go so far, though. Above all, foreign investors need certainty over their intellectual property rights, including clearly defined and easily enforceable patent rights.

If this protection is strong, companies will be more likely to invest in local R&D facilities, or enter into partnerships with local companies. New products will be launched early into Saudi Arabia, as innovators will have no fear of their valuable IP rights being compromised.

Saudi Arabia has the intellectual property basics in place, in line with its World Trade Organization commitments. In fact, the U.S. Chamber of Commerce’s 2017 International IP index noted Saudi Arabia has a “strong patenting environment.”

Yet, recent developments risk derailing this progress. Just months after granting a patent for a new medicine to a company based in the United States, the Saudi Food and Drug Administration (SFDA) reneged on the deal.

The Saudi patent for Hepatitis drug Daclatasvir was granted by the Patent Office of the Gulf Cooperation council (which encompasses Saudi Arabia) to BMS in Dec 2016. Nevertheless, the SFDA granted marketing approval to a generic version manufactured Saudi company in May 2017, despite the BMS patent still being in force. Granting marketing approval to generic copies of the product in this way is arguably a breach of patent rights.

Likewise, the SDFA has also rececoontly allowed local companies to manufacture generic versions of another medicine developed by another U.S. biotech company — potentially contrary to World Trade Organization rules surrounding the protection of clinical test data, itself an important intellectual property right.

Saudi IP law allows for 5-year period in which generic companies may not use the clinical trial data submitted to regulatory authorities by originator drug manufacturers to gain marketing approval ("data exclusivity"). Gilead Sciences was granted marketing approval by the SFDA in 2014 for its product Sofosbuvir. The SFDA has subsequently granted marketing approval for generic versions of this product made by a Saudi and Egyptian company — within the 5-year data exclusivity window. This could be a breach of Saudi data exclusivity regulations.

Taken together, such actions send a hostile message to foreign investors that their valuable IP rights are not safe in Saudi Arabia. Such hostility will undermine Saudi’s economic ambition by scaring off valuable investment and skills.

They also act as an irritant to U.S.-Saudi relations, with the Trump administration indicating a higher prioritization of IP enforcement amongst its trading partners.

#### US Saudi Coop key to prevent nuclear proliferation

Emily B. Landau and Shimon Stein 18 [Landau is senior research associate at the Institute for National Security Studies, where she is also director of the Arms Control and Regional Security Project. Stein was Israel's ambassador to Germany from 2001 to 2007. Previously, he participated in the Arms Control and Regional Security working group, as well as negotiations of the Comprehensive Nuclear Test Ban Treaty, and served as head of the Regional Security, Arms Control, and Nonproliferation Department at the Israel Ministry of Foreign Affairs.], 12-4-2018, "Can the United States Prevent Saudi Arabia from Getting Nuclear Weapons?," National Interest, <https://nationalinterest.org/feature/can-united-states-prevent-saudi-arabia-getting-nuclear-weapons-37812> {OS}

The United States has always been very concerned about the proliferation risks involved in nuclear cooperation, and in 2008 it was able to achieve a memorandum of understanding with Saudi Arabia on nuclear energy cooperation whereby the latter pledged to acquire nuclear fuel from international markets, rather than producing it indigenously. But ten years later, it seems that Saudi Arabia no longer views itself as bound by that understanding. The current challenge for the United States is how to insist on what is known as a 123 agreement with Saudi Arabia, meaning that the agreement explicitly denies Saudi Arabia the right to work on sensitive nuclear technologies (enrichment capabilities and plutonium reprocessing), without driving it into the hands of other nuclear suppliers, such as Russia, China and South Korea, that may be less worried about ensuring these restrictions.¶ There are concerns that the Trump administration might be willing to concede to Saudi Arabia sensitive capabilities, and the fact that it is not willing to divulge information regarding the status of the negotiations does not bode well in this regard. The administration is keenly aware of the link to Iran’s nuclear posture, and that the Joint Comprehensive Plan of Action (JCPOA) set a very negative precedent for nuclear cooperation with other states when it legitimized Iran’s enrichment capabilities. While Iran must cap its stockpile of enriched uranium for the duration of the deal, it is allowed—under the explicit terms of the deal—to work on R&D into an entire range of advanced centrifuges. Iran has plans to install and operate these centrifuges eleven years into the deal. There is a real question of how these capabilities can be denied to states like Saudi Arabia who are in good standing with the NPT, whereas Iran—who blatantly violated the nonproliferation treaty—was granted the right to continue with these dangerous enrichment-related activities.

#### Saudi prolif draws in India and Pakistan – goes nuclear

Edelman 11—Fellow at the Center for Strategic and Budgetary Assessments. Former Undersecretary for Defense—AND—Andrew Krepinevich—President of the Center for Strategic and Budgetary Assessments—AND—Evan Montgomery—Research Fellow at the Center for Strategic and Budgetary Assessments (Eric, The dangers of a nuclear Iran, FA 90;1, http://www.csbaonline.org/wp-content/uploads/2010/12/2010.12.27-The-Dangers-of-a-Nuclear-Iran.pdf)

