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#### Counterplan Text – Member states of the World Trade Organization ought to consult the World Health Organization on whether or not the member nations of the World Trade Organization ought to eliminate patent protections for medicines. The World Health Organization ought to publicly declare that their decision on whether or not member nations of the World Trade Organization ought to eliminate patent protections for medicines will represent their future decisions on all intellectual property protections on medicines.

#### The Plan’s unilateral action by the WTO on medical IP undermines WHO legitimacy – forcing a perception of WHO action against Patents is key to re-assert it – they say yes.

Rimmer 4, Matthew. "The race to patent the SARS virus: the TRIPS agreement and access to essential medicines." Melbourne Journal of International Law 5.2 (2004): 335-374.

<https://law.unimelb.edu.au/__data/assets/pdf_file/0007/1681117/Rimmer.pdf> (BA (Hons), LLB (Hons) (Australian National University), PhD (New South Wales); Lecturer at ACIPA, the Faculty of Law, The Australian National University)//SidK + Elmer

The WHO has been instrumental in coordinating the international network of research on the SARS virus. It has emphasised the need for collaboration between the network participants. The WHO presented the containment of the SARS virus as ‘one of the biggest success stories in public health in recent years’.206 However, it **was less active in the debate over patent law** and public health epidemics. The 56th World Health Assembly considered the relationship between intellectual property, innovation and public health. It stressed that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.207 However, there was much disagreement amongst the member states as to what measures would be appropriate. The WHO has made a number of **aspirational statements** about patent law and access to essential medicines. Arguably, though, the organisation could be a much more informed and vocal advocate. Initially, the WHO did not view the patent issues related to SARS as being within its field of activities. The agency **did not even seem aware of the patent proceedings**, leaving individual research institutions without guidance. Spokesman Dick Thompson said: ‘What we care about is [that] the international collaboration continues to function. Patents, they don’t really concern us’.208 The director of WHO’s Global Influenza project, Klaus Stöhr, expressed his opinion that the patent filings would not interfere with the international cooperation on the SARS research: ‘I don’t think this will undermine the collaborative spirit of the network of labs’.209 However, he believed that, after the international network of researchers had identified the coronavirus, it was necessary to rely upon companies to commercialise such research. Klaus Stöhr conceded: ‘At a certain point of time you have to give way for competitive pharmaceutical companies’.210 On a policy front, the WHO **remained deferential** to the WTO over the debate over patent law and access to essential medicines, observing: Owing to the inconclusive nature of the studies conducted to date, and because of the effect that potentially significant price increases could have on access to drugs in poor countries, WHO is currently monitoring and evaluating the effects of TRIPS on the prices of medicines. It is also monitoring the TRIPS impact on other important issues such as transfer of technology, levels of research and development for drugs for neglected diseases, and the evolution of generic drug markets.211 In such a statement, the WHO appears diffident, **unwilling to take on more than a spectator** role. Such a position is arguably too timid, given the gravity of national emergencies, such as the SARS virus. The organisation could take a much stronger stance on the impact of the **TRIPS** Agreement on public health concerns. The WHO has since enunciated a position statement on the patenting of the SARS virus. A number of high ranking officials from the organisation have commented on the need to ensure that international research into the SARS virus is not impeded by competition over patents. Arguably though, the **WHO should not be limited to a mere spectator role in such policy discussions. It needs to play an active advocacy role in the debate over patent law and access to essential medicines**. The WHO released a position statement on ‘Patent Applications for the SARS Virus and Genes’ on 29 May 2003.212 The organisation stressed that it had no per se objection to the patenting of the SARS virus: Some people have objected to the SARS patent applications on the ground that the virus and its genes should not be patentable because they are mere discoveries, not inventions. This distinction no longer prevents the granting of patents; the novel claim rests not with the virus itself but with its isolation, and likewise with the identification of the genetic sequence not its mere occurrence. Many patents have been issued on viruses and genetic sequences, though the appropriate policies to follow in such cases — particularly as genomic sequencing becomes more routine and less ‘inventive’ — remain matters of dispute.213 Furthermore, it recognised that public institutions could legitimately use patents as a defensive means to prevent undue commercial exploitation of the research: The “defensive” use of patents can be a legitimate part of researchers’ efforts to make their discoveries (and further discoveries derived therefrom) widely available to other researchers, in the best collaborative traditions of biomedical science.214 The WHO affirmed the need for further cooperation between research organisations in respect of the SARS virus: ‘For continued progress against SARS, it is essential that we nurture the spirit of the unprecedented, global collaboration that rapidly discovered the novel virus and sequenced its genome’.215 The WHO announced its intention to monitor the effects of patents (and patent applications) on the speed with which SARS diagnostic tests, treatments, and vaccines are developed and made available for use, and on the manner in which prices are set for these technologies. It observed: In the longer term, the manner in which SARS patent rights are pursued could have a profound effect on the willingness of researchers and public health officials to collaborate regarding future outbreaks of new infectious diseases. WHO will therefore examine whether the terms of reference for such collaborations need to be modified to ensure that the credit for any intellectual property developed is appropriately attributed, that revenues derived from licensing such property are devoted to suitable uses, and that legitimate rewards for innovative efforts do not impose undue burdens on efforts to make tests, therapies, and preventive measure available to all.216 It maintained that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.219 The Assembly requested that the Director-General continue to support Member States in the exchange and transfer of technology and research findings, according high priority to access to antiretroviral drugs to combat HIV/AIDS and medicines to control tuberculosis, malaria and other major health problems, in the context of paragraph 7 of the Doha Declaration which promotes and encourages technology transfer.220 The WHO also considered a report on the emergence of the SARS virus and the international response to the infectious disease.221 It was ‘deeply concerned that SARS ... poses a serious threat to global health security, the livelihood of populations, the functioning of health systems, and the stability and growth of economies’.222 The Committee on Infectious Diseases requested that the Director-General ‘mobilize global scientific research to improve understanding of the disease and to develop control tools such as diagnostic tests, drugs and vaccines that are accessible to and affordable by Member States’.223 The Director-General of the WHO, Dr Gro Harlem Brundtland, **told the World Health** Assembly that there was a need to build trust and forge solidarity in the face of public health epidemics: ‘**Ensuring that patent regimes stimulate research and do not hinder international scientific cooperation** is a critical challenge — whether the target is SARS or any other threat to human health’.224 Similarly, Dr Marie-Paule Kieny, Director of the WHO Initiative for Vaccine Research, said: If we are to develop a SARS vaccine more quickly than usual, we have to continue to work together on many fronts at once, on scientific research, intellectual property and patents issues, and accessibility. It is a very complicated process, involving an unprecedented level of international cooperation, which is changing the way we work.225 She emphasised that patents and intellectual property issues and their safeguards can help rather than hinder the rapid development of SARS vaccines and ensure that, once developed, they are available in both industrialised and developing countries.226 C Summary The WHO should play a much more active role in the policy debate over patent law and access to essential medicines. James Love, the director of the Consumer Project on Technology, run by Ralph Nader, is critical of the WHO statement on ‘Intellectual Property Rights, Innovation, and Public Health’.227 He maintains that the Assembly could have addressed ‘practical examples, like SARS’ and cites the report in The Washington Post that notes that a number of commercial companies are investing in SARS research.228 The non-government organisation Médecins Sans Frontières has been critical in the past of the passive role played by the WHO in the debate over access to essential medicines: ‘As the world’s leading health agency, and armed with the clear mandate of recent World Health Assembly resolutions, the WHO can and should **do much more’**.229 The WHO should become a vocal advocate for public health concerns at the WTO and its TRIPS Council — especially in relation to patent law and the SARS virus. It must staunchly defend the rights of member states to incorporate measures in their legislation that protect access to medicines — such as compulsory licensing, parallel imports, and measures to accelerate the introduction of generic pharmaceutical drugs. It needs to develop a clearer vision on global equity pricing for essential medicines. The race to patent the SARS virus seems to be an inefficient means of allocating resources. A number of public research organisations — including the BCCA, the CDC and HKU — were compelled to file patents in respect of the genetic coding of the SARS virus. Such measures were promoted as ‘defensive patenting’ — a means to ensure that public research and communication were not jeopardised by commercial parties seeking exclusive private control. However, there are important drawbacks to such a strategy. The filing of patents by public research organisations may be prohibitively expensive. It will also be difficult to resolve the competing claims between the various parties — especially given that they were involved in an international research network together. Seth Shulman argues that there is a need for international cooperation and communication in dealing with public health emergencies such as the SARS virus: The success of a global research network in identifying the pathogen is an example of the huge payoff that can result when researchers put aside visions of patents and glory for their individual laboratories and let their work behave more like, well, a virus. After all, the hallmark of an opportunistic virus like the one that causes SARS is its ability to spread quickly. Those mounting a response need to disseminate their information and innovation just as rapidly.230 There is a danger that such competition for patent rights may undermine trust and cooperation within the research network. Hopefully, however, such concerns could be resolved through patent pooling or joint ownership of patents. Furthermore, a number of commercial companies have filed patent applications in respect of research and development into the SARS virus. There will be a need for cooperation between the public and private sectors in developing genetic tests, vaccines, and pharmaceutical drugs that deal with the SARS virus. There is also a need to reform the patent system to deal with international collaborative research networks — such as that created to combat the SARS virus. Several proposals have been put forward. There has been a renewed debate over whether patents should be granted in respect of genes and gene sequences. Some commentators have maintained that the SARS virus should fall within the scope of patentable subject matter — to promote research and development in the field. However, a number of critics of genetic technology have argued that the SARS virus should not be patentable because it is a discovery of nature, and a commercialisation of life. There has been a discussion over the lack of harmonisation over the criteria of novelty and inventive step between patent regimes. As Peter Yu comments, ‘[w]hile [the] US system awards patents to those who are the first to invent, the European system awards patents to those who are the first to file an application’.231 There have been calls for the requirement of utility to be raised. There have also been concerns about prior art, secret use and public disclosure. Representative Lamar Smith of Texas has put forward the CREATE Act, which recognises the collaborative nature of research across multiple institutions. Such reforms are intended to ensure that the patent system is better adapted to deal with the global nature of scientific inquiry. The race to patent the SARS virus also raises important questions about international treaties dealing with access to essential medicines. The public health epidemic raises similar issues to other infectious diseases — such as AIDS, malaria, tuberculosis, influenza, and so forth. The WHO made a public statement about its position on the patenting of the SARS virus. It has stated that it will continue to monitor developments in this field. Arguably, there is a need for the WHO to play a larger role in the debate **over patent law and** access to essential medicines. **Not only could it mediate legal disputes** over patents in respect of essential medicines, it could be a vocal advocate in policy discussions. The WTO has also played an important role in the debate over patent law and access to essential medicines. A number of public interest measures could be utilised to secure access to patents relating to the SARS virus including compulsory licensing, parallel importation and research exceptions. The appearance of the SARS virus shows that there should be an open-ended interpretation of the scope of diseases covered by the Doha Declaration on the TRIPS Agreement and Public Health. Important lessons should be learned from the emergence of the SARS virus, and the threat posed to global health. As the World Health Report 2003 notes: SARS will not be the last new disease to take advantage of modern global conditions. In the last two decades of the 20th century, new diseases emerged at the rate of one per year, and this trend is certain to continue. Not all of these emerging infections will transmit easily from person to person as does SARS. Some will emerge, cause illness in humans and then disappear, perhaps to recur at some time in the future. Others will emerge, cause human illness and transmit for a few generations, become attenuated, and likewise disappear. And still others will emerge, become endemic, and remain important parts of our human infectious disease ecology.232 Already, in 2004, there have been worries that pharmaceutical drug companies and patent rights are impeding efforts to prevent an outbreak of bird flu — avian influenza.233 There is a need to ensure that the patent system is sufficiently flexible and adaptable to cope with the appearance of new infectious diseases.234

#### WHO Cred key to Global Right to Health – medicine access is critical.

* Note the Bottom Paragraph is at the bottom of the PDF – I put a paragraph break to indicate it as such – no words are missing.

