## 1.

### FW

#### Minimizing harm mathematically concludes in prioritizing avoiding existential risk

**Bostrom 11**

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But even this reflection fails to bring out the seriousness of existential risk. What makes existential catastrophes especially bad is not that they would show up robustly on a plot like the one in figure 3, causing a precipitous drop in world population or average quality of life. Instead, their significance lies primarily in the fact that they would destroy the future. The philosopher Derek Parfit made a similar point with the following thought experiment: I believe that if we destroy mankind, as we now can, this outcome will be *much* worse than most people think. Compare three outcomes: (1) **Peace.** (2) **A nuclear** **war that kills 99%** of the world’s existing population. (3) **A nuclear war that kills 100%.** (2) would be worse than (1), and (3) would be worse than (2). Which is the greater of these two differences? Most people believe that the greater difference is between (1) and (2). **I believe that the difference between (2) and (3) is *very much* greater.** … The Earth will remain habitable for at least another billion years. Civilization began only a few thousand years ago. If we do not destroy mankind, these few thousand years may be only a tiny fraction of the whole of civilized human history. The difference between (2) and (3) may thus be the difference between this tiny fraction and all of the rest of this history. If we compare this possible history to a day, what has occurred so far is only a fraction of a second. (10: 453-454) To calculate the loss associated with an existential catastrophe, we must consider how much value would come to exist in its absence. **It turns out that the ultimate potential for Earth-originating intelligent life is literally astronomical**. One gets a large number even if one confines one’s consideration to the potential for biological human beings living on Earth. If we suppose with Parfit that our planet will remain habitable for at least another billion years, and we assume that at least one billion people could live on it sustainably, then the potential exist for at least 1018 human lives. These lives could also be considerably better than the average contemporary human life, which is so often marred by disease, poverty, injustice, and various biological limitations that could be partly overcome through continuing technological and moral progress. However, the relevant figure is not how many people could live on Earth but how many descendants we could have in total. One lower bound of the number of biological human life-years in the future accessible universe (based on current cosmological estimates) is 1034 years.[[7]](http://www.existential-risk.org/concept.html#_ftn7) Another estimate, which assumes that future minds will be mainly implemented in computational hardware instead of biological neuronal wetware, produces a lower bound of 1054 human-brain-emulation subjective life-years (or 1071 basic computational operations).(4)[[8]](http://www.existential-risk.org/concept.html#_ftn8) If we make the less conservative assumption that future civilizations could eventually press close to the absolute bounds of known physics (using some as yet unimagined technology), we get radically higher estimates of the amount of computation and memory storage that is achievable and thus of the number of years of subjective experience that could be realized.[[9]](http://www.existential-risk.org/concept.html#_ftn9) Even if we use the most conservative of these estimates, which entirely ignores the possibility of space colonization and software minds, we find that the expected loss of an existential catastrophe is greater than the value of 1018 human lives. This implies that the expected value of reducing existential risk by a mere *one millionth of one percentage point* is at least ten times the value of a billion human lives. The more technologically comprehensive estimate of 1054 human-brain-emulation subjective life-years (or 1052 lives of ordinary length) makes the same point even more starkly. **Even if we give this allegedly lower bound on the cumulative output potential of a technologically mature civilization a mere 1% chance of being correct, we find that the expected value of reducing existential risk by a mere *one billionth of one billionth of one percentage point* is worth a hundred billion times as much as a billion human lives**. One might consequently argue that even the tiniest reduction of existential risk has an expected value greater than that of the definite provision of any “ordinary” good, such as the direct benefit of saving 1 billion lives. And, further, that the absolute value of the *indirect* effect of saving 1 billion lives on the total cumulative amount of existential risk—positive or negative—is almost certainly larger than the positive value of the direct benefit of such an action.[[10]](http://www.existential-risk.org/concept.html#_ftn10)

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## 2.

### China Rise DA

#### China is using a lack of alternate COVID vaccines to engage in aggressive vaccine diplomacy and expand influence – the Plan’s increase of access to perceptively more efficacious vaccines devastates those efforts.