There is, however, at least one state that could receive significant outside support: Saudi Arabia. And if it did, proliferation could accelerate throughout the region. Iran and Saudi Arabia have long been geopolitical and ideological rivals. Riyadh would face tremendous pressure to respond in some form to a nuclear-armed Iran, not only to deter Iranian coercion and subversion but also to preserve its sense that Saudi Arabia is the leading nation in the Muslim world. The Saudi government is already pursuing a nuclear power capability, which could be the first step along a slow road to nuclear weapons development. And concerns persist that it might be able to accelerate its progress by exploiting its close ties to Pakistan. During the 1980s, in response to the use of missiles during the Iran-Iraq War and their growing proliferation throughout the region, Saudi Arabia acquired several dozen css-2 intermediate-range ballistic missiles from China. The Pakistani government reportedly brokered the deal, and it may have also oªered to sell Saudi Arabia nuclear warheads for the css-2s, which are not accurate enough to deliver conventional warheads eªectively. There are still rumors that Riyadh and Islamabad have had discussions involving nuclear weapons, nuclear technology, or security guarantees. This “Islamabad option” could develop in one of several different ways. Pakistan could sell operational nuclear weapons and delivery systems to Saudi Arabia, or it could provide the Saudis with the infrastructure, material, and technical support they need to produce nuclear weapons themselves within a matter of years, as opposed to a decade or longer. Not only has Pakistan provided such support in the past, but it is currently building two more heavy-water reactors for plutonium production and a second chemical reprocessing facility to extract plutonium from spent nuclear fuel. In other words, it might accumulate more fissile material than it needs to maintain even a substantially expanded arsenal of its own. Alternatively, Pakistan might oªer an extended deterrent guarantee to Saudi Arabia and deploy nuclear weapons, delivery systems, and troops on Saudi territory, a practice that the United States has employed for decades with its allies. This arrangement could be particularly appealing to both Saudi Arabia and Pakistan. It would allow the Saudis to argue that they are not violating the npt since they would not be acquiring their own nuclear weapons. And an extended deterrent from Pakistan might be preferable to one from the United States because stationing foreign Muslim forces on Saudi territory would not trigger the kind of popular opposition that would accompany the deployment of U.S. troops. Pakistan, for its part, would gain financial benefits and international clout by deploying nuclear weapons in Saudi Arabia, as well as strategic depth against its chief rival, India. The Islamabad option raises a host of difficult issues, perhaps the most worrisome being **how India would respond**. Would it **target Pakistan**’s weapons in Saudi Arabia with its own conventional or nuclear weapons? How would this expanded nuclear competition influence **stability** during a crisis in either the Middle East or South Asia? Regardless of India’s reaction, any decision by the Saudi government to seek out nuclear weapons, by whatever means, would be **highly destabilizing**. It would increase the incentives of other nations in the Middle East to pursue nuclear weapons of their own. And it could increase their ability to do so by eroding the remaining barriers to nuclear proliferation: each additional state that acquires nuclear weapons **weakens the nonprolif**eration **regime**, even if its particular method of acquisition only circumvents, rather than violates, the npt. Were Saudi Arabia to acquire nuclear weapons, the Middle East would count three nuclear-armed states, and perhaps more before long. It is unclear how such an n-player competition would unfold because most analyses of nuclear deterrence are based on the U.S.- Soviet rivalry during the Cold War. It seems likely, however, that the interaction among three or more nuclear-armed powers would be more prone to **miscalc**ulation and **escalation** than a bipolar competition. During the Cold War, the United States and the Soviet Union only needed to concern themselves with an attack from the other.Multipolar systems are generally considered to be less stable than bipolar systems because coalitions can shift quickly, upsetting the balance of power and creating incentives for an attack. More important, emerging nuclear powers in the Middle East might not take the costly steps necessary to preserve regional stability and avoid a nuclear exchange. For nuclear-armed states, **the bedrock of deterrence** is the knowledge that each side has a secure second-strike capability, so that no state can launch an attack with the expectation that it can wipe out its opponents’ forces and avoid a devastating retaliation. However, **emerging nuclear powers might not invest in** expensive but **survivable capabilities** such as hardened missile silos or submarinebased nuclear forces. Given this likely vulnerability, the close proximity of states in the Middle East, and the very short flight times of ballistic missiles in the region, any new nuclear powers might be compelled to “launch on warning” of an attack or even, during a crisis, to use their nuclear forces preemptively. Their governments might also delegate launch authority to lower-level commanders, heightening the possibility of miscalculation and escalation. Moreover, if early warning systems were not integrated into robust command-and-control systems, the risk of an unauthorized or accidental launch would increase further still. And without sophisticated early warning systems, a nuclear attack might be unattributable or attributed incorrectly. That is, assuming that the leadership of a targeted state survived a first strike, it might not be able to accurately determine which nation was responsible. And this uncertainty, when combined with the pressure to respond quickly, would create a significant risk that it would retaliate against the wrong party, potentially triggering **a regional nuclear war.** Most existing nuclear powers have taken steps to protect their nuclear weapons from unauthorized use: from closely screening key personnel to developing technical safety measures, such as permissive action links, which require special codes before the weapons can be armed. Yet there is no guarantee that emerging nuclear powers would be willing or able to implement these measures, creating a significant risk that their governments might lose control over the weapons or nuclear material and that nonstate actors could gain access to these items. Some states might seek to mitigate threats to their nuclear arsenals; for instance, they might hide their weapons. In that case, however, a single intelligence compromise could leave their weapons vulnerable to attack or theft.

#### Even a limited nuclear war would cause extinction – best science.

Cribb 17 (Julian, BA Classics@WesternAusstralia, FoundingEditor@ScienceAlert, Surviving the 21st Century, Springer)

The most publicised horrors of nuclear war, over the past half-century, were blast damage, fi reball burns and radiation sickness, as they were in Hiroshima and Nagasaki, leading to a perception that those well away from target areas might be spared. Scientists however demur, arguing that the biggest killer of all is likely to be a ‘ nuclear winter ’ , triggered by the immense quantities of dust and smoke from burning cities and forests lofted into the upper atmosphere, and the simultaneous stripping of the Earth’s protective ozone layer: “In the aftermath… vast areas of the earth could be subjected to prolonged darkness, abnormally low temperatures, violent windstorms, toxic smog and persistent radioactive fallout.” This would be compounded by the collapse of farming and food production, transport, energy grids, healthcare, sanitation and central government. Even in regions remote from the actual blasts people would starve, die from freezing temperatures as much as 30 °C below normal, from radiation sickness and a pandemic of skin cancers, pollution and loss of immunity to ordinary diseases. The nuclear winter is in effect the antithesis of global warming, a shock cooling of the entire planet, but one lasting several years only. However, “A number of biologists contend the extinction of many species … - including the human species— is a real possibility,” they say (Turco et al. 2012 ). In the 1980s a group of courageous scientists 1 alerted the leaders of both the US and Russia to the dangers of a nuclear winter. In an atomic war, they warned, there will be no winners. Th en-Soviet president Mikhail Gorbachev took their counsel to heart: “Models made by Russian and American scientists showed that a nuclear war would result in a nuclear winter that would be extremely destructive to all life on Earth; the knowledge of that was a great stimulus to us, to people of honor and morality, to act in that situation,” he subsequently related (Hertsgard 2000 ). US President Ronald Reagan concurred: “A nuclear war cannot be won and must never be fought,” he said in his State of the Union Address in 1984 (Reagan 1984 ). Marking this watershed moment in history Al Gore recounted in his Nobel Prize oration in 2007 “More than two decades ago, scientists calculated that nuclear war could throw so much debris and smoke into the air that it would block life- giving sunlight from our atmosphere, causing a ‘nuclear winter.’ Th eir eloquent warnings here in Oslo helped galvanize the world’s resolve to halt the nuclear arms race.” How large a nuclear release is required to precipitate a nuclear winter is still subject to technical debate, but with the greatly improved models developed for climate science, recent estimates suggest as few as 50 Hiroshima-sized bombs (15 kilotonnes each) would do it—or the use of only one weapon in every 200 from the global nuclear arsenal (Robock 2009 ). Th is puts a very different complexion on the contemporary risks facing humanity. First, it suggests that even a limited conflict among lesser actors in the arms race, for example between Pakistan and India, India and China or Israel and Iran, and involving mainly the use of “battlefi eld” nukes could still imperil the entire world. In Lights Out: how it all ends , nuclear experts Alan Robock and Brian Toon examined the eff ects of a regional war (Robock and Toon 2012 ). To begin with, they argue, a ‘limited nuclear war’ is highly unlikely as, with the release of a handful of battlefi eld nukes, things will very quickly spiral out of control as communications fail and panic spreads, mushrooming into a more general conflict involving dozens of weapons spread over a much wider region. Firestorms in the megacities would throw up a shocking amount of smoke, ash and dust—around 70 billion tonnes is the estimate for an India/Pakistan clash. Running this through climate models they found it would block out sunlight, chilling the planet by an average 1.25° for up to 10 years—enough to cause crop-killing frosts , even in midsummer. Th is would sharply reduce and in some regions eliminate farm production for several years. Normal world grain stocks are suffi cient to feed humanity for only about 2–3 months, so one of the fi rst round eff ects of the war would be worldwide panic and fi nancial collapse as food supplies give out and grain prices soar astronomically. A billion people living on the margins of hunger would probably perish within weeks, and billions more over the ensuing months. In the early twenty-fi rst century at least eight nations, on this calculus, have the tools to terminate civilisation, and possibly the human species, on their own, while at least two more aspire to the power to do so. Meanwhile the shadow of possible nuclear and chemical terrorism, and their consequences, is lengthening.