Bluestone 3, Ken. "Strengthening WHO's position should be a priority for the new Director-General." The Lancet 361.9351 (2003): 2. (Senior Policy Adviser, Voluntary Service Overseas (VSO))//Elmer

To meet these challenges, WHO must strengthen its resolve to maintain its **independence and lead its member states**, **even at the risk of causing controversy**. A meaningful example is the role that WHO can have in **ensuring access to medicines** for the world’s poorest people. WHO is the only global institution that has the **remit to drive this agenda forward**, yet has failed to do so convincingly. The new Director-General must support and reinvigorate the advocacy efforts of the organisation and provide a proper counterbalance to the interests of the pharmaceutical industry and wealthy member states. As the new Director-General takes office, they will face the dual challenge of **seeing that** the broadest possible public health interpretation of the World Trade Organization’s Doha Agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS) **is not lost, and** of seizing an opportunity to bring about an international framework for sustainable and predictable tiered pricing of medicines. Without the active intervention of a public health advocate at the level of WHO, there is a risk that both of these initiatives **could founder.** Some people in positions of power still do not have high expectations of WHO or its new Director-General. But for the world’s poorest people, the overwhelming majority of whom live in developing countries, this person’s legacy could literally make the difference between life and death. Ken Bluestone Senior Policy Adviser, Voluntary Service Overseas (VSO)

New leader should re-establish WHO’s credibility The credibility of WHO’s advocacy of the right to health for all has been eroded in recent years. A large reason is WHO’s **failure to challenge the pharmaceutical** industry on access to medicines for people with HIV/AIDS and other diseases. WHO’s collaboration with the industry in the “Accelerated Access” programme on antiretroviral medicines sounds good. In fact, the programme has served as a cover for the organisation’s frequent acceptance of industry arguments for restricting treatment access. To re-establish WHO’s credibility, the new Director-General must lead the organisation to stand consistently with those most deprived of health services. Kenneth Roth, Executive Director, Human Rights Watch.

#### Right to Health solves Nationalist Populism.

Friedman 17 Eric Friedman March 2017 “New WHO Leader Will Need Human Rights to Counter Nationalistic Populism” <https://www.hhrjournal.org/2017/03/new-who-leader-will-need-human-rights-to-counter-populism/> (JD, Project Leader of the Platform for a Framework Convention on Global Health at the O’Neill Institute for National and Global Health Law at the Georgetown University Law Center in Washington, DC)//Elmer

The need for WHO leadership on human rights—and for global leadership on health and human rights beyond WHO—has always been present, yet has become ever more pressing. A reactionary, nationalist populism has been gaining momentum, particularly in the United States and parts of Europe, and some of its most disturbing features, such as xenophobia and disregard for international law and institutions, are surfacing elsewhere. Persisting health challenges—such as immense national and **global health inequities**, with universal health coverage and the Sustainable Development Goals offering some hope of lessening them—and growing threats such as outbreaks of infectious disease, worsening antimicrobial resistance, and climate change demand the type of leadership that the right to health entails. In this immensely challenging environment, WHO needs to become a 21st century institution that has the gravitas and credibility to carve a path through these obstacles towards global health justice. The next WHO Director-General, to be elected in May, must lead the organization there. The right to health can light the way ahead, with reforms to, and driven by, WHO. These reforms must develop an internal governance that is far more welcoming of civil society, with WHO member states significantly increasing contributions so work on the social determinants of health can expand, and with enhanced transparency and accountability. Furthermore, reforms are needed so that WHO leads on global health equity and human rights, including through national health equity strategies and, above all, the Framework Convention on Global Health (FCGH). The FCGH could help bring the right to health to the next level by capturing core aspects of the right to health, such as: 1) participation and accountability, setting clear standards for people’s participation in health policy-making at all levels, and establishing multi-layered health accountability frameworks with standards to which all nations would be held; 2) equity, including by catalyzing national health equity strategies—which must be developed through broad participation, itself a potentially empowering process—and advancing data disaggregation and more equitable financing; 3) financial resources, with global norms on national and international health financing responsibilities; and 4) respecting and promoting the right to health in all policies, from setting standards on health impact assessments—including participatory processes in developing them, human rights standards, an equity focus, and follow-up processes—to firmly ensuring the primacy of the right to health in other legal regimes that may undermine. From an earlier WHO treaty, the Framework Convention on Tobacco Control, we know the power of international law to significantly advance health, with the transformative power of legally binding global health norms. As a treaty, the FCGH would increase political accountability and accountability through the courts, while helping protect health other treaty-based international regimes, such as trade. It would also be a bold assertion of global solidarity for global justice, as so urgently needed, “demonstrating that the community of **nations are indeed stronger together**.” One candidate for the WHO Director-General election, David Nabarro, has recognized the value and civil society support that FCGH has already received, and the need to further explore the treaty (mentioned at 1:46:38 mark). A good first step would be establishing a WHO working group on the FCGH, with broad participation, particularly from states, civil society, and representatives of communities most affected by health inequities, along with relevant international agencies. We see signs of **resistance of the dangerous nationalist populism**, from protests that persist and judicial checks on one of the administration’s vilest acts (an immigration and refugee travel ban, with its effects falling heaviest on Muslims) in the United States to the rejection of the far-right candidate in the elections in the Netherland. Such resistance can prevent some of the worst impacts on the right to health, from discrimination against migrants to cuts to programs vital for health. Meanwhile, let’s construct an edifice for the future of health and human rights, even as we stand against its destruction. WHO, right to health, and FCGH leadership ought to be a core part of that endeavor.

#### Populism is an existential threat.

de Waal 16 Alex de Waal 12-5-2016 “Garrison America and the Threat of Global War” <http://bostonreview.net/war-security-politics-global-justice/alex-de-waal-garrison-america-and-threat-global-war> (Executive Director of the World Peace Foundation at the Fletcher School at Tufts University)//Elmer

Polanyi recounts how economic and financial crisis led to global calamity. Something similar could happen today. In fact we are already in a steady unpicking of the liberal peace that glowed at the turn of the millennium. Since approximately 2008, the historic decline in the number and lethality of wars appears to have been reversed. Today’s wars are not like World War I, with formal declarations of war, clear war zones, rules of engagement, and definite endings. But they are wars nonetheless. What does a world in global, generalized war look like? We have an unwinnable “war on terror” that is metastasizing with every escalation, and which has blurred the boundaries between war and everything else. We have deep states—built on a new oligarchy of generals, spies, and private-sector suppliers—that are strangling liberalism. We have emboldened middle powers (such as Saudi Arabia) and revanchist powers (such as Russia) rearming and taking unilateral military action across borders (Ukraine and Syria). We have massive profiteering from conflicts by the arms industry, as well as through the corruption and organized crime that follow in their wake (Afghanistan). We have impoverishment and starvation through economic warfare, the worst case being Yemen. We have “peacekeeping” forces fighting wars (Somalia). We have regional rivals threatening one another, some with nuclear weapons (India and Pakistan) and others with possibilities of acquiring them (Saudi Arabia and Iran). Above all, today’s generalized war is a conflict of destabilization, with big powers intervening in the domestic politics of others, buying influence in their security establishments, bribing their way to big commercial contracts and thereby corroding respect for government, and manipulating public opinion through the media. Washington, D.C., and Moscow each does this in its own way. Put the pieces together and a global political market of rival plutocracies comes into view. Add virulent reactionary populism to the mix and it resembles a war on democracy. What more might we see? Economic liberalism is a creed of optimism and abundance; reactionary protectionism feeds on pessimistic scarcity. If we see punitive trade wars and national leaders taking preemptive action to secure strategic resources within the walls of their garrison states, then old-fashioned territorial disputes along with accelerated state-commercial grabbing of land and minerals are in prospect. We could see mobilization against immigrants and minorities as a way of enflaming and rewarding a constituency that can police borders, enforce the new political rightness, and even become electoral vigilantes. Liberal multilateralism is a system of seeking common wins through peaceful negotiation; case-by-case power dealing is a zero-sum calculus. We may see regional arms races, nuclear proliferation, and opportunistic power coalitions to exploit the weak. In such a global political marketplace, we would see middle-ranking and junior states rewarded for the toughness of their bargaining, and foreign policy and security strategy delegated to the CEOs of oil companies, defense contractors, bankers, and real estate magnates. The United Nations system appeals to leaders to live up to the highest standards. The fact that they so often conceal their transgressions is the tribute that vice pays to virtue. A cabal of plutocratic populists would revel in the opposite: applauding one another’s readiness to tear up cosmopolitan liberalism and pursue a latter-day mercantilist naked self-interest. Garrison America could opportunistically collude with similarly constituted political-military business regimes in Russia, China, Turkey, and elsewhere for a new realpolitik global concert, redolent of the early nineteenth-century era of the Congress of Vienna, bringing a façade of stability for as long as they collude—and war when they fall out. And there is a danger that, in response to a terrorist outrage or an international political crisis, President Trump will do something stupid, just as Europe’s leaders so unthinkingly strolled into World War I. The multilateral security system is in poor health and may not be able to cope. Underpinning this is a simple truth: the plutocratic populist order is a future that does not work. If illustration were needed of the logic of hiding under the blanket rather than facing difficult realities, look no further than Trump’s readiness to deny climate change. We have been here before, more or less, and from history we can gather important lessons about what we must do now. The importance of defending civility with democratic deliberation, respecting human rights and values, and maintaining a commitment to public goods and the global commons—including the future of the planet—remain evergreen. We need to find our way to a new 1945—and the global political settlement for a tamed and humane capitalism—without having to suffer the catastrophic traumas of trying everything else first.

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#### Covid exposed new vulnerabilities and motivation for bioterror BUT technical challenges still outweigh.

Koblentz and Kiesel 7/14 [Gregory D. Koblentz (Deputy Director of the Biodefense Graduate Program and Assistant Professor of Government and Politics in the Department of Public and International Affairs at George Mason University) and Stevie Kiesel (Biodefense PhD Student, Schar School of Policy and Government, George Mason University). “The COVID-19 Pandemic: Catalyst or Complication for Bioterrorism?”. Studies in Conflict & Terrorism. Published online 14 Jul 2021. Accessed 7/22/21. <https://www.tandfonline.com/doi/abs/10.1080/1057610X.2021.1944023?journalCode=uter20> //Xu recut Adam]

Since COVID-19 was declared a pandemic in March 2020, there has been no major bioterrorist incident that challenges or validates the core beliefs of the optimists, pessimists, or pragmatists. Extremists with violent apocalyptic or accelerationist ideologies—chiefly jihadists and far-right extremists—have sought to capitalize on the pandemic, but they still rely on conventional weapons. Based on available open-source information, terrorist interest in weaponizing SARS-CoV-2 seems limited. While some individuals and groups who subscribe to violent apocalyptic or accelerationist ideologies have shown some interest in crudely spreading the virus, most terrorists have sought to exploit the conditions the pandemic created rather than the virus itself. An increase in the risk of bioterrorism cannot be completely discounted as the equipment, knowledge, and expertise to work with high-risk pathogens is increasingly available and there are a small number of groups with the ideologies and objectives consistent with the use of biological weapons. Still, important technical barriers to acquiring and using a biological weapon capable of causing mass casualties, even far below the effects of a pandemic pathogen, will remain even after the pandemic is contained. While COVID-19 graphically demonstrated the vulnerability of modern societies to infectious diseases, the lessons learned from this experience, if properly implemented, should significantly improve the capability of governments around the world to detect and respond to future pandemics as well as deliberate disease outbreaks. Counterterrorism and biodefense efforts should not be dictated by the latest “‘risk of the month’ policies crafted in the wake of visible or highly publicized events.”117 Instead, strategies for reducing the likelihood and consequences of bioterrorism in the wake of the COVID-19 pandemic should be based on a realistic appraisal of the risk and investments should be optimized to strengthen preparedness against the full spectrum of biological threats.

#### IP protections are the only limit on proliferating dual-use biotech – losing patents puts financial pressure on companies to outsource R&D, which skyrockets bioterror acquisition.