Zhao 4-29 Suisheng Zhao 4-29-2021 "Why China’s vaccine diplomacy is winning" <https://www.eastasiaforum.org/2021/04/29/why-chinas-vaccine-diplomacy-is-winning/> (Professor and Director of the Center for China–US Cooperation at the Josef Korbel School of International Studies, University of Denver)//Elmer

Chinese COVID-19 vaccines have been shipped to more than **80 countries** for market or emergency use. Among them, 53 countries received vaccines for free (including developing countries in Africa and some strategically important Asian countries such as the Philippines and Pakistan) and 27 middle-income countries paid for doses. Rolling out of vaccines to developing countries, Beijing has framed itself as **a solution to the pandemic** rather than the origin of the coronavirus. China’s advanced vaccine diplomacy stands in contrast **to the ‘me first policies’** of the **United States and the European Union**. With a shortfall in supplies, US and EU leaders have faced high infection rates and death tolls at home and feel the need to inoculate their domestic populations first. This has left the world’s poorest and most vulnerable people without vaccine supply and at risk. China has not faced these problems and can afford to send vaccines abroad. Just by showing up and helping plug gaps in the global supply of vaccines, China has g**ained ground** in vaccine diplomacy. President Xi Jinping pledged that Chinese vaccines would be provided as a global public good. But a large portion of Chinese vaccines are not free — some countries have paid Chinese vaccine makers. Still the absence of the United States and European Union from vaccine diplomacy **is not lost** on countries struggling to put shots in people’s arms. Many countries would prefer US or EU-made Pfizer and Moderna vaccines over China’s vaccines if given the choice, **yet they cannot access them**. These countries are desperate and have jumped at the opportunity to receive Chinese vaccines. Chinese companies are also more willing than their western counterparts **to strike licensing deals** to produce vaccines in foreign countries. For example, Indonesia has become a regional hub for Sinovac’s CoronaVac through its state pharmaceuticals company Bio Farma. The United Arab Emirates (UAE) chose Sinopharm because it was willing to conduct phase three clinical trials in the UAE and build native vaccine production capabilities. Sinopharm also arranged to manufacture its vaccine in the UAE for regional distribution. Beijing’s vaccine diplomacy involves propaganda to boost **perceptions of China as a generous and responsible power**. Chinese media has covered every delivery of vaccine shipment. The scene is set by a standard script. When a cargo plane lands, it is greeted by senior local leaders accompanied by Chinese ambassadors fawning over the vaccine cargo. Vaccine diplomacy has helped **increase China’s influence** and enabled it to capitalise **on new opportunities**. China has rolled vaccines out to participants of its Belt and Road Initiative (**BRI**) **and enhanced preferential access to jabs alongside investments in infrastructure and connectivity projects**. According to an April Think Global Health report, of the 56 countries to which China pledged doses, all but one were participants in its BRI. Naming it the Health Silk Road, vaccine diplomacy has provided a foothold for China’s pharmaceutical industry that has been plagued by scandals and low levels of trust at home and abroad. Making Sinovac and Sinopharm household names in foreign countries, China may change these perceptions. Although Chinese vaccine makers were among the earliest in the world to begin clinical trials and self-reported some key results, many have not published complete data in peer-reviewed journals. This has fuelled scepticism about their safety and effectiveness. Gao Fu, director of China’s Centre for Disease Control and Prevention, noted in April that Chinese vaccines were not as effective as hoped and mixing them was among the strategies being considered to boost their effectiveness. Some countries have been reluctant to greenlight Chinese vaccines. Singapore received its first shipment of Sinovac vaccines in February, but Singaporean regulators have not approved its use, moving ahead with using Pfizer and Moderna vaccines. Polish President Andrzej Duda spoke with President Xi about buying Chinese jabs in March. Yet Poland’s health authorities have recommended against using Chinese vaccines because of a lack of data. Concerns have also arisen about whether China’s production capacity is able to keep pace with an ever-expanding list of overseas customers and its domestic vaccination campaign. The Turkish government ordered 20 million doses of China’s Sinovac vaccine. But delayed shipments forced the government to repeatedly revise its vaccination timetable. Egypt purchased a total of 40 million doses of the vaccine from Sinopharm in January but had received only a tiny percentage of its vaccine order from China by the middle of April. This tension will intensify as China’s domestic demand for vaccines increases. China has continued with vaccine diplomacy in the absence of the United States and other Western countries. These countries should compete and cooperate with China to overcome bottlenecks in the global distribution of vaccines and ensure that all nations, particularly developing countries, receive the vaccines they need to finally beat COVID-19.