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#### Biotech is the new frontier; America is ahead but China is dangerously close

Gupta 6/11 [Gaurav Gupta, Biotech Investor, Founder of Ascendant BioCapital, a life science investment firm based in New York. Previously, Gaurav worked at OrbiMed Advisors, and served as a resident in neurological surgery at Columbia University Medical Center. He has co-authored over a dozen articles in peer-reviewed journals, filed a patent on a device for use in spine surgery, and edited a book on the technical and ethical implications of using tissue engineered products in the operating room. Dr. Gupta obtained his M.D. from the Stanford University School of Medicine, where he was a Paul and Daisy Soros Fellow, and B.S. and M.S.E. in biomedical engineering from Johns Hopkins University, where he was a Charles R. Westgate Scholar.) “As Washington Ties Pharma’s Hands, China Is Leaping Ahead” Barron’s Magazine: Commentary, China., 6/11/2021] RM

There should be no doubt that we are living at the dawn of a golden age of biomedical innovation. The American scientific engine that produced Covid-19 vaccines in record time was fueled by a convergence of advances in genomics, biomarkers, data science, and manufacturing years in the making. The first Food and Drug Administration approvals of a host of new product formats—oligonucleotide, bispecific, oncolytic virus, CAR-T, and lentivirus/AAV—all took place within the last decade. These represent an unprecedented expansion of the armamentarium that physicians have at their disposal to treat and cure disease. In the last few years, [47% of all new medicines](https://www.efpia.eu/media/554521/efpia_pharmafigures_2020_web.pdf) were invented by U.S. biopharma companies, with [homegrown startups](https://www.cbo.gov/publication/57126) driving the majority of innovation. The bulk of the remainder were developed by foreign companies specifically for the U.S. market.

An indirect benefit of these trends is that most novel therapeutics undergo clinical development and early commercial launch here in the U.S. The rest of the world understands that the American patient has earlier and broader access to groundbreaking therapies via these mechanisms. Indeed, the past decade is filled with examples of medical “firsts” for American patients: the first cure for Hepatitis C, the first gene therapy for blindness, the first immunotherapy for cancer. Future rewards will be greater still if we preserve our current system of incentivizing and protecting innovation.

The remarkable innovation capacity of our biopharmaceutical industry ought to be a source of national pride. Yet while “Made in America” is the global standard for medicines in development today, misguided policy risks ceding our scientific prowess to other countries in the future. This is particularly true in the case of China, where biotechnology has become a strategic pillar for the health of its people and economy.

From 2016 to 2020, the market capitalization of all Chinese biopharma companies increased exponentially from [$1 billion to over $200 billion](https://www.bloomberg.com/news/articles/2021-03-01/xi-mobilizes-china-for-tech-revolution-to-cut-dependence-on-west). China saw over [$28 billion](https://www.bioworld.com/articles/506978-china-sees-five-year-highs-in-life-sciences-investments-and-partnering) invested in its life sciences sector in 2020, double the previous year’s amount. Returns on China’s investment are already arriving. The FDA approved a drug developed in China for the first time ever in 2019. While China’s innovation capacity currently remains behind America’s, my experiences as a biopharma professional make it clear they are doing everything they can to catch up and catch up fast.

In fact, when I speak to Chinese biotechnology executives, they boast that they can run clinical trials faster than their U.S. counterparts. The danger of misguided policies that disincentivize pharmaceutical innovation in the U.S. is effectively driving that same innovation to China. If we close off the market in the U.S. at the same time that China is opening its market to innovative new products, then we will see companies choose to first launch impactful novel medicines in China, based on clinical trials conducted in China. Because the FDA rarely accepts data generated entirely outside the U.S., this relocation of research capacity will negatively affect Americans’ access to cutting-edge therapies.

The biotechnology field is advancing rapidly. Promising technologies such as targeted protein degradation and gene editing are perhaps not far from being developed into impactful medicines, and the U.S. risks these technologies being mastered by Chinese companies.

It is widely held that allowing China to gain an asymmetric edge in critical technologies such as AI or quantum computing could destabilize the geopolitical balance of power. The same is true of biotechnology. Chinese scientists were the first to edit the genomes of human embryos, in [contravention](https://www.sciencemag.org/news/2019/12/chinese-scientist-who-produced-genetically-altered-babies-sentenced-3-years-jail) of international standards, and the U.S. national security community believes China is [pushing ahead](https://www.nbcnews.com/politics/national-security/china-has-done-human-testing-create-biologically-enhanced-super-soldiers-n1249914) with experimental concepts for biological and cognitive enhancement of soldiers and civilians. American policy should be focused on protecting, rather than undermining, the global dominance of our biotechnology industry.

#### The plan recapitulates IP to China, destroying competitive advantages

WSJ 5/6 [Wall Street Journal Editorial Board, WSJ Opinion Philosophy: “We speak for free markets and free people, the principles, if you will, marked in the watershed year of 1776 by Thomas Jefferson's Declaration of Independence and Adam Smith's “Wealth of Nations.” So over the past century and into the next, the Journal stands for free trade and sound money; against confiscatory taxation and the ukases of kings and other collectivists; and for individual autonomy against dictators, bullies and even the tempers of momentary majorities.” Edited by Paul A. Gigot and Daniel Henninger, “Biden’s Vaccine IP Debacle: His patent heist is a blow to the Covid fight and U.S. biotech.” The WSJ Opinion: Review and Outlook, May 6, 2021] RM

We’ve already criticized President Biden’s bewildering decision Wednesday to endorse a patent waiver for Covid vaccines and therapies. But upon more reflection this may be the single worst presidential economic decision since Nixon’s wage-and-price controls.

In one fell swoop he has destroyed tens of billions of dollars in U.S. intellectual property, set a destructive precedent that will reduce pharmaceutical investment, and surrendered America’s advantage in biotech, a key growth industry of the future. Handed an American triumph of innovation and a great soft-power opportunity, Mr. Biden throws it all away.