Finlay 10 [Brian Finlay (President and Chief Executive Officer of the Stimson Center, M.A. from the Norman Patterson School of International Affairs at Carleton University, a graduate diploma from the School of Advanced International Studies, the Johns Hopkins University and an honors B.A. from Western University in Canada). “The Bioterror Pipeline: Big Pharma, Patent Expirations, and New Challenges to Global Security”. The Fletcher Forum of World Affairs. Vol. 34, No. 2 (Summer 2010), pp. 51-64. <https://www.jstor.org/stable/45289504?seq=1#metadata_info_tab_contents> //Xu]

Until recently, these investment risks were frequently mitigated by income generated from past drug development successes. In most markets, that income was guaranteed by strict patent protections that closed the window to outside competition for a set period of time. More recently, however, the uncertainty of R&D investments has been complicated not only by the global economic downturn, but more importantly by looming patent expirations that will open many of big pharma's patent-protected drugs to generic competition. Between 2007 and 2012, more than three dozen drugs will lose patent protection, removing an estimated $67 billion from big pharma's annual sales.33 With existing drug development pipelines unable to fill the gaps, biopharmaceutical companies are under intense pressure not only to cut costs - which would provide only temporary relief to the bottom line - but also to rapidly replenish their development pipelines. Some industry analysts have described this "perfect storm" as an "existential" moment for big pharma.34 Many pharmaceutical companies have approached this challenge by accelerating and widening the outsourcing and off-shoring of both R&D and manufacturing, and by aggressively buying promising assets from small biotech companies through acquisitions and strategic alliances. Interestingly, these partnerships are less frequently linked with American or even Western-owned and-operated companies than in the past. Many pharmaceutical giants like Indiana-based Eli Lilly are turning to alliances with firms in Asia and elsewhere around the world, outsourcing key technical operations. Instead of functioning as fully integrated firms, big pharma companies have found value in networked relationships with independent small to large firms, universities, and non-profit biotechnology laboratories around the globe.35 The net result has accelerated technology proliferation - for both beneficial and nefarious uses - far beyond the traditional hubs for biotech innovation. Pharma's increasingly desperate search to seed and ultimately acquire innovative new biotechnologies means that foreign (non- Western) markets are pulling ahead in biotech innovation. Indeed, the quantity of biotech companies outside the United States has grown remarkably in recent years: in Israel, the number grew from 30 in 1990 to about 160 in 2000; in Brazil, from 76 in 1993 to 354 in 2001; and remarkably, in South Korea, from one in 2000 to 23 in 2003. 36 More generally, the Asia-Pacific region has emerged as one of the world s fastest-growing biotechnology hubs, with the growth of publicly traded companies handily outpacing growth in the United States and Europe over recent years.37 As fruitful partnerships lead big pharma to increasingly generate resources, technologies, and knowledge, these capacities spin off new competitor firms in a self-executing multiplier effect. With the number of facilities and highly trained individuals increasing, the likelihood of a serious biological accident or nefarious incident will similarly rise, which will be particularly risky when dual-use technologies are introduced into insufficiently regulated markets. CONCLUSIONs In statements, U.S. officials continue to cite several countries believed to have or to be pursuing a biological weapons capability.38 But globalization exports the challenge of bioproliferation far beyond these geographic boundaries and transcends multiple societal layers well beyond government actors. As a result, it is increasingly clear that states no longer have a monopoly on dual-use biological R&D. Recent evidence suggests a growing threat of terrorist acquisition of biological weapons. As technological advancement in the life sciences is progressively pushed into countries of the Global South, some of which are also potential hotbeds for terrorist activity, the nexus of science and terrorism becomes especially acute.While far from perfect, the current system of stringent controls levied by Western governments over the biopharmaceutical sector has proven remarkably effective, especially given the diffusion of technologies and the ease of their redirection for hostile purposes. As the biotech revolution continues to widen, however, advanced industrialized governments are increasingly playing catch-up with changing technological realities. As these technologies proliferate, security analysts have become uneasy with the lack of controls in many states. The dearth of legal controls, the lack of rigor in their enforcement, and the growth in private-actor involvement in dual-use activities has sobering implications for global security.

#### COVID resulted in mass on-shoring of R&D – only price incentives can convince them to stay.

Mullin 20 Rick Mullin 4-27-2020 "COVID-19 is reshaping the pharmaceutical supply chain" <https://cen.acs.org/business/outsourcing/COVID-19-reshaping-pharmaceutical-supply/98/i16> (BA English Literature, Drew University, 1980. Business journalist covering engergy, chemicals, pharmaceuticals, and information technology for various publications including Chemical Week since 1983)//Elmer

“We do not pretend to have a unique explanation to the potential shortage of medicine,” Perfetti says. “But every day we are facing consequences of unavailability of starting materials from not only China but the Eastern part of the world.” This issue was brought in sharp focus with the closure of plants—and even entire industrial parks—in China’s 2017 environmental crackdown, he says. Industry executives acknowledge the irony that the very companies that spent the past 20 years outsourcing the supply of chemicals and APIs to China are now asking for support to bring it back. But they dismiss the criticism, responding that capitalist industries have to compete globally on price. Their request for support, they say, aims to establish a more level, competitive playing field. “We have to deal with the reality that pricing plays an important role in the availability of drugs, primarily if they are generic,” the BPTF’s DiLoreto says. “We have to find a way to provide additional incentives for manufacturing to come back to the US. Whatever those financial incentives are, the government will have to start taking it seriously.”

#### Bioterrorism causes Extinction – overcomes any conventional defense.

Walsh 19, Bryan. End Times: A Brief Guide to the End of the World. Hachette Books, 2019. (Future Correspondent for Axios, Editor of the Science and Technology Publication OneZero, Former Senior and International Editor at Time Magazine, BA from Princeton University)//Elmer

I’ve lived through disease outbreaks, and in the previous chapter I showed just how unprepared we are to face a widespread pandemic of flu or another new pathogen like SARS. But a deliberate outbreak caused by an engineered pathogen would be far worse. We would face the same agonizing decisions that must be made during a natural pandemic: whether to ban travel from affected regions, how to keep overburdened hospitals working as the rolls of the sick grew, how to accelerate the development and distribution of vaccines and drugs. To that dire list add the terror that would spread once it became clear that the death and disease in our midst was not the random work of nature, but a deliberate act of malice. We’re scared of disease outbreaks and we’re scared of terrorism—put them together and you have a formula for chaos. As deadly and as disruptive as a conventional bioterror incident would be, an attack that employed existing pathogens could only spread so far, limited by the same laws of evolution that circumscribe natural disease outbreaks. But a virus engineered in a lab to break those laws could spread faster and kill quicker than anything that would emerge out of nature. It can be designed to evade medical countermeasures, frustrating doctors’ attempts to diagnose cases and treat patients. If health officials manage to stamp out the outbreak, it could be reintroduced into the public **again and again.** It could, with the right mix of genetic traits, even wipe us off the planet, making engineered viruses a genuine existential threat. And such an attack may not even be that difficult to carry out. Thanks to advances in biotechnology that have rapidly reduced the skill level and funding needed to perform gene editing and engineering, what might have once required the work of an army of virologists employed by a nation-state could soon be done by a handful of talented and trained individuals. Or maybe just one. When Melinda Gates was asked at the South by Southwest conference in 2018 to identify what she saw as the biggest threat facing the world over the next decade, she didn’t hesitate: “A bioterrorism event. Definitely.”2 She’s far from alone. In 2016, President Obama’s director of national intelligence James Clapper identified CRISPR as a “weapon of mass destruction,” a category usually reserved for known nightmares like nuclear bombs and chemical weapons. A 2018 report from the National Academies of Sciences concluded that biotechnology had rewritten what was possible in creating new weapons, while also increasing the range of people capable of carrying out such attacks.3 That’s a fatal combination, one that plausibly threatens the future of humanity like nothing else. “The existential threat that would be most available for someone, if they felt like doing something, would be a bioweapon,” said Eric Klien, founder of the Lifeboat Foundation, a nonprofit dedicated to helping humanity survive existential risks. “It would not be hard for a small group of people, maybe even just two or three people, to kill a hundred million people using a bioweapon. There are probably a million people currently on the planet who would have the technical knowledge to pull this off. It’s actually surprising that it hasn’t happened yet.”

### 1NC – OFF

#### Counterplan Text - Resolved: The member nations of the World Trade Organization ought to

#### eliminate intellectual property protections for medicines except for orphan drugs.

#### prioritize distribution of orphan drugs to the Global South.

#### Orphan drug legislation is specifically key to stimulate research into rare diseases

Horgan et. al 20 D, Moss B, Boccia S, Genuardi M, Gajewski M, Capurso G, Fenaux P, Gulbis B, Pellegrini M, Mañú Pereira M, M, Gutiérrez Valle V, Gutiérrez Ibarluzea I, Kent A, Cattaneo I, Jagielska B, Belina I, Tumiene B, Ward A, Papaluca M: Time for Change? The Why, What and How of Promoting Innovation to Tackle Rare Diseases – Is It Time to Update the EU’s Orphan Regulation? And if so, What Should be Changed? Biomed Hub 2020;5:1-11. doi: 10.1159/000509272 [https://www.karger.com/Article/Fulltext/509272#](https://www.karger.com/Article/Fulltext/509272) //sid

The European Union’s (EU) Regulation (EC) No. 141/2000 on orphan medicinal products (OMPs) (referred to as “the regulation” in this paper) states that “patients suffering from rare conditions should be entitled to the same quality of treatment as other patients,” and concludes that “it is therefore necessary to stimulate the research, development and bringing to the market of appropriate medications by the pharmaceutical industry” [[1](https://www.karger.com/Article/Fulltext/509272#ref1)]. Rare diseases had already been identified as a priority area for Community action within the framework for action in the field of public health [[2](https://www.karger.com/Article/Fulltext/509272#ref2)], and the regulation’s stated aim is – “to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” It set up a mechanism to ensure that “orphan medicinal products eligible for incentives should be easily and unequivocally identified,” with the condition that “objective criteria for designation should be established” [[3](https://www.karger.com/Article/Fulltext/509272#ref3)]. The core incentive of the regulation is the granting of 10 years (+2 years for paediatric orphan medicines) of marketing exclusivity and a range of financial and scientific provisions granted via the European Medicines Agency to support product development and application for Marketing Authorisation. Nearly two decades later, the success of the measure has been demonstrated. Investment both from public research funders and from companies of all sizes in rare disease research has resulted in the approval of more than 150 orphan drugs – compared with just eight therapies for rare diseases available before the adoption of the regulation. That translates into a lot of patient benefit. With clinical research stimulated by the legislation, the EU sees some 2,000 clinical trials providing still more innovation or hope for treatments in the current R&D pipeline [[4](https://www.karger.com/Article/Fulltext/509272#ref4)]. But over the intervening years, the limitations in the functioning of the legislation have become apparent too, and these merit attention if the beneficial effects for patients and caregivers are to be maximised [[5](https://www.karger.com/Article/Fulltext/509272#ref5)]. This paper explores the successes and limitation of both the regulation and its implementation mechanisms in the current regulatory context, and suggests some improvements that could maximise its benefits and boost rare disease research even further. The discussion needs to be precise if it is to be effective. Review of the functioning of the regulation may coincide with a period of more intense scrutiny and concerns over containing the rise of expenditure to ensure sustainability of healthcare systems, with a particular focus on expensive innovation which are often developed within the orphan conditions. While there is undoubted importance in the wider but distinct debate over healthcare costs, it does not bear directly on reviewing the orphan medicines regulation [[6](https://www.karger.com/Article/Fulltext/509272#ref6)]. At the same time, economic questions do, however, have relevance to the debate on orphans, since patients’ access to the medicines that become available is conditioned by the national arrangements for reimbursement or listing of products: there is an increasing tension between the potential access to agents that can modify or even cure rare diseases, and the models for reimbursement available to European payers. Part of this hesitancy can be ascribed to the novelty of the challenges presented by many innovative treatments, which by their nature present unknowns to payers. Clearly, there is also a need to deal with uncertainty with regard to value demonstration, especially when value or values are perceived not to be sufficiently demonstrated. The risk is that such powerful economic reservations can have a cumulative negative impact on the motivation for pursuing research into rare disease treatments – thus running counter to the guiding principle of the legislation itself [[7](https://www.karger.com/Article/Fulltext/509272#ref7)]. Current value assessment rules across Europe for orphan drugs remain largely inadequate and can become a real fourth hurdle to effective patient access to those treatments [[8](https://www.karger.com/Article/Fulltext/509272#ref8)]. The regulation’s stimulation of new product development has also helped promote the development of EU biotech companies. The last two decades have witnessed the emergence of more than 150 small and medium enterprises (SMEs) focusing on rare diseases. No wonder that one of the prominent Members of the European Parliament over this period, Francoise Grossetête, emphasised the importance of the regulation in addressing “real medical needs” and generating “therapeutic breakthroughs” [[9](https://www.karger.com/Article/Fulltext/509272#ref9)]. The underlying strength of the concept of providing incentives for R&D in areas of unmet need is confirmed by the fact that Germany and other Member States are now exploring whether OMP-type incentives could contribute to solving the major risks of antimicrobial resistance (AMR), through promoting development of new anti-bacterials even where simple market economics do not provide sufficient motivation for investment [[10](https://www.karger.com/Article/Fulltext/509272#ref10)]. Thanks to increased investments and the associated efforts thus made possible, some rare diseases now benefit from effective treatments. There are leading examples in the area of haemophilia, paroxysmal nocturnal haemoglobinuria (PNH), and some lysosomal storage diseases such as Gaucher. The full list of conditions for which “orphans medicines” have been launched in Europe is too extensive to reproduce here, but by way of illustration it ranges from rare cancers to rare variants of common diseases (pulmonary hypertension, neonatal diabetes) and to rare congenital, mostly childhood-onset disorders (Gaucher, cystinosis, inherited hyperammonaemias) [[11](https://www.karger.com/Article/Fulltext/509272#ref11)]. However, these tales of success should not lead to any delusions that the process has been – or is becoming – easy. Successes in developing innovative treatments are hard-won. Without consistent and determined effort, innovation does not happen – and innovation in rare diseases is all the more challenging. The key elements of the innovation process are well documented, but the nature of the challenges is perhaps not always fully appreciated by those outside the healthcare sector, being seen as costs and not as investments. Rare diseases are categorized as “orphan diseases” because their occurrence in a small number of patients means that, despite apparent high unmet medical need, there is limited scientific understanding, making it difficult to justify the development risk and investment to develop new treatments. The OMP regulation was developed explicitly to support efforts in this field of innovation [[12](https://www.karger.com/Article/Fulltext/509272#ref12)].