#### Waivers are a critical issue in the perceptual ineptness of America and the West.

Pratt and Levin 4-29 Simon Frankel Pratt and Jamie Levin 4-29-2021 "Vaccines Will Shape the New Geopolitical Order" <https://archive.is/OgDcA#selection-847.23-857.11> (Simon Frankel Pratt is a lecturer in the School of Sociology, Politics, and International Studies at the University of Bristol. Jamie Levin is an assistant professor of political science at St. Francis Xavier University in Canada.)//Elmer

While home to vaccines produced by the likes of Pfizer, Moderna, AstraZeneca, and Johnson & Johnson—all now household names and whose vaccines are considered more efficacious—governments of these states have demonstrated a **reluctance to supply doses** to much of the rest of the world at the expense of domestic vaccination rates. The United States and the U.K. have exported almost none, and the EU is clamping down. They have similarly been **unwilling to waive patents**, allowing for production of these vaccines where they are most needed. This suggests that the United States and the EU are slow to fully exploit the geopolitical opportunities of vaccine diplomacy or at least are not willing to do so with the same alacrity and **enthusiasm as other states**. That may change as time goes on, however, and the result will be worsened inequities within already inequitable trade relationships between these countries and the global south.

#### Chinese leadership solves existential threats.

Yamei 18 Shen Yamei 18, Deputy Director and Associate Research Fellow of Department for American Studies, China Institute of International Studies, 1-9-2018, "Probing into the “Chinese Solution” for the Transformation of Global Governance," CAIFC, <http://www.caifc.org.cn/en/content.aspx?id=4491>