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India and South Africa have been pushing to suspend patents at the World Trade Organization for months. They claim that waiving IP protections for Covid vaccines and therapies is necessary to expand global access, but their motivation is patently self-interested.

Both are large producers of generic drugs, though they have less expertise and capacity to make complex biologics like mRNA vaccines. They want to force Western pharmaceutical companies to hand over IP free of charge so they can produce and export vaccines and therapies for profit. Their strategy has been to shame Western leaders into surrendering with the help of Democrats in the U.S.

But suspending IP isn’t necessary to expand supply and will impede safe vaccine production. The global vaccine supply is already increasing rapidly thanks to licensing agreements the vaccine makers have made with manufacturers around the world.

Pfizer and BioNTech this week said they aimed to deliver three billion doses this year, up from last summer’s 1.2 billion estimate. Moderna increased its supply forecast for this year to between 800 million and a billion from 600 million. AstraZeneca says it has built a supply network with 25 manufacturing organizations in 15 countries to produce three billion doses this year.

AstraZeneca and Novavax have leaned heavily on manufacturers in India to produce billions of doses reserved for lower-income countries. But India has restricted vaccine exports to supply its own population. IP simply isn’t restraining vaccine production.

Busting patents also won’t speed up production, since it would take months for these countries to set up new facilities. Competition will increase for scarce ingredients, and less efficient manufacturers with little expertise would make it harder for licensed partners to produce vaccines.

There’s also the problem of safety. Johnson & Johnson has experienced quality problems at an Emergent plant making its vaccines, and that’s in Baltimore. Imagine the potential problems with unlicensed producers in, say, Malaysia or Brazil. If vaccines made there have complications, confidence in licensed vaccines could plummet too. And who would Pfizer and Moderna sue to get their reputations back?

The economic self-damage is also hard to fathom. The U.S. currently has a competitive advantage in biotech and biologics manufacturing, which could be a growing export industry. Waiving IP protections for Covid vaccines and medicines will give away America’s crown pharmaceutical jewels and make the U.S. and world more reliant on India and China for pharmaceuticals.

Moderna has been working on mRNA vaccines for a decade. Covid represents its first success. Ditto for Novavax, which has been at it for three decades. Small biotech companies in the U.S. have been studying how to create vaccines using nasal sprays, pills and patches.

Thanks to Mr. Biden, all this could become the property of foreign governments. Licensing agreements allow developers to share their IP while maintaining quality control. Breaking patents and forcing tech transfers will enable China and low-income countries to manufacture U.S. biotech products on their own.

China’s current crop of vaccines are far less effective than those in the West, but soon Beijing might be able to purvey Pfizer knock-offs. The U.S. has spent years deploring China’s theft of American IP, and now the Biden Administration may voluntarily let China could reap profits from decades of American innovation.

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Instead of handing over American IP to the world, Mr. Biden could negotiate bilateral vaccine agreements and export excess U.S. supply. If Mr. Biden wants to increase global supply safely, the U.S. could spend more to help the companies produce more for export. Then the jobs would go to Americans. We thought this was the point of the production deal Mr. Biden negotiated between J&J and Merck.

Alas, this President seems to be paying more attention these days to Elizabeth Warren, Bernie Sanders, Alexandria Ocasio-Cortez and Nancy Pelosi. They think vaccines and new drugs can be conjured by government as a public good with no incentive for risk-taking or profit. This really is destructive socialism.

Mr. Biden ought to listen to Angela Merkel. Pfizer’s partner BioNTech is a German firm, and the German Chancellor said Thursday that she opposes the WTO heist: “The protection of intellectual property is a source of innovation and it must remain so in the future.”

At least IP is safe in Germany. Mr. Biden has sent a signal around the world that nobody’s intellectual property is safe in America.

#### China uses biotech offensively—uncertainty means you should err negative

Kania and Vonrndick 19 [Elsa Kania is an Adjunct Senior Fellow with the Technology and National Security Program at the Center for a New American Security. She is also a Ph.D. candidate in Harvard University’s Department of Government. Her views are her own. Wilson VornDick consults on national security, emerging technologies, and China for Duco and Rane.) “Weaponizing Biotech: How China's Military Is Preparing for a 'New Domain of Warfare'” Defense One, Commentary, China, Biowarfare, 8/14/2019] RM

We may be on the verge of a brave new world indeed. Today’s advances in biotechnology and genetic engineering have exciting applications in medicine — yet also alarming implications, including for military affairs. China’s national strategy of military-civil fusion (军民融合) has highlighted biology as a priority, and the People’s Liberation Army could be at the forefront of expanding and exploiting this knowledge.

The PLA’s keen interest is reflected in strategic writings and research that argue that advances in biology are contributing to changing the form or character (形态) of conflict. For example:

In 2010’s War for Biological Dominance (制生权战争), Guo Jiwei (郭继卫), a professor with the Third Military Medical University, emphasizes the impact of biology on future warfare.

In 2015, then-president of the Academy of Military Medical Sciences He Fuchu (贺福初) argued that biotechnology will become the new “strategic commanding heights” of national defense, from biomaterials to "brain control" weapons. Maj. Gen. He has since become the vice president of the Academy of Military Sciences, which leads China’s military science enterprise.

Biology is among seven "new domains of warfare" discussed in a 2017 book by Zhang Shibo (张仕波), a retired general and former president of the National Defense University, who concludes: “Modern biotechnology development is gradually showing strong signs characteristic of an offensive capability,” including the possibility that “specific ethnic genetic attacks” (特定种族基因攻击) could be employed.

The 2017 edition of Science of Military Strategy (战略学), a textbook published by the PLA’s National Defense University that is considered to be relatively authoritative, debuted a section about biology as a domain of military struggle, similarly mentioning the potential for new kinds of biological warfare to include “specific ethnic genetic attacks.”

These are just a few examples of an extensive and evolving literature by Chinese military scholars and scientists who are exploring new directions in military innovation.

Following these lines of thinking, the PLA is pursuing military applications for biology and looking into promising intersections with other disciplines, including brain science, supercomputing, and artificial intelligence. Since 2016, the Central Military Commission has funded projects on military brain science, advanced biomimetic systems, biological and biomimetic materials, human performance enhancement, and “new concept” biotechnology.

Gene Editing

Meanwhile, China has been leading the world in the number of trials of the CRISPR gene-editing technology in humans. Over a dozen clinical trials are known to have been undertaken, and some of these activities have provoked global controversy. It’s not clear whether Chinese scientist He Jiankui, may have received approval or even funding from the government for editing embryos that became the world’s first genetically modified humans. The news provoked serious concerns and backlash around the world and in China, where new legislation has been introduced to increase oversight over such research. However, there are reasons to be skeptical that China will overcome its history and track record of activities that are at best ethically questionable, or at worst cruel and unusual, in healthcare and medical sciences.