#### Orphan diseases require time intensive care and affect millions.

**Lancet 19** [Lancet, 2-1-2019, accessed on 9-6-2021, The Lancet Diabetes & Endocrinology, "Spotlight on rare diseases", https://www.thelancet.com/journals/landia/article/PIIS2213-8587(19)30006-3/fulltext]//sid

Feb 28 is Rare Disease Day, the theme of which this year is “bridging health and social care”. This 12th annual [Rare Disease Day](https://www.rarediseaseday.org/page/news/theme-2019)highlights the need for better coordination of medical, social, and support services to lessen the burden that rare diseases—often complex, chronic, and disabling—have on the everyday lives of patients, their families, and carers. As a recent [Europe-wide survey](http://download2.eurordis.org.s3.amazonaws.com/rbv/2017_05_09_Social%20survey%20leaflet%20final.pdf)found that 80% of patients and carers had difficulty completing daily tasks, 70% found organising care time-consuming (with 60% finding it hard to manage), and 67% felt that health, social, and local services communicated poorly with each other, the theme of Rare Disease Day 2019 is timely. More than 6000 [rare diseases](https://globalgenes.org/rare-diseases-facts-statistics/) (80% with a genetic component) affect more than 300 million people worldwide. While an individual disease might be classed as rare (defined as affecting less than 1 in 2000 of the general population in the European Union or fewer than 200 000 people in the USA), the sheer number of rare diseases means that the overall numbers quickly stack up: 3·5 million people in the UK, 30 million across Europe, and 30 million in the USA are affected. Whether a single rare disease affects thousands or just one person, the impact on the affected individual and those around them can be devastating: 50% of rare diseases affect children, 30% of whom will die before age 5 years. Rare diseases present myriad challenges for patients, their families, and caregivers, including the time it takes to obtain a correct diagnosis for many patients. In a [survey](https://globalgenes.org/wp-content/uploads/2013/04/ShireReport-1.pdf) of patients and caregivers in the USA and UK, patients reported that it took on average 7·6 years in the USA and 5·6 years in the UK to get a proper diagnosis, during which time patients typically visited eight physicians (four primary care and four specialist) and received two to three misdiagnoses. As there is no approved treatment for 95% of rare diseases, a diagnosis can be a crushing reality check for patients and their families, rather than bringing hope and reassurance. As such, rare diseases impose a considerable emotional toll on patients and their caregivers. Other challenges include a lack of information and resources, the financial cost of care, and difficulty in accessing appropriate medical expertise, which is compounded by a lack of specialist training programmes for medical professionals. In this issue of The Lancet Diabetes & Endocrinology, we publish a call-to-action to address the [unmet need for subspecialty training](http://dx.doi.org/10.1016/S2213-8587(18)30369-3) in adult rare (inherited metabolic) diseases, which is crucial given that 50% of rare diseases present in adulthood and children surviving rare diseases eventually transition to adult care.

#### Rare diseases disproportionately affect people of color

**RDDC, No Date** (RDDC, No Date, accessed on 9-6-2021, Rare Disease Diversity Coalition, "Charting thePath Forwardfor Equity inRare Diseases", <https://3hqwxl1mqiah5r73r2q7zll1-wpengine.netdna-ssl.com/wp-content/uploads/2021/03/RDDC_Path_Forward_Final.pdf>)//sid

While the rare disease community continues to face hurdles generally, people of color face additional hurdles in their quest for care . Barriers to diagnosis and treatment for people of color often have deadly consequences . Flaws across the entire system have a compounding effect on the care that Black, Native American, Hispanic, Asian, and Pacific Islander Americans with rare diseases receive . Americans of color continue to be underrepresented in genome-wide association studies and clinical research trials, leading to a lack of understanding about effective treatments, particularly in diverse populations . Despite making up more than 38 percent of the U .S . population, people of color comprise only 16 percent of research study participants .20 On the patient side, people of color are less likely to have affordable access to health care and rare disease experts .21 To make matters worse, some rare diseases disproportionately impact people of color . For instance, sarcoidosis, sickle cell anemia, thalassemia, and some forms of lupus are known to affect minority populations at higher rates than the general population .22 And implicit bias particularly harms people of color with rare diseases .23

#### **R&D’s key to innovation – otherwise, future pandemics.**

Marjanovic et al. ’20 (Sonja; Ph.D. at the University of Cambridge; May 2020; “How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis”; RAND; <https://www.rand.org/pubs/perspectives/PEA407-1.html>; Accessed: 8-31-2021; AU)

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.**

#### Future pandemics will cause extinction

Bar-Yam 16 Yaneer Bar-Yam 7-3-2016 “Transition to extinction: Pandemics in a connected world” <http://necsi.edu/research/social/pandemics/transition> (Professor and President, New England Complex System Institute; PhD in Physics, MIT)//Elmer

Watch as one of the more aggressive—brighter red — strains rapidly expands. After a time it goes extinct leaving a black region. Why does it go extinct? The answer is that it spreads so rapidly that it kills the hosts around it. Without new hosts to infect it then dies out itself. That the rapidly spreading pathogens die out has important implications for evolutionary research which we have talked about elsewhere [1–7]. In the research I want to discuss here, what we were interested in is the effect of adding long range transportation [8]. This includes natural means of dispersal as well as unintentional dispersal by humans, like adding airplane routes, which is being done by real world airlines (Figure 2). When we introduce long range transportation into the model, the success of more aggressive strains changes. They can use the long range transportation to find new hosts and escape local extinction. Figure 3 shows that the more transportation routes introduced into the model, the more higher aggressive pathogens are able to survive and spread. As we add more long range transportation, there is a critical point at which pathogens become so aggressive that the entire host population dies. The pathogens die at the same time, but that is not exactly a consolation to the hosts. We call this the phase transition to extinction (Figure 4). With increasing levels of global transportation, human civilization may be approaching such a critical threshold. In the paper we wrote in 2006 about the dangers of global transportation for pathogen evolution and pandemics [8], we mentioned the risk from Ebola. Ebola is a horrendous disease that was present only in isolated villages in Africa. It was far away from the rest of the world only because of that isolation. Since Africa was developing, it was only a matter of time before it reached population centers and airports. While the model is about evolution, it is really about which pathogens will be found in a system that is highly connected, and Ebola can spread in a highly connected world. The traditional approach to public health uses historical evidence analyzed statistically to assess the potential impacts of a disease. As a result, many were surprised by the spread of Ebola through West Africa in 2014. As the connectivity of the world increases, past experience is not a good guide to future events. A key point about the phase transition to extinction is its suddenness. Even a system that seems stable, **can be destabilized** by a few more long-range connections, and connectivity is continuing to increase. So how close are we to the tipping point? We don’t know but it would be good to find out before it happens. While Ebola ravaged three countries in West Africa, it only resulted in a handful of cases outside that region. One possible reason is that many of the airlines that fly to west Africa stopped or reduced flights during the epidemic [9]. In the absence of a clear connection, public health authorities who downplayed the dangers of the epidemic spreading to the West might seem to be vindicated. As with the choice of airlines to stop flying to west Africa, our analysis didn’t take into consideration how people respond to epidemics. It does tell us what the outcome will be unless we respond fast enough and well enough to stop the spread of future diseases, which may not be the same as the ones we saw in the past. As the world becomes more connected, the dangers increase. Are people in western countries safe because of higher quality health systems? Countries like the U.S. have highly skewed networks of social interactions with some very highly connected individuals that can be “superspreaders.” The chances of such an individual becoming infected may be low but events like a mass outbreak pose a much greater risk if they do happen. If a sick food service worker in an airport infects 100 passengers, or a contagion event happens in mass transportation, an outbreak could very well prove unstoppable.

### 1NC – OFF

#### CP Text – The United States federal government ought to establish a global leadership role in production and distribution of medicines and treatments by engaging in talks with NATO and the G-7 and expanding support of neutral medical distribution programs to bridge the North-South Divide and encourage public-private partnerships and facilitate overseas licensing agreements with the Global South without reducing intellectual property rights.