As the world is in a period of great development, transformation and adjustment, the international power comparison is undergoing profound changes, global governance is reshuffling and traditional governance concepts and models are confronted with challenges. The international community is expecting China to play a bigger role in global governance, which has given birth to the Chinese solution. A. To Lead the Transformation of the Global Governance System. The “shortcomings” of the existing global governance system are prominent, which can hardly ensure global development. First, the traditional dominant forces are seriously imbalanced*.* The US and Europe that used to dominate the global governance system have been beset with structural problems, with their economic development stalling, social contradictions intensifying, populism and secessionism rising, and states trapped in internal strife and differentiation. These countries have not fully reformed and adjusted themselves well, but rather pointed their fingers at globalization and resorted to retreat for self-insurance or were busy with their own affairs without any wish or ability to participate in global governance, which has encouraged the growth of “anti-globalization” trend into an interference factor to global governance. Second, the global governance mechanism is relatively lagging behind. Over the years of development, the strength of emerging economies has increased dramatically, which has substantially upset the international power structure, as the developing countries as a whole have made 80 percent of the contributions to global economic growth. These countries have expressed their appeal for new governance and begun policy coordination among themselves, which has initiated the transition of global governance form “Western governance” to “East-West joint governance”, but the traditional governance mechanisms such as the World Bank, IMF and G7 failed to reflect the demand of the new pattern, in addition to their lack of representation and inclusiveness. Third, the global governance rules are developing in a fragmented way, with governance deficits existing in some key areas. With the diversification and in-depth integration of international interests, the domain of global governance has continued to expand, with actors multiplying by folds and action intentions becoming complicated. As relevant efforts are usually temporary and limited to specific partners or issues, global governance driven by requests of “diversified governance” lacks systematic and comprehensive solutions. Since the beginning of this year, there have been risks of running into an acephalous statein such key areas as global economic governance and climate change*.* Such emerging issues as nuclear security and international terrorism have suffered injustice because of power politics*.* The governance areas in deficit, such as cyber security, polar region and oceans, have “reversely forced” certain countries and organizations to respond hastily*.* All of these have made the global governance system trapped in a dilemma and call urgently for a clear direction of advancement. B. To Innovate and Perfect the International Order. Currently, whether the developing countries or the Western countries of Europe and the US are greatly discontent with the existing international order as well as their appeals and motivation for changing the order are unprecedentedly strong. The US is the major creator and beneficiary of the existing hegemonic order, but it is now doubtful that it has gained much less than lost from the existing order, faced with the difficulties of global economic transformation and obsessed with economic despair and political dejection. Although the developing countries as represented by China acknowledge the positive role played by the post-war international order in safeguarding peace, boosting prosperity and promoting globalization, they criticize the existing order for lack of inclusiveness in politics and equality in economy, as well as double standard in security, believing it has failed to reflect the multi-polarization trend of the world and is an exclusive “circle club”. Therefore, there is much room for improvement. For China, to lead the transformation of the global governance system and international order not only supports the efforts of the developing countries to uphold multilateralism rather than unilateralism, advocate the rule of law rather than the law of the jungle and practice democracy rather than power politics in international relations, but also is an important subject concerning whether China could gain the discourse power and development space corresponding to its own strength and interests in the process of innovating and perfecting the framework of international order. C. To Promote Integration of the Eastern and Western Civilizations. Dialog among civilizations, which is the popular foundation for any country’s diplomatic proposals, runs like a trickle moistening things silently. Nevertheless, in the existing international system guided by the “Western-Centrism”, the Western civilization has always had the self-righteous superiority, conflicting with the interests and mentality of other countries and having failed to find the path to co-existing peacefully and harmoniously with other *civilizations.* So to speak, many problems of today, including the growing gap in economic development between the developed and developing countries against the background of globalization, the Middle East trapped in chaos and disorder, the failure of Russia and Turkey to “integrate into the West”, etc., can be directly attributed to lack of exchanges, communication and integration among civilizations. Since the 18th National Congress of CPC, Xi Jinping has raised the concept of “Chinese Dream” that reflects both Chinese values and China’s pursuit, re-introducing to the world the idea of “all living creatures grow together without harming one another and ways run parallel without interfering with one another”, which is the highest ideal in Chinese traditional culture, and striving to shape China into a force that counter-balance the Western civilization. He has also made solemn commitment that “we respect the diversity of civilizations …… cannot be puffed up with pride and depreciate other civilizations and nations”; “facing the people deeply trapped in misery and wars, we should have not only compassion and sympathy, but also responsibility and action …… do whatever we can to extend assistance to those people caught in predicament”, etc. China will rebalance the international pattern from a more inclusive civilization perspective and with more far-sighted strategic mindset, or at least correct the bisected or predominated world order so as to promote the parallel development of the Eastern and Western civilizations through mutual learning, integration and encouragement. D. To Pass on China’s Confidence. Only a short while ago, some Western countries had called for “China’s responsibility” and made it an inhibition to “regulate” China’s development orientation. Today, China has **become a source of stability** in an international situation full of uncertainties. Over the past 5 years, China has made outstanding contributions to the recovery of world economy under relatively great pressure of its own economic downturn. Encouraged by the “four confidences”, the whole of the Chinese society has burst out innovation vitality and produced innovation achievements, making people have more sense of gain and more optimistic about the national development prospect. It is the heroism of the ordinary Chinese to overcome difficulties and realize the ideal destiny that best explains China’s confidence. When this confidence is passed on in the field of diplomacy, it is expressed as: first, China’s posture is seen as more forging ahead and courageous to undertake responsibilities ---- proactively shaping the international agendas rather than passively accepting them; having clear-cut attitudes on international disputes rather than being equivocal; and extending international cooperation to comprehensive and dimensional development rather than based on the theory of “economy only”. In sum, China will actively seek understanding and support from other countries rather than imposing its will on others with clear-cut Chinese characteristics, Chinese style and Chinese manner. Second, China’s discourse is featured as a combination of inflexibility and yielding as well as magnanimous ---- combining the internationally recognized diplomatic principles with the excellent Chinese cultural traditions through digesting the Chinese and foreign humanistic classics assisted with philosophical speculations to make “China Brand, Chinese Voice and China’s Image get more and more recognized”. Third, the Chinese solution is more practical and intimate to people as well as emphasizes inclusive cooperation, as China is full of confidence to break the monopoly of the Western model on global development, “offering mankind a Chinese solution to explore a better social system”, and “providing a brand new option for the nations and peoples who are hoping both to speed up development and maintain independence”. II.Path Searching of the “Chinese Solution” for Global Governance Over the past years’ efforts, China has the ability to transform itself from “grasping the opportunity” for development to “creating opportunity” and “sharing opportunity” for common development, hoping to pass on the longing of the Chinese people for a better life to the people of other countries and promoting the development of the global governance system toward a more just and rational end. It has become the major power’s conscious commitment of China to lead the transformation of the global governance system in a profound way. A. To Construct the Theoretical System for Global Governance. The theoretical system of global governance has been the focus of the party central committee’s diplomatic theory innovation since the 18th National Congress of CPC as well as