But it is striking how many of China’s CRISPR trials are taking place at the PLA General Hospital, including to fight cancer. Indeed, the PLA’s medical institutions have emerged as major centers for research in gene editing and other new frontiers of military medicine and biotechnology. The PLA’s Academy of Military Medical Sciences, or AMMS, which China touts as its “cradle of training for military medical talent,” was recently placed directly under the purview of the Academy of Military Science, which itself has been transformed to concentrate on scientific and technological innovation. This change could indicate a closer integration of medical science with military research.

In 2016, an AMMS doctoral researcher published a dissertation, “Research on the Evaluation of Human Performance Enhancement Technology,” which characterized CRISPR-Cas as one of three primary technologies that might boost troops’ combat effectiveness. The supporting research looked at the effectiveness of the drug Modafinil, which has applications in cognitive enhancement; and at transcranial magnetic stimulation, a type of brain stimulation, while also contending that the “great potential” of CRISPR-Cas as a “military deterrence technology in which China should “grasp the initiative” in development.

AI + Biotech

The intersection of biotechnology and artificial intelligence promises unique synergies. The vastness of the human genome — among the biggest of big data — all but requires AI and machine learning to point the way for CRISPR-related advances in therapeutics or enhancement.

In 2016, the potential strategic value of genetic information led the Chinese government to launch the National Genebank (国家基因库), which intends to become the world’s largest repository of such data. It aims to “develop and utilize China’s valuable genetic resources, safeguard national security in bioinformatics (生物信息学), and enhance China’s capability to seize the strategic commanding heights” in the domain of biotechnology.

The effort is administered by BGI, formerly known as Beijing Genomics Inc., which is Beijing’s de facto national champion in the field. BGI has established an edge in cheap gene sequencing, concentrating on amassing massive amounts of data from a diverse array of sources. The company has a global presence, including laboratories in California and Australia.

U.S. policymakers have been concerned, if not troubled, by the company’s access to the genetic information of Americans. BGI has been pursuing a range of partnerships, including with the University of California and with the Children’s Hospital of Philadelphia on human genome sequencing. BGI’s research and partnerships in Xinjiang also raise questions about its linkage to human rights abuses, including the forced collection of genetic information from Uighurs in Xinjiang.

There also appear to be links between BGI’s research and military research activities, particularly with the PLA’s National University of Defense Technology. BGI’s bioinformatics research has used Tianhe supercomputers to process genetic information for biomedical applications, while BGI and NUDT researchers have collaborated on several publications, including the design of tools for the use of CRISPR.

Biotech’s Expansive Frontier

It will be increasingly important to keep tabs on the Chinese military’s interest in biology as an emerging domain of warfare, guided by strategists who talk about potential “genetic weapons” and the possibility of a “bloodless victory.” Although the use of CRISPR to edit genes remains novel and nascent, these tools and techniques are rapidly advancing, and what is within the realm of the possible for military applications may continue to shift as well. In the process, the lack of transparency and uncertainty of ethical considerations in China’s research initiatives raise the risks of technological surprise.

#### Independently – bioterror and strikes

Moore 20 Scott Moore, Director of the Penn Global China Program at the University of Pennsylvania, Young Professional and Water Resources Management Specialist at the World Bank Group, and Environment, Science, Technology, and Health Officer for China at the U.S. Department of State, Giorgio Ruffolo Post-Doctoral Research Fellow with the Belfer Center for Science and International Affairs at Harvard University, Truman, Fulbright, and Rhodes Scholar., The Brookings Institution - Global China - Assessing China's Growing Role in the World, "CHINA’S ROLE IN THE GLOBAL BIOTECHNOLOGY SECTOR AND IMPLICATIONS FOR U.S. POLICY", APRIL 2020, https://www.brookings.edu/wp-content/uploads/2020/04/FP\_20200427\_china\_biotechnology\_moore.pdf - BD

IMPLICATIONS

The certainty that China will play an increasingly important role in the global biotechnology sector poses several issues for U.S. policymakers. The gravest of these pertain to national security. Though there is presently no sign that China’s capabilities exceed those of the United States, some researchers have noted that biotechnology is a focus of increasing attention by the People’s Liberation Army.42 U.S. policymakers and security analysts have also raised concerns that the dominant market position of Chinese firms in producing active pharmaceutical ingredients might allow Beijing to disrupt U.S. access to lifesaving drugs in the event of a conflict.43 On the other hand, the use of tools like CRISPR, which is increasingly inexpensive and easy to use, by terrorists and non-state actors to potentially create novel bioweapons poses severe security threats to both the United States and China. It would seem to be in the interest of all states, including China, to strengthen efforts, currently led mostly by the private sector, to prevent dangerous actors from gaining access to DNA templates and other relevant materials.44

Though these prospects are alarming, the theft and use of biomedical data presents more immediate policy concerns. American life sciences research institutions have been subject to what U.S. officials characterize as prolific intellectual property theft and non-traditional intelligence collection by Chinese actors.45 At home, Beijing has already incorporated biometric data on certain populations, such as the Uighur minority group, into its already-formidable social control and surveillance apparatus.46 Chinese actors also appear to have targeted foreign citizens for covert biomedical data collection.47 Last year, the U.S. government forced a Chinese firm to sell its majority stake in an American social network that aggregates health care data from users, primarily over worries this information could be used to persuade Americans with access to sensitive information to spy for China.48 Such added U.S. government scrutiny has contributed to a sharp decline in Chinese investment in the U.S. biotechnology sector. Though small overall, such investment had been growing rapidly, and in 2018 the biotechnology sector constituted the single largest source of Chinese investment in the U.S. overall, surpassing real estate.49

As this impact suggests, access to and control over biomedical data also has profound implications for the economic competitiveness of the U.S. biotechnology sector. Many frontier areas of biotechnology, including the use of artificial intelligence for biomedical applications, depend on access to large quantities of individual patient data. Chinese biotechnology firms are likely to have access to larger quantities of such data than their competitors elsewhere thanks to the size of China’s population and relatively weak rules governing data collection and sharing. An existing biomedical database of patients from China’s national health care system, for example, allegedly covers some 600 million patients.50

The Chinese government is moreover increasingly aggressive about preventing foreign firms and organizations from accessing such data. In 2016, biomedical data was proclaimed a “national strategic resource,”51 and the export of such data is strictly controlled. Rules specifically bar any foreign use of Chinese biomedical data that “may jeopardize national security, national interests, or public security,” and in 2018 these were used to shut down several high-profile scientific collaborations including one involving Peking University and the University of Oxford.52 It should be noted, however, that while data quantity is important, so is data quality, and a combination of poor and inconsistent record-keeping and limited population diversity may diminish the utility of biomedical data produced in China for key applications like therapeutics development.53 In any case, the availability of biomedical datasets will be a key determinant of the relative competitiveness of the U.S. and Chinese biotechnology industries going forward.