#### The CP solves vaccine distribution and re-vitalizes American influence BUT US leadership is key.

Gayle et Al 21 Helene Gayle, Gordon LaForge, and Anne-Marie Slaughter 3-19-2021 "American Can-and Should-Vaccinate the World" <https://archive.is/wtVC2#selection-1369.0-1369.54> (Helene D. Gayle, MD, MPH, has been president and CEO of The Chicago Community Trust, one of the nation’s oldest and largest community foundations, since October 2017. Under her leadership, the Trust has adopted a new strategic focus on closing the racial and ethnic wealth gap in the Chicago region. For almost a decade, Dr. Gayle was president and CEO of CARE, a leading international humanitarian organization. An expert on global development, humanitarian, and health issues, she spent 20 years with the Centers for Disease Control, working primarily on HIV/AIDS.)//Elmer

After a virtual “Quad summit” last Friday, the leaders of the United States, India, Japan, and Australia announced that they would cooperate to deliver one billion vaccine doses in the Indo-Pacific, directly countering China’s lead in distributing vaccines to the region. The agreement brings together Indian manufacturing and U.S., Japanese, and Australian financing, logistics, and technical assistance to help immunize hundreds of millions of people by the end of 2022. Headlines over the weekend proclaimed that the administration of U.S. President Joe Biden was preparing to catch up in global vaccine diplomacy. Yesterday the administration took a further step in this direction, leaking to reporters that it would lend four million AstraZeneca doses to Mexico and Canada. These initiatives come not a moment too soon. In tackling the worst global crisis of a lifetime, the United States has so far been upstaged. Russia and China have aggressively marketed and distributed their vaccines to foreign countries, largely to advance foreign policy goals. Russia is using the jab to bolster its image and investment prospects and to drive a wedge between EU countries. China is donating doses to gain leverage in territorial disputes and expand its influence under the Belt and Road Initiative. Both Moscow and Beijing have moved to undercut the United States in its own backyard by supplying vaccines to Latin America. The Biden administration is right to want to take the lead in vaccinating the world, for a host of reasons both self-interested and altruistic. But it should not fall into the trap of trying to beat Russia and China at their own game—handing out vaccines to specific countries based on their geostrategic importance and the amount of attention they are receiving from rival powers. Rather, Biden should pursue abroad the sort of “all in” unity approach that he has proclaimed at home. His administration should focus less on strategic advantage than on vaccinating the largest number of people worldwide in the shortest amount of time. In so doing, the United States would concentrate on what the world’s peoples have in common—susceptibility to this and many other viruses—regardless of the nature of their governments. ALL IN AND ALL OUT The United States has successfully mobilized its own and international resources to respond to regional crises in the past. In 2003, President George W. Bush started the U.S. President’s Emergency Plan for AIDS Relief, the largest global health program focused on a single disease in history. PEPFAR brought together U.S. agencies, private companies, and local civil society groups to help sub-Saharan Africa and Southeast Asia get the AIDS crisis under control, saving millions of lives. In 2004, a tsunami in the Indian Ocean caused more than 220,000 deaths and billions in damage, and the United States led an urgent, similarly inclusive humanitarian relief and recovery effort that rescued victims, hastened reconstruction, and built lasting goodwill in South and Southeast Asia. Biden can improve on Bush’s precedent by going global, and he has already taken steps toward doing so. Under President Donald Trump, the United States refused to participate in the COVID-19 Vaccine Global Access (COVAX) Facility, an international partnership that aims to guarantee COVID-19 vaccine access for the entire world. The Biden administration reversed this stance immediately and contributed $4 billion, making the United States the largest donor to the effort. Still, even if COVAX meets the ambitious target of delivering two billion doses to developing nations by the end of 2021, it will be able to vaccinate only 20 percent of those countries’ populations. Just imagine, however, what could happen if Washington were to treat COVID-19 as the equivalent of the enemy in a world war or the pandemic as a global version of the regional AIDS and Ebola epidemics of years past. Imagine, in other words, what all-out mobilization would look like if the United States treated the COVID-19 pandemic like the global threat that it is. Washington would lead a multilateral, whole-of-society effort to help COVAX vaccinate the world. The government would activate the military and call upon allies in the G-7 and NATO for a major assistance operation that speeds the flow of vaccine supplies and strengthens delivery systems. As it has pledged to do in the Quad summit deal, the U.S. government would use the State Department, U.S. Agency for International Development (USAID), Centers for Disease Control and Prevention (CDC), and other civilian agencies and development programs to help countries with their national vaccination programs. And it would enlist companies, nonprofits, and civil society organizations to help increase vaccine production, raise funding, and provide technical assistance to foreign counterparts. The U.S. government should undertake exactly such an effort, right now: an all-out response for an all-in global vaccination campaign. Such a campaign would advance U.S. economic and security interests and reboot American global leadership after years of decline. Rather than perpetuate the transactional, friend-by-friend vaccine diplomacy of China and Russia, a U.S.-led vaccine effort could invigorate a new multilateralism that is more pragmatic and inclusive than the twentieth-century international order and better adapted to tackling twenty-first-century global threats. Washington would do well to remember that if COVID-19 does come back, authoritarian governments will be able to lock down their populations more quickly and effectively than democracies will, so even in competitive terms, America’s best bet really is to eradicate the novel coronavirus. The United States has a momentous opportunity to prove both that democracy can deliver and that American ideals truly are universal. By offering a model of global cooperation that draws on a far wider range of resources than any one government can provide, the United States can lead a vaccine effort that builds on the strengths of its open and pluralist society. President Biden would demonstrate unequivocally that the United States is not only “back” but looking—and leading—far ahead. THE CASE FOR GOING REALLY BIG The COVID-19 pandemic is the most extensive humanitarian and economic catastrophe of modern times. Though it lacks the cataclysmic impact of a natural disaster, its toll is far worse and more widespread. A reported 2.6 million have died from COVID-19, though that is certainly an undercount; one analysis of premature and excess mortality estimates 20.5 million years of life have been lost. According to the World Bank, the pandemic pushed as many as 124 million into extreme poverty in 2020, the first year of increase in two decades. The Economist estimates that two years of COVID-19 will cost the world $10.3 trillion—a downturn the World Bank says is twice as deep as the Great Recession. Ultimately, the only way to arrest, let alone reverse, this collapse is global vaccination. The Biden administration learned an important lesson from the government’s response to the 2008 financial crisis: do not be afraid to go big. The American Rescue Plan does just that, funneling $1.9 trillion into many different parts of the economy. The administration should heed the same advice when it comes to vaccinating the world. An all-out effort will have the greatest and quickest impact on the fight against COVID-19—and the impact it will have is squarely in America’s self-interest. The United States has much to gain from an accelerated recovery of the global economy. A study from the Eurasia Group estimated that vaccinating low- and middle-income nations would generate at least $153 billion for the United States and nine other developed economies in 2021 and up to $466 billion by 2025. Even if the United States vaccinates its entire population, its economic recovery will still drag so long as its trading partners don’t have full access to the vaccine and the pandemic continues. As Biden has said, “We’re not going to be ultimately safe until the world is safe.” Moreover, today’s pandemic will not be the last. The partnerships and public health infrastructure that the United States builds to inoculate the world from this coronavirus will also defend it against the next deadly pathogen or health threat. Protecting the nation against disease cannot be separated from protecting the world.

#### Waiving IP rights undercuts the perception of American medical innovation superiority which allows China and Russia to expand influence – a unilaterally-led global effort jumpstarts Vaccine Diplomacy in the face of Chinese and Russian weakness.

Sasse 5-17 Ben Sasse 5-17-2021 "U.S. Can Stop the Pandemic and Counter China" <https://archive.is/NOKMj#selection-4197.0-4265.96> (Ben Sasse has a bachelor's degree in government from Harvard University, a Master of Arts in liberal studies from St. John's College and master's and doctoral degrees in American history from Yale University. He taught at the University of Texas and served as an assistant secretary in the U.S. Department of Health and Human Services.)//Elmer

Covid-19 exploded in part because the Chinese Communist Party was apathetic about other nations’ health and covered up the pandemic during its initial months by lying to and through international public-health organizations. The vaccines that will now beat Covid-19 should likewise spread rapidly world-wide because the U.S. cares for the health of our neighbors around the globe. The world should know that this virus grew deadlier because of a tyrannical system’s paranoia, and the life-saving remedy is emerging from the innovative power of democratic capitalism. Washington is late to vaccine diplomacy but not too late. The framing of every new program as a “Marshall Plan” for this or that is overused, but this is a genuine once-in-a-generation opportunity to show the world what U.S. leadership looks like. Covid-19 came from China. The most effective vaccines against it come from the United States of America. The U.S. should set a goal of vaccinating more than one billion people around the world by Thanksgiving—and without dumping intellectual property, a foolish act with perverse consequences. Consider both the idealist and realist cases for stepping into this global leadership role. This terrible virus has wrought a continuing humanitarian crisis. A second wave is devastating India: Hospitals are full, oxygen tanks are scarce, and makeshift crematoriums are struggling to keep up. As the virus sweeps through remote villages, bodies are washing up on the shores of the Ganges River. As a country dedicated to the principle that all are created equal, the U.S. won’t turn our back on these men, women and children. Now the two realist cases: First, all available data indicate the vaccines developed by the U.S. pharmaceutical industry—the result of years of research, accelerated by the public-private Operation Warp Speed—are by far the best in the world. But most people and nations don’t know that. Instead the Chinese Communist Party has exploited the suffering of the developing world to advance its own interests. In its usual mafioso fashion, Beijing has made delivery of vaccines contingent on the recipient nation’s breaking diplomatic ties with Taiwan, or agreeing to use Huawei—China’s tech giant/espionage agency—to provide 5G internet service. China has charged astronomical prices for garbage vaccines. The second realist case for vaccine diplomacy is the danger that the virus will mutate to evade vaccines. America’s vaccines can stop this—they’ve proved effective against all known global strains—but it’s a race against time. Unfortunately, the Biden administration wants to surrender America’s Covid-19 vaccine technology to anyone who wants it—including China. That is the substance of the May 5 announcement that the U.S. will enter into negotiations at the World Trade Organization to waive the Agreement on Trade-Related Aspects of International Property Rights for Covid vaccine technology. This would do little to speed the distribution of effective vaccines, but it would create substantial disincentives to invest in innovation. The mRNA technology at the heart of our vaccines is the result of decades of American investment and labor, and it’s a leg up on the next global health crisis. Ceding this advantage to the Chinese Communist Party all but guarantees that we will lose the next vaccine race, and that Beijing will have the upper hand abroad. China’s corrupt leadership won’t need to hack our databases; they’ll simply use our freely surrendered technological advances to undermine us abroad. There’s a better way. America can vaccinate a billion people around the globe. It’s going to take work and investment. The administration should make vaccine diplomacy the State Department’s top budget priority and begin working with pharmaceutical companies on cost-sharing agreements. We need to encourage public-private partnerships and facilitate overseas licensing agreements to enable American pharmaceutical companies to export vaccines without surrendering their legal rights. We need to encourage donations from America’s unused vaccine supply. Getting personal protective equipment, oxygen and ventilators into doctors’ hands abroad is saving lives every day, so we should expand exports of these and related items. Likewise, we should break open the supply-chain bottleneck that is thwarting the delivery of cargo. The developing world lacks vaccine manufacturing, storage and distribution capacities—and none of these problems are solved by an IP giveaway. A U.S. public-private program to advance vaccine diplomacy will help more people more quickly. These vaccines must be accompanied by a message that reaches from heads of state to remote villages. The State Department can spearhead an information blitz that reminds government leaders every vaccine dose taken from the Chinese Communist Party has dangers and strings attached, but America offers an immediate solution. It’s not only party leaders and heads of state who need to understand the benefits. When the U.S. fights famine, we send bags of rice with the American flag. When the U.S. fights Covid-19, every Band-Aid and bag of cotton balls needs to be stamped with Old Glory. Every person who accepts an American vaccine should know exactly where it came from. In less than a year, American physicians, scientists and pharmaceutical companies confronted an extremely potent virus, created multiple effective vaccines, and produced enough of them to inoculate the majority of our 330 million citizens. This extraordinary achievement is a testament to American innovation and to our system of free competition, targeted private-public partnership and robust legal protections. The Chinese alternative—a system of state-sponsored mismanagement, deception and coercion—has shown itself to be not only a failure, but a failure big enough to infect the globe. The message is simple: Americans are here to help. Uncle Sam, not Chairman Xi, can end Covid-19.

#### Vaccine Diplomacy is a zero-sum game for influence – China and Russia are taking over battleground states to expand their sphere of influence.