an important component of the theory of socialism with Chinese characteristics for a new era, which is not only the sublimation of China’s interaction with the world from “absorbing and learning” to “cooperation and mutual learning”, but also the cause why so many developing countries have turned from “learning from the West” to “exploring for treasures in the East”. In the past 5 years, the party central committee, based on precise interpretation of the world pattern today and serious reflection on the future development of mankind, has made a sincere call to the world for promoting the development of global governance system toward a more just and rational end, and proposed a series of new concepts and new strategies including engaging in major power diplomacy with Chinese characteristics, creating the human community with common destiny, promoting the construction of new international relationship rooted in the principle of cooperation and win-win, enriching the strategic thinking of peaceful development, sticking to the correct benefit view, formulating the partnership network the world over, advancing the global economic governance in a way of mutual consultation, joint construction and co-sharing, advocating the joint, comprehensive, cooperative and sustainable security concept, and launching the grand “Belt and Road” initiative. The Chinese solution composed of these contents, not only fundamentally different from the old roads of industrial revolution and colonial expansion in history, but also different from the market-driven neo-liberalism model currently advocated by Western countries and international organizations, stands at the height of the world and even mankind, seeking for global common development and having widened the road for the developing countries to modernization, which is widely welcomed by the international community. B. To Supplement and Perfect the Global Governance System. **Currently, the international political practice in global governance is mostly problem-driven without creating a set of relatively independent, centralized and integral power structures, resulting in the existing global governance systemcharacterized as both extensive and unbalanced.** China has been engaged in reform and innovation, while maintaining and constructing the existing systems, producing some thinking and method with Chinese characteristics. First, China sees the UN as a mirror that reflects the status quo of global governance, which should act as the leader of global governance, and actively safeguards the global governance system with the UN at the core. Second, China is actively promoting the transforming process of such recently emerged international mechanisms as G20, BRICS and SCO, perfecting them through practice, and boosting Asia-Pacific regional cooperation and the development of economic globalization. China is also promoting the construction of regional security mechanism through the Six-Party Talks on Korean Peninsula nuclear issue, Boao Forum for Asia, CICA and multilateral security dialog mechanisms led by ASEAN so as to lay the foundation for the future regional security framework. Third, China has initiated the establishment of AIIB and the New Development Bank of BRICS, creating a precedent for developing countries to set up multilateral financial institutions. The core of the new relationship between China and them lies in “boosting rather than controlling” and “public rather than private”, which is much different from the management and operation model of the World Bank, manifesting the increasing global governance ability of China and the developing countries as well as exerting pressure on the international economic and financial institution to speed up reforms. Thus, in leading the transformation of the global governance system, China has not overthrown the existing systems and started all over again, but been engaged in innovating and perfecting; China has proactively undertaken international responsibilities, but has to do everything in its power and act according to its ability. C. To Reform the Global Governance Rules. Many of the problems facing global governance today are deeply rooted in such a cause that the dominant power of the existing governance system has taken it as the tool to realize its own national interests first and a platform to pursue its political goals. Since the beginning of this year, the US has for several times requested the World Bank, IMF and G20 to make efforts to mitigate the so-called global imbalance, abandoned its commitment to support trade openness, cut down investment projects to the middle-income countries, and deleted commitment to support the efforts to deal with climate change financially, which has made the international systems accessories of the US domestic economic agendas, dealing a heavy blow to the global governance system. On the contrary, the interests and agendas of China, as a major power of the world, are open to the whole world, and China in the future “will provide the world with broader market, more sufficient capital, more abundant goods and more precious opportunities for cooperation”, while having the ability to make the world listen to its voice more attentively. With regard to the subject of global governance, China has advocated that what global governance system is better cannot be decided upon by any single country, as the destiny of the world should be in the hands of the people of all countries. In principle, all the parties should stick to the principle of mutual consultation, joint construction and co-sharing, resolve disputes through dialog and differences through consultation. Regarding the critical areas, opening to the outer world does not mean building one’s own backyard, but building the spring garden for co-sharing; the “Belt and Road” initiative is not China’s solo, but a chorus participated in by all countries concerned. China has also proposed international public security views on nuclear security, maritime cooperation and cyber space order, calling for efforts to make the global village into a “grand stage for seeking common development” rather than a “wrestling arena”; we cannot “set up a stage here, while pulling away a prop there”, but “complement each other to put on a grand show”. From the orientation of reforms, efforts should be made to better safeguard and expand the legitimate interests of the developing countries and increase the influence of the emerging economies on global governance. Over the past 5 years, China has attached importance to full court diplomacy, gradually coming to the center stage of international politics and proactively establishing principles for global governance. By hosting such important events as IAELM, CICA Summit, G20 Summit, the Belt and Road International Cooperation Forum and BRICS Summit, China has used theseplatforms to elaborate the Asia-Pacific Dream for the first time to the world, expressing China’s views on Asian security and global economic governance, discussing with the countries concerned with the Belt and Road about the synergy of their future development strategies and setting off the “BRICS plus” capacity expansion mechanism, in which China not only contributes its solution and shows its style, but also participates in the shaping of international principles through practice. On promoting the resolution of hot international issues, China abides by the norms governing international relations based on the purposes and principles of the UN Charter, and insists on justice, playing a constructive role as a responsible major power in actively promoting the political accommodation in Afghanistan, mediating the Djibouti-Eritrea dispute, promoting peace talks in the Middle East, devoting itself to the peaceful resolution of the South China Sea dispute through negotiations. In addition, China’s responsibility and quick response to international crises have gained widespread praises, as seen in such cases as assisting Africa in its fight against the Ebola epidemic, sending emergency fresh water to the capital of Maldives and buying rice from Cambodia to help relieve its financial squeeze, which has shown the simple feelings of the Chinese people to share the same breath and fate with the people of other countries. D. To Support the Increase of the Developing Countries’ Voice. The developing countries, especially the emerging powers, are not only the important participants of the globalization process, but also the important direction to which the international power system is transferring. With the accelerating shift of global economic center to emerging markets and developing economies, the will and ability of the developing countries to participate in global governance have been correspondingly strengthened. As the biggest developing country and fast growing major power, China has the same appeal and proposal for governance as other developing countries and already began policy coordination with them, as China should comply with historical tide and continue to support the increase of the developing countries’ voice in the global governance system. **To this end, China has pursued the policy of “dialog but not confrontation, partnership but not alliance”, attaching importance to the construction of new type of major power relationship and global partnership network, while making a series proposals in the practice of global governance that could represent the legitimate interests of the developing countries and be conducive to safeguarding global justice, including supporting an open, inclusive, universal, balanced and win-win economic globalization; promoting the reforms on share and voting mechanism of IMF to increase the voting rights and representation of the emerging market economies; financing the infrastructure construction and industrial upgrading of other developing countries through various bilateral or regional funds; and helping other developing countries to respond to such challenges as famine, refugees, climate change and public hygiene by debt forgiveness and assistance.**