A final, and more hopeful, policy implication of China’s growing role in biotechnology is its potential to help address shared global challenges like infectious disease prevention and biodiversity protection. In the near term, the COVID-19 crisis has highlighted the need for expanded international cooperation on epidemiological data collection and analysis, vaccine development, and other areas related to biotechnology. While China’s openness to such cooperation at the moment is unclear, there are likely to be future opportunities to engage China in COVID-19 tracing, vaccine development, and deployment initiatives in third countries, especially in the less-developed world. In the longer term, synthetic biology, especially the use of gene drives to rapidly spread genetic modifications throughout a population, offers great promise to eliminate insect-borne diseases like malaria, and could also help endangered species adapt to climate change effects. As the 21st century advances, advanced biotechnology will both demand new forms of global governance and present new arenas for both competition and cooperation between researchers, business leaders, and policymakers.54

### OFF

#### Text: the member nations of the World Trade Organization ought to reduce IP protections for genomic medicines except provide incentives for orphan drugs.

#### Only exclusive patent protection rights paired with incentives can solve malaria, leprosy, and initially rare diseases. Grabowski 02

Henry Grabowski, Patents, Innovation and Access to New Pharmaceuticals, *Journal of International Economic Law*, Volume 5, Issue 4, December 2002, Pages 849–860, <https://doi.org/10.1093/jiel/5.4.849>

In 1983, Congress passed the Orphan Drug Act, which provided a variety of incentives to undertake R&D on orphan drug indications (defined in a subsequent law as diseases or medical conditions which affect fewer than 200,000 patients).37 The economic incentives included in the Act involved R&D tax credits, a clinical research grants programme, accelerated reviews at the FDA, and a guaranteed market exclusivity period of 7 years from the date of FDA approval (this was separate from any normal patent protection that might also apply to these products). Funding for R&D has also been provided by various non-profit foundations focused on particular rare illnesses. The effect of these incentives on the development of new orphan drugs has been impressive. In the period between 1983 and 1999, more than 200 drugs and biologicals for rare diseases have been introduced.38 This represents more than a 12-fold annual increase compared to the decade prior to the enactment of the law, when fewer than 10 such products came to the market for the entire 10-year period. In a recent paper, Professor Frank Lichtenberg has shown that the Act has had a favourable effect on mortality from rare illnesses. While the number of deaths from rare diseases had been increasing faster than those from other diseases in the 5-year period prior to 1983, the number of deaths from rare diseases declined, both in absolute terms and relative to other deaths, in the post-1983 period.39 To attack the ‘orphan disease’ problem confronting third world countries for diseases like malaria and leprosy, one needs an international counterpart to the US Orphan Drug Act. From a scientific standpoint, it is an auspicious time to proceed with such a programme, given the recent advances in genom- ics which enhance the possibility of developing significant new vaccines and therapies for infectious diseases prevalent in less affluent countries. As in the case of the Orphan Drug Act, a multifaceted approach is necessary including R&D subsidies to firms with promising new technologies. These could be funded through government as well as non-profit charitable entities and public-private partnerships. Given the low-income base of third world mar- kets, success of these programmes might well hinge upon guarantees to pur- chase amounts of economically sustainable products that are successfully developed. The purchase agreements could be tied to up-front commitments from the firms on the product’s price within third-world markets. Michael Kremer has characterized R&D incentive programmes based on purchase guarantees as ‘pull’ programmes and analyzed how they could be designed in the context of new vaccines for third-world diseases.40 A variety of risk- and reward-sharing arrangements between pharmaceutical firms and funding sponsors could be envisioned. The objectives would be to provide incentives for new R&D programmes for diseases in developing countries. For example, under the Gates Foundation-sponsored International AIDS Vaccine Initiative (IAVI), firms have received grants to partially sup- port development of AIDS vaccines targeted to African strains of the disease. The firms retain international patent rights to the technology, but have agreed to supply any approved vaccines developed from this programme at a small margin over cost to developing countries. Such terms can be particularly attractive to earlier stage biotech firms seeking funding for proof of principle for a new technology with multiple applications. Similarly, the Global Alli- ance for TB Drug Development has recently announced a memorandum of understanding with Chiron for the development of a new TB drug for which no royalties would be due on sales in less-developed countries.41 In summary, the success of the US Orphan Drug Act in stimulating R&D investment and innovation for diseases with low expected market potential provides a useful model for the orphan disease problem confronting less indus- trialized countries. While the characteristics of particular programmes may differ significantly from those employed in the case of the US Orphan Drug Act, the basic principle of public and private risk sharing within the context of a system of market incentives would appear to be a fruitful guiding principle.

#### Orphan drug targeting has prevented hundreds of thousands of deaths and is k2 combating HIV mortality. Lichtenberg 01

Lichtenberg, Frank R. "The effect of new drugs on mortality from rare diseases and HIV." (2001). <https://www.nber.org/papers/w8677>

I have investigated the effect of large increases in the number of drugs available to treat rare diseases and HIV on mortality associated with them. Figure 9 indicates that mortality from both diseases declined dramatically following increases in drug approvals. Before the Orphan Drug Act went into effect (between 1979 and 1984), mortality from (initially) rare diseases grew at the same rate as mortality from other diseases. In contrast, during the next five years, mortality from (initially) rare diseases grew more slowly than mortality from other diseases. I estimate that one additional orphan drug approval in year t prevents 211 deaths in year t+1 and ultimately prevents 499 deaths, and that about 108 thousand deaths from rare diseases will ultimately be prevented by all of the 216 orphan drugs that have been approved since 1983. Deaths are more closely related to the number of orphan product designations than they are to the number of approvals. Consistent with previous patient-level studies of HIV, I find that new drugs played a key role in the post-1995 decline in HIV mortality. I estimate that one additional HIV drug approval in year t will prevent 5986 HIV deaths in year t+1 and ultimately prevent 33,819 HIV deaths. HIV drug approvals have reduced mortality both directly and indirectly (via increased drug consumption). HIV mortality depends on both 15 the quality and the quantity of medications consumed, and new drug approvals have a sizeable impact on drug consumption: one additional HIV drug approval in year t results in 1.2 million additional HIV drug units consumed in year t+1 and ultimately result in 3.6 million additional HIV drug units consumed.

### WTO Cred

#### **Alt causes to WTO cred—rules ignored, protectionism, no dispute settlement, lack of US commitment.**

Schott 20 [Jeffrey J. Schott is a senior fellow at the Peterson Institute for International Economics. He is a member of the State Department’s Advisory Committee on International Economic Policy and was previously cochairman of the Trade and Environment Policy Advisory Committee for the U.S. Trade Representative. 5-4-2020 The WTO is Dead ... Long Live the WTO Milken Institute Review https://www.milkenreview.org/articles/the-wto-is-dead-long-live-the-wto] SW 9-5-2021

When 123 nations signed the accord creating a truly global body to oversee international commerce in 1994, the new World Trade Organization was hailed as a major step toward a modern, rules-based regime that would advance the effort of global open trade. What a difference, alas, a quarter-century made.