Smith 4-2 Alexander Smith 4-2-2021 "Russia and China are beating the U.S. at vaccine diplomacy, experts say" <https://www.nbcnews.com/news/world/russia-china-are-beating-u-s-vaccine-diplomacy-experts-say-n1262742> (a senior reporter for NBC News Digital based in London.)//Elmer

Of the near 250 million vaccine doses it had produced so far, China has sent 118 million to 49 countries, according to Airfinity, a pharmaceuticals analytics company based in London. Russia has sent vaccines to 22 different countries, and India has exported or donated 64 million of the nearly 150 million shots it has produced, according to Airfinity, which some experts interpret as New Delhi's attempt to counterbalance the vaccine diplomacy overtures of its regional rival, Beijing. By contrast, the U.S. has delivered just over 200 million vaccine doses to is own population, according to the Centers for Disease Control and Prevention. It has agreed to share only a tiny number — around 4 million AstraZeneca-Oxford University shots that it wasn't using anyway — with Mexico and Canada. The West's own vaccine nationalism has created a vacuum in which lower-and middle-income countries have been unable to get access to shots. And Beijing and Moscow have been only too happy to step in. 'Political suicide' The majority of Chinese and Russian vaccine doses have gone "where Western powers and Russia and China have been competing for years for more influence," said Agathe Demarais the global forecasting director at the Economist Intelligence Unit, a research group based in London. One key battleground is Egypt, which gets $1.3 billion in U.S. aid every year but whose human rights situation has led to strained ties with the West. It ordered tens of millions of doses from Pfizer, AstraZeneca, Sinopharm and Russia's Sputnik V program. But the first to arrive in Cairo in January were from China. "For the man on the street" in African countries using the vaccines, "Russia and China become somewhat more attractive as possible models for going forward," said Campbell, the former ambassador to Nigeria. "Arguably, it will help increase the attractiveness of authoritarian forms of government at the expense of more democratic forms of government." The pandemic has also allowed Russia to build relationships in Latin America beyond its traditional foothold of Venezuela, Shannon said, while the call between the Russian and Bolivian presidents was clearly linked to their vaccine deal, Demarais said. The Bolivian presidency didn't respond to a request for comment. And in Eastern Europe, use of Chinese and Russian shots allowed Serbia and Hungary to soar ahead of neighbors struggling with choked Western supplies.

#### Expanding Chinese SOI causes Nuclear War.

Brands 20 Hal Brands 4-20-2020 “Don’t Let Great Powers Carve Up the World Spheres of Influence Are Unnecessary and Dangerous” <https://www.foreignaffairs.com/articles/china/2020-04-20/dont-let-great-powers-carve-world> (Henry A. Kissinger Distinguished Professor of Global Affairs at the Johns Hopkins School of Advanced International Studies (SAIS), a resident scholar at the American Enterprise Institute, and a Bloomberg Opinion columnist)//Elmer

Opposition to spheres of influence, in other words, is a part of U.S. diplomatic DNA. The reason for this, Charles Edel and I argued in 2018, is that spheres of influence clash with fundamental tenets of U.S. foreign policy. Among them is the United States’ approach to security, which holds that safeguarding the country’s vital interests and physical well-being requires preventing rival powers from establishing a foothold in the Western Hemisphere or dominating strategically important regions overseas. Likewise, the United States’ emphasis on promoting liberty and free trade translates to a concern that spheres of influence—particularly those dominated by authoritarian powers—would impede the spread of U.S. values and allow hostile powers to block American trade and investment. Finally, spheres of influence do not mesh well with American exceptionalism—the notion that the United States should transcend the old, corrupt ways of balance-of-power diplomacy and establish a more humane, democratic system of international relations. Of course, that intellectual tradition did not stop the United States from building its own sphere of influence in Latin America from the early nineteenth century onward, nor did it prevent it from drawing large chunks of Europe, East Asia, and the Middle East into a global sphere of influence after World War II. Yet the same tradition has led the United States to run its sphere of influence far more progressively than past great powers, which is why far more countries have sought to join that sphere than to leave it. And since hypocrisy is another venerable tradition in global affairs, it is not surprising that Americans would establish their own, relatively enlightened sphere of influence while denying the legitimacy of everyone else’s. That endeavor reached its zenith in the post–Cold War era, when the collapse of the Soviet bloc made it possible to envision a world in which Washington’s sphere of influence—also known as the liberal international order—was the only game in town. The United States maintained a world-beating military that could intervene around the globe; preserved and expanded a global alliance structure as a check on aggression; and sought to integrate potential challengers, namely Beijing and Moscow, into a U.S.-led system. It was a remarkably ambitious project, as Allison rightly notes, but it was the culmination of, rather than a departure from, a diplomatic tradition reaching back two centuries. GIVE THEM AN INCH… The post–Cold War moment is over, and the prospect of a divided world has returned. Russia is projecting power in the Middle East and staking a claim to dominance in its “near abroad.” China is seeking primacy in the western Pacific and Southeast Asia and using its diplomatic and economic influence to draw countries around the world more tightly into its orbit. Both have developed the tools needed to coerce their neighbors and keep U.S. forces at bay. Allison is one of several analysts who have recently advanced the argument that the United States should make a virtue of necessity—that it should accept Russian and Chinese spheres of influence, encompassing some portion of eastern Europe and the western Pacific, as the price of stability and peace. The logic is twofold: first, to create a cleaner separation between contending parties by clearly marking where one’s influence ends and the other’s begins; and second, to reduce the chances of conflict by giving rising or resurgent powers a safe zone along their borders. In theory, this seems like a reasonable way of preventing competition from turning into outright conflict, especially given that countries such as Taiwan and the Baltic states lie thousands of miles from the United States but on the doorsteps of its rivals. Yet in reality, a spheres-of-influence world would bring more peril than safety. Russia’s and China’s spheres of influence would inevitably be domains of coercion and authoritarianism. Both countries are run by illiberal, autocratic regimes; their leaders see democratic values as profoundly threatening to their political survival. If Moscow and Beijing dominated their respective neighborhoods, they would naturally seek to undermine democratic governments that resist their control—as China is already doing in Taiwan and as Russia is doing in Ukraine—or that challenge, through their very existence, the legitimacy of authoritarian rule. The practical consequence of acceding to authoritarian spheres of influence would be to intensify the crisis of democracy that afflicts the world today. The United States would suffer economically, too. China, in particular, is a mercantilist power already working to turn Asian economies toward Beijing and could one day put the United States at a severe disadvantage on the world’s most economically dynamic continent. Washington should not concede a Chinese sphere of influence unless it is also willing to compromise the “Open Door” principles that have animated its statecraft for over a century. Such costs might be acceptable in exchange for peace and security. But spheres of influence during the Cold War did not prevent the Soviets from repeatedly testing American redlines in Berlin, causing high-stakes crises in which nuclear war was a real possibility. Nor did those spheres prevent the two sides from competing sharply, and sometimes violently, throughout the “Third World.” Throughout history, spheres-of-influence settlements, from the Thirty Years’ Peace between Athens and Sparta to the Peace of Amiens between the United Kingdom and Napoleonic France have often ended, sooner or later, in war.

#### Hegemony is crucial to solve genocide and ethnic violence

Lieber 2005 – PhD from Harvard, Professor of Government and International Affairs at Georgetown, former consultant to the State Department and for National Intelligence Estimates (Robert, “The American Era”, pages 51-52)//Elmer

The United States possesses the military and economic means to act assertively on a global basis, but should it do so, and if so, how? In short, if the United States conducts itself in this **way, will the world be safer** and more stable, and is such a role in America’s national interest? Here, the anarchy problem is especially pertinent. The capacity of the United Nations to act, especially in coping with the most urgent and deadly problems, is severely limited, and in this sense, the demand for “global governance” far exceeds the supply. Since its inception in 1945, there have only been two occasions (Korea in 1950 and Kuwait in 1991) when the U.N. Security Council authorized the use of force, and in both instances the bulk of the forces were provided by the United States. In the most serious cases, especially those involving international terrorism, the proliferation of weapons of mass destruction, ethnic cleansing, civil war, and mass murder, if America does not take the lead, no other country or organization is willing or able to respond effectively. The deadly cases of Bosnia (1991–95) and Rwanda (1994) make this clear. In their own way, so did the demonstrations by the people of Liberia calling for American intervention to save them from the ravages of predatory militias in a failed state. And the weakness of the international reaction to ethnic cleansing, rape, and widespread killing in the Darfur region of Western Sudan provides a more recent example.

#### Nuke war causes extinction AND outweighs other existential risks

-checked (sid)

PND 16. internally citing Zbigniew Brzezinski, Council of Foreign Relations and former national security adviser to President Carter, Toon and Robock’s 2012 study on nuclear winter in the Bulletin of Atomic Scientists, Gareth Evans’ International Commission on Nuclear Non-proliferation and Disarmament Report, Congressional EMP studies, studies on nuclear winter by Seth Baum of the Global Catastrophic Risk Institute and Martin Hellman of Stanford University, and U.S. and Russian former Defense Secretaries and former heads of nuclear missile forces, brief submitted to the United Nations General Assembly, Open-Ended Working Group on nuclear risks. A/AC.286/NGO/13. 05-03-2016. <http://www.reachingcriticalwill.org/images/documents/Disarmament-fora/OEWG/2016/Documents/NGO13.pdf> //Re-cut by Elmer

Consequences human survival 12. Even if the 'other' side does NOT launch in response the smoke from 'their' burning cities (incinerated by 'us') will still make 'our' country (and the rest of the world) uninhabitable, potentially inducing global famine lasting up to decades. Toon and Robock note in ‘Self Assured Destruction’, in the Bulletin of Atomic Scientists 68/5, 2012, that: 13. “A nuclear war between Russia and the United States, even after the arsenal reductions planned under New START, could produce a nuclear winter. Hence, an attack by either side could be suicidal, resulting in self assured destruction. Even a 'small' nuclear war between India and Pakistan, with each country detonating 50 Hiroshima-size atom bombs--only about 0.03 percent of the global nuclear arsenal's explosive power--as air bursts in urban areas, could produce so much smoke that temperatures would fall below those of the Little Ice Age of the fourteenth to nineteenth centuries, shortening the growing season around the world and threatening the global food supply. Furthermore, there would be massive ozone depletion, allowing more ultraviolet radiation to reach Earth's surface. Recent studies predict that agricultural production in parts of the United States and China would decline by about **20 percent** for four years, and by 10 percent for a decade.” 14. A conflagration involving USA/NATO forces and those of Russian federation would most likely cause the deaths of most/nearly all/all humans (and severely impact/extinguish other species) as well as destroying the delicate interwoven techno-structure on which latter-day 'civilization' has come to depend. Temperatures would drop to below those of the last ice-age for up to 30 years as a result of the lofting of up to 180 million tonnes of very black soot into the stratosphere where it would remain for decades. 15. Though human ingenuity and resilience shouldn't be underestimated, human survival itself is arguably problematic, to put it mildly, under a 2000+ warhead USA/Russian federation scenario. 16. The Joint Statement on Catastrophic Humanitarian Consequences signed October 2013 by 146 governments mentioned 'Human Survival' no less than 5 times. The most recent (December 2014) one gives it a highly prominent place. Gareth Evans’ ICNND (International Commission on Nuclear Non-proliferation and Disarmament) Report made it clear that it saw the threat posed by nuclear weapons use as one that at least threatens what we now call 'civilization' and that potentially threatens human survival with an immediacy that even climate change does not, though we can see the results of climate change here and now and of course the immediate post-nuclear results for Hiroshima and Nagasaki as well.