Now the WTO is increasingly seen as sclerotic. Its rules badly need updating and the dispute-settlement process is breaking down. Multilateral trade talks have collapsed; efforts to conclude even modest deals at the upcom-ing June 2020 meeting of trade ministers seem unlikely. Indeed, it’s no exaggeration to say that the WTO faces an existential crisis. Here, I offer some perspective on what has gone wrong and how to make it right in the face of widespread skepticism that a global rules-based trade system remains viable.

Grim Realities

There’s no getting around the fact that the WTO’s rules are widely abused or flat-out ignored. Even after the heralded U.S.-China trade deal was announced in January, the U.S. and China continue to violate WTO obligations on a grand scale, with about $425 billion of two-way merchandise trade still subject to duties that violate WTO obligations of both countries. Rules on subsidies, intellectual property and investment, last updated in the 1990s, are inadequate and in-complete, allowing countries to circumvent their market-access commitments with financial support for domestic firms and farmers, and to encourage the misappropriation of foreign technology.

Equally alarming, the exemption to the WTO rules allowing trade restrictions for compelling reasons of national security protection has been grossly misapplied by U.S. officials to protect domestic steel, aluminum and possibly auto producers — and by Japan and Korea to justify high-tech trade restrictions. If countries continue to brazenly invoke national security rationales to justify plain and simple protectionism, commitments to open markets that are central to WTO obligations will become increasingly worthless.

At the same time, the WTO’s dispute-settlement process, which has helped to resolve almost 600 cases since 1995, has been seriously impaired by the idling of its Appellate Body (AB). All countries have the right to appeal dispute-panel decisions, which are then held in abeyance pending completion of the appeal. But since last December, the AB has been reduced to only one member out of the normal complement of seven. That’s because U.S. officials have blocked the appointments of AB members until other WTO countries approve changes in dispute procedures demanded by the United States.

Now, since three members are needed to form a panel to hear appeals, the whole appeals process has been placed in suspended animation. The situation has broad-ranging implications for the multilateral trading system. Preventing new appeals of panel rulings will, of course, allow disputing parties to block implementation of the rulings. This will encourage unilateral actions by countries strong enough to pressure partners and will discourage new rule-making negotiations because of uncertainty that rules will be enforced.

What Would It Take?

Can the WTO system be put back on track? Doing so would require the recognition that its rulebook, along with the process of resolving disputes about those rules, needs substantial renovation. It also requires the recognition that the world’s key problems require global solutions, in which the top traders — the U.S., the European Union, Japan and China — work together in common cause.

That’s a tough row to hoe, especially given current U.S.-China and U.S.-EU frictions. But it is doable, if WTO members reorder their priorities and focus on narrow, pragmatic solutions. To see a way forward, it makes sense to digress a moment to see how we got here.

Throughout the postwar era, the United States led the charge to strengthen the multilateral trading system and to lower barriers to trade and investment. U.S. negotiators led by example: U.S. tariff cuts accounted for a large share of the liberalization undertaken in the first four rounds of postwar negotiations under the General Agreement on Tariffs and Trade, when tariffs were high to protect industrial recovery in war-decimated economies. U.S. officials opened and led all eight GATT rounds of more or less successful reform — plus the Doha Round (named after the city in which it was started), the first multilateral trade negotiation of the WTO era.

Almost the entire WTO rulebook was crafted in the period 1947-1994, when trans- Atlantic nations dominated world trade and China’s footprint was barely noticeable. Since then, technological developments have transformed the way we produce, transport, market and finance goods and services. The Doha Round, begun in late 2001, was meant to make WTO rules more relevant for 21st-century economies. In the event, the giant package of trade reforms developed in the Doha Round, so close to completion in 2008, was felled by the slingshot blows of India and a few other countries seeking special protection for their farmers and industries. WTO rules have been virtually unchanged since then, with the Trade Facilitation Agreement (2013) and updates to the Government Procurement Agreement (2014) the only modest changes.

The WTO’s prospects are not bright. In particular, it’s unclear whether the United States is willing to invest in a multilateral effort.

As I am writing this, the WTO’s prospects are not bright. In particular, it’s unclear whether the United States is willing to invest in a multilateral effort. Under the Trump administration, the United States, the lead architect of the postwar trading system, has been quick to criticize flaws in WTO agreements but half-hearted in its commitment to reform. The president has made no secret of his preference to deal with trading partners and allies one on one, where they are more likely to accept U.S. demands in deference to broader strategic relations.

Why is the WTO so unpopular in Washington these days? Simply put, President Trump believes past U.S. administrations paid too much and got too little in return from U.S. trading partners in previous multilateral trade agreements.

His complaints target several interrelated problems. First, largely for historical reasons alluded to above, U.S. tariffs are frozen in the WTO at lower levels than for other major trading nations. Trump is particularly galled that European auto tariffs are four times higher than U.S. auto tariffs. But under existing WTO rules, if U.S. officials want to raise these “bound” tariffs, they have to offer other WTO members something in return.

Second, too many countries avoid WTO tariff obligations, most notably by invoking special exemptions for developing countries. Any WTO member can self-designate as a developing country — as Singapore and South Korea have done in the past. And third, WTO rules weren’t designed for big economies (think China) that feel free to intervene in markets to achieve government goals. Nor were they built to accommodate the big-data world of digital trade.

Accordingly, the White House wants past WTO deals redone, with an updated rulebook to address Chinese industrial policies (especially support for state-owned enterprises). It wants a freer hand for U.S. officials to raise tariffs under WTO antidumping, safeguards and national security exceptions (where Trump’s current tariffs against China, Europe and others plainly violate current WTO norms). And it wants the removal of most developing- country trade preferences in current and prospective trade deals.

U.S. trade officials don’t want U.S. policies to be subject to binding enforcement of WTO rules. Defanging the AB permanently would enable them to achieve that result.

#### Biden’s “multilateralism” hasn’t changed anything—it’s even worse

Baschuk 21 [Bryce Baschuk, World Trade Reporter, Bloomberg LP Biden Picks Up Where Trump Left Off in Hard-Line Stances at WTO February 22, 2021 <https://www.bloomberg.com/news/articles/2021-02-22/biden-picks-up-where-trump-left-off-in-hard-line-stances-at-wto>] 9/5/2021

President Joe Biden’s administration dashed hopes for a softer approach to the World Trade Organization by pursuing a pair of his predecessor’s strategies that critics say risk undermining the international trading system.

The U.S. delegation to the WTO, in a statement Monday obtained by Bloomberg, backed the Trump administration’s decision to label Hong Kong exports as “Made in China” and said the U.S. cites national-security exemption in Hong Kong dispute U.S. blocks new appellate members, citing systemic concerns

WTO had no right to mediate the matter because the organization’s rules permit countries to take any action to protect their “essential security interests.” “The situation with respect to Hong Kong, China, constitutes a threat to the national security of the United States,” the U.S. delegation said. “Issues of national security are not matters appropriate for adjudication in the WTO dispute-settlement system.”