## 1NC – Case

### 1NC – AT: Underview

Reject 1AR theory- A] 7-6 time skew means it’s endlessly aff biased B] I don’t have a 3nr which allows for endless extrapolation C] 1AR theory is skewed to the aff because they have a 2ar judge psychology warrant which is also a reason why they shouldn’t get 2ar weighing

Infinite abuse claims are wrong- A] Spikes solve-you can just preempt paradigms in the 1AC B] Functional limits- 1nc is only 7 minutes long

Better debating solves time trade off and this is a reason you shouldn’t read theory so that the 1ar has more time to cover offs – stop whining

### 1NC – AT: Framework

#### Reducing existential risks is the top priority in any coherent moral theory

Plummer 15 (Theron, Philosophy @St. Andrews http://blog.practicalethics.ox.ac.uk/2015/05/moral-agreement-on-saving-the-world/)

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But that is a huge mistake. Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; it is not the view that the latter don’t matter. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. We should also take into account moral uncertainty. What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. It is enough for my claim that there is moral agreement in the relevant sense if, at least given certain empirical claims about what future lives would most likely be like, all minimally plausible moral views would converge on the conclusion that we should try to save the world. While there are some non-crazy views that place significantly greater moral weight on avoiding suffering than on promoting happiness, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless seem to be fairly implausible views. And even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve. Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast. We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period. Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.” (From chapter 36 of On What Matters)

#### AT – Kessler

#### 1---Probability 1st Collapses – everything can be more probable in the absolute AND impossible to measure risk of probability which links to the paralysis argument

#### 2---We’re not the “most absurd scenarios”---we have robust proof of our internal links, and impacts---the bright line is arbitrary and low

#### 3---Weigh magnitude times probability---“probability first” framing is rooted in psychological biases and leads to mass death

Clarke 08 [Lee, member of a National Academy of Science committee that considered decision-making models, Anschutz Distinguished Scholar at Princeton University, Fellow of AAAS, Professor Sociology (Rutgers), Ph.D. (SUNY), “Possibilistic Thinking: A New Conceptual Tool for Thinking about Extreme Events,” Fall, Social Research 75.3, JSTOR]

In scholarly work, the subfield of disasters is often seen as narrow. One reason for this is that a lot of scholarship on disasters is practically oriented, for obvious reasons, and the social sciences have a deep-seated suspicion of practical work. This is especially true in sociology. Tierney (2007b) has treated this topic at length, so there is no reason to repeat the point here. There is another, somewhat unappreciated reason that work on disaster is seen as narrow, a reason that holds some irony for the main thrust of my argument here: disasters are unusual and the social sciences are generally biased toward phenomena that are frequent. Methods textbooks caution against using case stud- ies as representative of anything, and articles in mainstreams journals that are not based on probability samples must issue similar obligatory caveats. The premise, itself narrow, is that the only way to be certain that we know something about the social world, and the only way to control for subjective influences in data acquisition, is to follow the tenets of probabilistic sampling. This view is a correlate of the central way of defining rational action and rational policy in academic work of all varieties and also in much practical work, which is to say in terms of probabilities. The irony is that probabilistic thinking has its own biases, which, if unacknowledged and uncorrected for, lead to a conceptual neglect of extreme events. This leaves us, as scholars, paying attention to disasters only when they happen and doing that makes the accumulation of good ideas about disaster vulnerable to issue-attention cycles (Birkland, 2007). These conceptual blinders lead to a neglect of disasters as "strategic research sites" (Merton, 1987), which results in learning less about disaster than we could and in missing opportunities to use disaster to learn about society (cf. Sorokin, 1942). We need new conceptual tools because of an upward trend in frequency and severity of disaster since 1970 (Perrow, 2007), and because of a growing intellectual attention to the idea of worst cases (Clarke, 2006b; Clarke, in press). For instance, the chief scientist in charge of studying earthquakes for the US Geological Service, Lucile Jones, has worked on the combination of events that could happen in California that would constitute a "give up scenario": a very long-shaking earthquake in southern California just when the Santa Anna winds are making everything dry and likely to burn. In such conditions, meaningful response to the fires would be impossible and recovery would take an extraordinarily long time. There are other similar pockets of scholarly interest in extreme events, some spurred by September 11 and many catalyzed by Katrina. The consequences of disasters are also becoming more severe, both in terms of lives lost and property damaged. People and their places are becoming more vulnerable. The most important reason that vulnerabilities are increasing is population concentration (Clarke, 2006b). This is a general phenomenon and includes, for example, flying in jumbo jets, working in tall buildings, and attending events in large capacity sports arenas. Considering disasters whose origin is a natural hazard, the specific cause of increased vulnerability is that people are moving to where hazards originate, and most especially to where the water is. In some places, this makes them vulnerable to hurricanes that can create devastating storm surges; in others it makes them vulnerable to earthquakes that can create tsunamis. In any case, the general problem is that people concentrate themselves in dangerous places, so when the hazard comes disasters are intensified. More than one-half of Florida's population lives within 20 miles of the sea. Additionally, Florida's population grows every year, along with increasing development along the coasts. The risk of exposure to a devastating hurricane is obviously high in Florida. No one should be surprised if during the next hurricane season Florida becomes the scene of great tragedy. The demographic pressures and attendant development are wide- spread. People are concentrating along the coasts of the United States, and, like Florida, this puts people at risk of water-related hazards. Or consider the Pacific Rim, the coastline down the west coasts of North and South America, south to Oceania, and then up the eastern coast- line of Asia. There the hazards are particularly threatening. Maps of population concentration around the Pacific Rim should be seen as target maps, because along those shorelines are some of the most active tectonic plates in the world. The 2004 Indonesian earthquake and tsunami, which killed at least 250,000 people, demonstrated the kind of damage that issues from the movement of tectonic plates. (Few in the United States recognize that there is a subduction zone just off the coast of Oregon and Washington that is quite similar to the one in Indonesia.) Additionally, volcanoes reside atop the meeting of tectonic plates; the typhoons that originate in the Pacific Ocean generate furiously fatal winds. Perrow (2007) has generalized the point about concentration, arguing not only that we increase vulnerabilities by increasing the breadth and depth of exposure to hazards but also by concentrating industrial facilities with catastrophic potential. Some of Perrow's most important examples concern chemical production facilities. These are facilities that bring together in a single place multiple stages of production used in the production of toxic substances. Key to Perrow's argument is that there is no technically necessary reason for such concentration, although there may be good economic reasons for it. The general point is that we can expect more disasters, whether their origins are "natural" or "technological." We can also expect more death and destruction from them. I predict we will continue to be poorly prepared to deal with disaster. People around the world were appalled with the incompetence of America's leaders and orga- nizations in the wake of Hurricanes Katrina and Rita. Day after day we watched people suffering unnecessarily. Leaders were slow to grasp the importance of the event. With a few notable exceptions, organi- zations lumbered to a late rescue. Setting aside our moral reaction to the official neglect, perhaps we ought to ask why we should have expected a competent response at all? Are US leaders and organiza- tions particularly attuned to the suffering of people in disasters? Is the political economy of the United States organized so that people, espe- cially poor people, are attended to quickly and effectively in noncri- sis situations? The answers to these questions are obvious. If social systems are not arranged to ensure people's well-being in normal times, there is no good reason to expect them to be so inclined in disastrous times. Still, if we are ever going to be reasonably well prepared to avoid or respond to the next Katrina-like event, we need to identify the barriers to effective thinking about, and effective response to, disas- ters. One of those barriers is that we do not have a set of concepts that would help us think rigorously about out-sized events. The chief toolkit of concepts that we have for thinking about important social events comes from probability theory. There are good reasons for this, as probability theory has obviously served social research well. Still, the toolkit is incomplete when it comes to extreme events, especially when it is used as a base whence to make normative judgments about what people, organizations, and governments should and should not do. As a complement to probabilistic thinking I propose that we need possibilistic thinking. In this paper I explicate the notion of possibilistic thinking. I first discuss the equation of probabilism with rationality in scholarly thought, followed by a section that shows the ubiquity of possibilis- tic thinking in everyday life. Demonstrating the latter will provide an opportunity to explore the limits of the probabilistic approach: that possibilistic thinking is widespread suggests it could be used more rigorously in social research. I will then address the most vexing prob- lem with advancing and employing possibilistic thinking: the prob- lem of infinite imagination. I argue that possibilism can be used with discipline, and that we can be smarter about responding to disasters by doing so.

#### AT SV First -

#### 1---Prefer util---even if its flawed, alternatives are worse because they justify the same ends but create decision paralysis, and requires saying some lives are more valuable than others, which turns all their impacts

#### AT: Predictions

#### 1---Make them indict our internal links---their interp justifies arbitrarily lowering the risk of dropped args, which breaks the game and collapses into endless judge intervention based on how likely you think the DA is

#### 2---They have to win this creates a tiny risk of our impacts for you to disregard them entirely---even if they’re bad, ignoring ex risks is worse.

### 1NC – AT: Advantage

#### TRIPs waiver doesn’t solve- it doesn’t obligate countries to do anything, just makes it legal.

Mercurio 21 [Bryan; Professor of Law, The Chinese University of Hong Kong; "The IP Waiver for COVID-19: Bad Policy, Bad Precedent," 2021; 1-6. International Review of Intellectual Property and Competition Law.] Justin

It is not only the length of time which is an issue but also the ultimate impact of the waiver. A waiver simply means that a WTO Member would not be in violation of its WTO obligations if it does not protect and enforce the COVID-19-related IPRs for the duration of the waiver. The waiver would thus allow Members to deviate from their international obligations but not obligate Members to suspend protection and enforcement of the IPRs. Members like the US who support the waiver may not implement the necessary domestic legislation to waive IPRs within the jurisdiction. It is questionable whether the US could even legally implement the waiver given that IPRs are a matter of constitutional law.17

#### Pharma backlashes to the Plan – they’re aggressive lobbyists and will do anything to preserve patent rights.

Huetteman 19 Emmarie Huetteman 2-26-2019 “Senators Who Led Pharma-Friendly Patent Reform Also Prime Targets For Pharma Cash” <https://khn.org/news/senators-who-led-pharma-friendly-patent-reform-also-prime-targets-for-pharma-cash/> (former NYT Congressional correspondent with an MA in public affairs reporting from Northwestern University’s Medill School)//Elmer

Early last year, as lawmakers vowed to curb rising drug prices, Sen. Thom Tillis was named chairman of the Senate Judiciary Committee’s subcommittee on intellectual property rights, a committee that had not met since 2007. As the new gatekeeper for laws and oversight of the nation’s patent system, the North Carolina Republican signaled he was determined to make it easier for American businesses to benefit from it — a welcome message to the drugmakers who already leverage patents to block competitors and keep prices high. Less than three weeks after introducing a bill that would make it harder for generic drugmakers to compete with patent-holding drugmakers, Tillis opened the subcommittee’s first meeting on Feb. 26, 2019, with his own vow. “From the United States Patent and Trademark Office to the State Department’s Office of Intellectual Property Enforcement, no department or bureau is too big or too small for this subcommittee to take interest,” he said. “And we will.” In the months that followed, tens of thousands of dollars flowed from pharmaceutical companies toward his campaign, as well as to the campaigns of other subcommittee members — including some who promised to stop drugmakers from playing money-making games with the patent system, like Sen. John Cornyn (R-Texas). Tillis received more than $156,000 from political action committees tied to drug manufacturers in 2019, more than any other member of Congress, a new analysis of KHN’s Pharma Cash to Congress database shows. Sen. Chris Coons (D-Del.), the top Democrat on the subcommittee who worked side by side with Tillis, received more than $124,000 in drugmaker contributions last year, making him the No. 3 recipient in Congress. No. 2 was Sen. Mitch McConnell (R-Ky.), who took in about $139,000. As the Senate majority leader, he controls what legislation gets voted on by the Senate. Neither Tillis nor Coons sits on the Senate committees that introduced legislation last year to lower drug prices through methods like capping price increases to the rate of inflation. Of the four senators who drafted those bills, none received more than $76,000 from drug manufacturers in 2019. Tillis and Coons spent much of last year working on significant legislation that would expand the range of items eligible to be patented — a change that some experts say would make it easier for companies developing medical tests and treatments to own things that aren’t traditionally inventions, like genetic code. They have not yet officially introduced a bill. As obscure as patents might seem in an era of public **outrage** **over** drug prices, the fact that **drugmakers** gave most **to** the **lawmakers working to change the patent system** belies how important securing **the exclusive right to market a drug, and keep competitors at bay, is to their bottom line**. “**Pharma will fight to the death to preserve patent rights**,” said Robin Feldman, a professor at the UC Hastings College of the Law in San Francisco who is an expert in intellectual property rights and drug pricing. “Strong patent rights are central to the games drug companies play to extend their monopolies and keep prices high.” Campaign contributions, closely tracked by the Federal Election Commission, are among the few windows into how much money flows from the political groups of drugmakers and other companies to the lawmakers and their campaigns. Private companies generally give money to members of Congress to encourage them to listen to the companies, typically through lobbyists, whose activities are difficult to track. They may also communicate through so-called dark money groups, which are not required to report who gives them money. Over the past 10 years, the **pharmaceutical industry** has **spent** about $**233 million per year on lobbying**, according to a new study published in JAMA Internal Medicine. That is more than any other industry, including the oil and gas industry. Why Patents Matter Developing and testing a new drug, and gaining approval from the Food and Drug Administration, can take years and cost hundreds of millions of dollars. Drugmakers are generally granted a six- or seven-year exclusivity period to recoup their investments. But drugmakers have found ways to extend that period of exclusivity, sometimes accumulating hundreds of patents on the same drug and blocking competition for decades. One method is to patent many inventions beyond a drug’s active ingredient, such as patenting the injection device that administers the drug. Keeping that arrangement intact, or expanding what can be patented, is where lawmakers come in. Lawmakers Dig In Tillis’ home state of North Carolina is also home to three major research universities and, not coincidentally, multiple drugmakers’ headquarters, factories and other facilities. From his swearing-in in 2015 to the end of 2018, Tillis received about $160,000 from drugmakers based there or beyond. He almost matched that four-year total in 2019 alone, in the midst of a difficult reelection campaign to be decided this fall. He has raised nearly $10 million for his campaign, with lobbyists among his biggest contributors, according to OpenSecrets. Daniel Keylin, a spokesperson for Tillis, said Tillis and Coons, the subcommittee’s top Democrat, are working to overhaul the country’s “antiquated intellectual property laws.” Keylin said the bipartisan effort protects the development and access to affordable, lifesaving medication for patients,” adding: “No contribution has any impact on how [Tillis] votes or legislates.” Tillis signaled his openness to the drug industry early on. The day before being named chairman, he reintroduced a bill that would limit the options generic drugmakers have to challenge allegedly invalid patents, effectively helping brand-name drugmakers protect their monopolies. Former Sen. Orrin Hatch (R-Utah), whose warm relationship with the drug industry was well-known, had introduced the legislation, the Hatch-Waxman Integrity Act, just days before his retirement in 2018. At his subcommittee’s first hearing, Tillis said the members would rely on testimony from private businesses to guide them. He promised to hold hearings on patent eligibility standards and “reforms to the Patent Trial and Appeal Board.” In practice, the Hatch-Waxman Integrity Act would require generics makers challenging another drugmaker’s patent to either take their claim to the Patent Trial and Appeal Board, which acts as a sort of cheaper, faster quality check to catch bad patents, or file a lawsuit. A study released last year found that, since Congress created the Patent Trial and Appeal Board in 2011, it has narrowed or overturned about 51% of the drugmaker patents that generics makers have challenged. Feldman said the drug industry “went berserk” over the number of patents the board changed and has been eager to limit use of the board as much as possible. Patent reviewers are often stretched thin and sometimes make mistakes, said Aaron Kesselheim, a Harvard Medical School professor who is an expert in intellectual property rights and drug development. Limiting the ways to challenge patents, as Tillis’ bill would, does not strengthen the patent system, he said. “You want overlapping oversight for a system that is as important and fundamental as this system is,” he said. As promised, Tillis and Coons also spent much of the year working on so-called Section 101 reform regarding what is eligible to be patented — “a very major change” that “would overturn more than a century of Supreme Court law,” Feldman said. Sean Coit, Coons’ spokesperson, said lowering drug prices is one of the senator’s top priorities and pointed to Coon’s support for legislation the pharmaceutical industry opposes. “One of the reasons Senator Coons is leading efforts in Congress to fix our broken patent system is so that life-saving medicines can actually be developed and produced at affordable prices for every American,” Coit wrote in an email, adding that “his work on Section 101 reform has brought together advocates from across the spectrum, including academics and health experts.” In August, when much of Capitol Hill had emptied for summer recess, Tillis and Coons held closed-door meetings to preview their legislation to stakeholders, including the Pharmaceutical Research and Manufacturers of America, or PhRMA, the brand-name drug industry’s lobbying group. “We regularly engage with members of Congress in both parties to advance practical policy solutions that will lower medicine costs for patients,” said Holly Campbell, a PhRMA spokesperson. Neither proposal has received a public hearing. In the 30 days before Tillis and Coons were named leaders of the revived subcommittee, drug manufacturers gave them $21,000 from their political action committees. In the 30 days following that first hearing, Tillis and Coons received $60,000. Among their donors were PhRMA; the Biotechnology Innovation Organization, the biotech lobbying group; and five of the seven drugmakers whose executives — as Tillis laid out a pharma-friendly agenda for his new subcommittee — were getting chewed out by senators in a different hearing room over patent abuse. Cornyn Goes After Patent Abuse Richard Gonzalez, chief executive of AbbVie Inc., the company known for its top-selling drug, Humira, had spent the morning sitting stone-faced before the Senate Finance Committee as, one after another, senators excoriated him and six other executives of brand-name drug manufacturers over how they price their products. Cornyn brought up AbbVie’s more than 130 patents on Humira. Hadn’t the company blocked its competition? Cornyn asked Gonzalez, who carefully explained how AbbVie’s lawsuit against a generics competitor and subsequent licensing deal was not what he would describe as anti-competitive behavior. “I realize it may not be popular,” Gonzalez said. “But I think it is a reasonable balance.” A minute later, Cornyn turned to Sen. Chuck Grassley (R-Iowa), who, like Cornyn, was also a member of the revived intellectual property subcommittee. This is worth looking into with “our Judiciary Committee authorities as well,” Cornyn said, effectively threatening legislation on patent abuse. The next day, Mylan, one of the largest producers of generic drugs, gave Cornyn $5,000, FEC records show. The company had not donated to Cornyn in years. By midsummer, every drug company that sent an executive to that hearing had given money to Cornyn, including AbbVie. Cornyn, who faces perhaps the most difficult reelection fight of his career this fall, ranks No. 6 among members of Congress in drugmaker PAC contributions last year, KHN’s analysis shows. He received about $104,000. Cornyn has received about $708,500 from drugmakers since 2007, KHN’s database shows. According to OpenSecrets, he has raised more than $17 million for this year’s reelection campaign. Cornyn’s office declined to comment. On May 9, Cornyn and Sen. Richard Blumenthal (D-Conn.) introduced the **Affordable Prescriptions for Patients Act,** which proposed to define two tactics used by drug companies to make it easier for the Federal Trade Commission to **prosecute** them: “**product-hopping**,” when drugmakers withdraw older versions of their drugs from the market to push patients toward newer, more expensive ones, and “**patent-thicketing**,” when drugmakers amass a series of patents to drag out their exclusivity and slow rival generics makers, who must challenge those patents to enter the market once the initial exclusivity ends. **PhRMA opposed the bill.** **The next day, it gave Cornyn $1,000**. Cornyn and Blumenthal’s bill would have been “very tough on the techniques that pharmaceutical companies use to extend patent protections and to keep prices high,” Feldman said. “The **pharmaceutical industry lobbied tooth and nail against it**,” she said. “And **when the bill finally came** out of committee, the strongest provisions — the **patent-thicketing provisions — had been stripped**.” In the months after the bill cleared committee and waited to be taken up by the Senate, Cornyn blamed Senate Democrats for blocking the bill while trying to secure votes on legislation with more direct controls on drug prices. The Senate has not voted on the bill.

#### List of supply shortages – there is no way the aff solves, but they decrease available vaccines.

[Laurie Garrett 21, (Columnist at Foreign Policy and former senior fellow for global health at the Council on Foreign Relations). 5/7/21, Stopping Drug Patents Has Stopped Pandemics Before, Foreign Policy, <https://foreignpolicy.com/2021/05/07/stopping-drug-patents-pandemics-coronavirus-hiv-aids/>] Justin

The vaccines aren’t easy to make. Manufacturing errors in a Maryland Emergent BioSolutions factory caused an 86 percent plummet in Johnson & Johnson vaccine supplies in early April. Complex steps in the process of isolating, purifying, preserving, storing, and delivering COVID-19 immunizations are each error-prone and require long lists of specialized chemicals and machinery.

The world is in the grips now of pipette tips shortages—used to suck out chemicals and viral samples from test tubes in key steps of vaccine making. Syringes are in short supply, prompting vaccinators to toss vaccine supplies for lack of means to administer them. The sterile containers used to hold vaccines are running out. From the earliest days of the 2020 pandemic, the sorts of protective gear and machinery vaccine researchers and makers require have been in short supply, exacerbated by trade tensions between the United States and China. Swabs used for COVID-19 testing and all aspects of equipment cleaning in sterile conditions are held up in a grotesque family dispute in Maine. There aren’t enough centrifuge tubes made worldwide to spin down cell samples. Moderna and Pfizer are constantly scrambling to find the ingredients used to make the microscopic fatty balls, called liposomes, that house the mRNA molecules and carry them safely into the bloodstream. Even the nucleic acids used to construct mRNA and a long list of special enzymes used to purify those samples are in horribly short supply, largely because their use overlaps with the manufacture of COVID-19 tests. Because such delicate chemicals and proteins must be handled at deep-freeze temperatures and transported swiftly for immediate use, the entire supply chain is vulnerable to the simplest of catastrophes: weather at an airport, a car crash that blocks truck traffic, power outages, or competition for cargo space.

Although waiving TRIPS requirements on COVID-19 vaccines is a spectacular, historic gesture, would-be generic makers worldwide will soon discover their efforts are stymied not by patents but for want of Avanti Polar Lipids’ liposome ingredients, Flexsafe RM special bags to hold liquid vaccines in bulk, phosphate-buffered saline solution, Distearoylphosphatidylcholine for liposome-making, 5’ cap for mRNA made by TriLink BioTechnologies, RNA polymerases—the list goes on, and on, and on. As the number of would-be vaccine makers grows, so will demand for thousands of such items, putting pressure on companies that are, in many cases, mom-and-pop operations. Worse, pressure on supplies critical for COVID-19 vaccine making is already resulting in a production loss of vital medicines for other diseases.

#### Lack of access is not a result of IP, but lack of infrastructure – the global south doesn’t have manufacturing capability or the necessary technological know-how to get access

#### Skill Disparities and Trade Secrets outweigh – Moderna proves IP isn’t the root cause.

Silverman 3-15 Rachel Silverman 3-15-2021 "Waiving vaccine patents won’t help inoculate poorer nations" <https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/> (Rachel Silverman is a policy fellow at the Center for Global Development)//Duong

Reality is more complicated, however. Because of the technical complexity of manufacturing coronavirus vaccines, waiving intellectual-property rights, by itself, would have **little effect**. It could even backfire, with companies using the move as an excuse to disengage from global access efforts. There are more effective ways to entice — and to pressure — companies to license and share their intellectual property and the associated know-how, without broadly nullifying patents. The Moderna vaccine illustrates the limits of freeing up intellectual property. Moderna announced in October that it would **not enforce IP rights** on its coronavirus vaccine — and yet it has **taken no steps to share information** about the vaccine’s design or manufacture, citing commercial interests in the underlying technology. Five months later, production of the Moderna vaccine remains entirely under the **company’s direct control** within its owned and contracted facilities. Notably, Moderna is also the only manufacturer of a U.S.- or British-approved vaccine not yet participating in Covax, a global-aid-funded effort (including a pledged $4 billion from the United States) to purchase vaccines for use in low- and middle-income countries. It is true, however, that activist pressure — including threats to infringe upon IP rights — can encourage originators to enter into voluntary licensing arrangements. So the global movement to liberate the vaccine patents may be useful, even if some advocates make exaggerated claims about the effects of waivers on their own. We focused on covid. Now our other patients are suffering. One reason patent waivers are unlikely to help much in this case is that vaccines are harder to make than ordinary drugs. Because most drugs are simple chemical compounds, and because the composition of the compounds is easily analyzable, competent chemists can usually reverse-engineer a production process with relative ease. When a drug patent expires, therefore — or is waived — generic companies can readily enter the market and produce competitive products, lowering prices dramatically. Vaccines, in contrast, are complex biological products. Observing their contents is insufficient to allow for imitation. Instead, to produce the vaccine, manufacturers need access to the developer’s “soft” IP — the proprietary recipe, cell lines, manufacturing processes and so forth. While some of this information is confidentially submitted to regulators and might theoretically be released in an extraordinary situation (though not without legal challenge), manufacturers are at an enormous disadvantage without the originator’s cooperation to help them set up their process and kick-start production. Even with the nonconsensual release of the soft IP held by the regulator, the process of trial and error would cause long delays in a best-case scenario. Most likely, the effort would end in expensive failure. Manufacturers also need certain raw ingredients and other materials, like glass vials and filtration equipment; overwhelming demand, paired with disruptive export restrictions, has constricted the global availability of some of these items.