Prior to 2016, WTO members generally steered clear of defending their trade actions on the basis of national security because doing so could encourage other nations to pursue protectionist policies that have little or nothing to do with hostile threats.

Steel Tariffs

That changed in 2018, when the Trump administration triggered a cold war-era law to justify tariffs on foreign imports of steel and aluminum. In response, a handful of U.S. trade partners, including Canada, the EU, and China filed disputes at the WTO and a ruling in those cases is expected later this year.

Since then, more nations -- including Saudi Arabia, India, Russia and others -- have cited the WTO’s national-security exemption in regional trade fights, leading trade experts to warn that such cases could erode the organization’s ability to mediate disputes.

The Biden administration on Monday said the U.S. has consistently argued that national-security disputes are not subject to WTO review because it would infringe on a member’s right to determine what is in its own security interests.

In spite of the U.S. objection, the WTO granted Hong Kong’s dispute inquiry and will establish a panel of experts to deliberate the matter and render a decision, which could take two to three years.

Appellate-Body Paralysis

At the same meeting, the Biden administration said it would not agree to appoint new members to the WTO’s appellate body, a seven-member panel of experts who until 2019 had the final say on trade disputes involving billions of dollars worth of international commerce.

The Biden administration said it could not do so because the U.S. “continues to have systemic concerns” with the functioning of the appellate body as have all previous administrations over the past 16 years.

Though the statement was not entirely unexpected, it confirms America’s bipartisan frustration with the functioning of the WTO appellate body and the new administration’s willingness to block new panelists until changes can be agreed.

Once Katherine Tai is confirmed as the U.S. Trade Representative, her office “looks forward to working with” WTO Director-General Ngozi Okonjo-Iweala to tackle the problems with WTO dispute settlement, including the unresolved issues over appellate-body overreach, USTR spokesman Adam Hodge said in an email. “These are long-standing, bipartisan concerns that we hope our trading partners will work with us to address,” he said.

The Trump administration broke precedent when it refused to consider any nominees to fill vacancies on the panel until there weren’t enough to sign off on new rulings. As a result, the WTO’s dispute-settlement system has been critically damaged because WTO members are now free to veto any adverse dispute rulings by appealing them into a legal void created by the appellate body’s paralysis.

#### Covid and 08 recession thump econ escalation

### Innovation

#### CRISPR innovation is non-uq – patent disputes are from 2012

#### No warrant why squo CRISPR isn’t sufficient – their card claims “continued innovation” in spite of patent disputes from 2012

#### IPR protections are key to sustain healthcare investments and manufacturing. Independently, it’s key to broader vaccine production.

Roberts 6/25/21 [James M. Roberts is a Research Fellow for Economic Freedom and Growth at the Heritage Foundation. Roberts' primary responsibility as one of The Heritage Foundation's lead experts in economic freedom and growth is to edit the Rule of Law and Monetary Freedom sections of [Index of Economic Freedom](https://www.heritage.org/index/). An influential annual analysis of the economic climate of countries throughout the world, the Index is co-published by Heritage and The Wall Street Journal.) “Biden’s OK of Global Theft of America’s Intellectual Property is Wrong, Dangerous.” 6/25/2021, The Heritage Foundation, Commentary—Public Health] RM

Last month, President Biden advocated removing international intellectual property rights (IPR) protections for American-made COVID-19 vaccines.

**Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes**.

The best way to prevent and treat new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production.

Three U.S. companies—Pfizer, Moderna, and Johnson & Johnson—created and manufactured the world’s most effective mRNA COVID vaccines in record time. An increasing majority of Americans have now been inoculated, but much of the developing world remains in desperate need of vaccines. Americans naturally want to help. The question is how.

Last month, President Biden advocated removing international intellectual property rights (IPR) protections for American-made COVID-19 vaccines. This, he said, would help make the vaccines more plentiful and available in needy countries. **It’s a short-sighted approach and doomed to fail.**

Mr. Biden wants to waive the World Trade Organization’s “Trade-Related Aspects of Intellectual Property Rights” (TRIPS) agreement for U.S. vaccines and let foreign countries issue “compulsory licenses“ allowing their domestic pharmaceutical companies to manufacture the medicines without adequately compensating the companies that invented them.

Practically speaking, countries such as India and South Africa are unlikely to manufacture the vaccines. They lack an advanced infrastructure for cold supply-chain distribution and many other crucial resources required by these products’ capital-intensive, state-of-the-art manufacturing process.

But the Biden policy is bad for many other reasons.

Developing breakthrough medications takes tremendous ingenuity and immense financial investments. **It’s an extraordinarily high-risk endeavor, and the prospect of making a profit is what convinces private companies to undertake those risks.**

Signaling that the United States will not fight to defend their intellectual property rights **actively undermines innovation and manufacturing** in American health care and medicines.

It also erodes patient protections by undermining quality control. Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes. Already there are reports of ineffective and even dangerous counterfeit COVID-19 vaccines being sold around the world.

Those pushing to break U.S. pharmaceutical patents say they want to do so for altruistic reasons. Consequently, they also insist that the prices for the medications be set far below their actual value.

But history shows us that forcing private companies to provide vaccines at an “affordable price,” regardless of the cost to the companies, actually impedes the manufacture of high-quality vaccines. Moreover, it inhibits the **future development of vaccines** needed to meet as-yet-unknown diseases.

Washington first imposed vaccine price controls as part of Hillary Clinton’s 1993 healthcare-for-all crusade. As the Wall Street Journal later noted, it was a body blow to the U.S. vaccine industry. Ironically, government-decreed prices left the companies unable to produce enough vaccines to meet Mrs. Clinton’s admittedly admirable goal of universal immunization of children. Since then, U.S. firms have largely eschewed the vaccine market because they could not recoup their R&D and manufacturing costs and earn enough profit to fund future innovation.

Ultimately, **compulsory licensing legalizes the theft of intellectual property**. Recognizing this, senators from both sides of the aisle have joined with other government officials and industry leaders to call on the administration to reverse this bad decision.

The U.S. patent protection system has served the nation well since its founding.  **It is and has been a bulwark of American prosperity**, but the strength of that protection has been weakening in the past few decades. **Compulsory licensing contributes to the erosion** of that protection.

As the U.S. and the rest of the world emerge from the pandemic, it is clear that more innovative medicines and vaccines will be needed for future protection from viruses and other emerging biological threats.

**The best way to prevent and treat those new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production**.

That way, U.S.-manufactured vaccines can be made available to all Americans quickly. And governments can subsidize their export and sale to other countries far more effectively and less expensively than through compulsory licensing schemes.

Meanwhile, let’s hope Mr. Biden listens to the more reasonable and less-agenda driven voices in this debate and reverses course on the TRIPS waiver.