#### That solves the Case – China has the vaccine production capacity to vaccinate the world.

Mallapaty 6-9 Smriti Mallapaty 6-9-2021 "China is vaccinating a staggering 20 million people a day" <https://www.nature.com/articles/d41586-021-01545-3> (She has a master of science degree in environmental technology from Imperial College London.)//Elmer

For more than a week, an average of about **20 million people** have been vaccinated against COVID-19 **every day in China**. At this rate, the nation would have fully vaccinated the entire UK population in **little more than six days**. China now accounts for more than half of the 35 million or so people around the world receiving a COVID-19 shot each day. Zoltán Kis, a chemical engineer in the Future Vaccine Manufacturing Research Hub at Imperial College London, doesn’t know of “anything **even close to those production scales**” for a vaccine. “The manufacturing efforts required in China to reach this high production throughput are tremendous,” he says. The majority of doses are of one of two vaccines, both of which have been approved for emergency use worldwide by the World Health Organization (WHO). CoronaVac — produced by Beijing-based company Sinovac — showed an efficacy of 51% against symptoms of COVID-19 in clinical trials, and much higher protection against severe disease and death. The second jab was developed in Beijing by state-owned firm Sinopharm and has demonstrated an efficacy of 79% against symptomatic disease and hospitalization. Supplying vaccines to the world China’s current vaccine production rate could potentially **make a significant dent in global demand**, says Kis; that would be “**a huge step in reducing the health-care and economic burden of the COVID-19 pandemic**”. China has already supplied 350 million doses of the two vaccines to more than 75 nations, and WHO approval should now trigger the further distribution of both vaccines to low-income countries. “China’s vaccination campaign got off to a slow start, but has rapidly picked up pace,” says Rongjun Chen, a biomaterials scientist also at the Future Vaccine Manufacturing Research Hub. As recently as mid-April, China was administering only about five million doses a day. According to an official at China’s National Health Commission, the nation aims to produce some three billion doses of COVID-19 vaccines in 2021 — and up to **five billion per year after that**. To achieve such high production rates, many things need to go according to plan across the entire production and distribution chain, from sourcing raw materials to manufacturing active ingredients, filling vials and distributing doses to vaccination centres, says Kis. “It is crucial that everything arrives at the right location at the right time.”

## Case

### WTO BAD

#### WTO Credibility is on the brink – patent waivers are the make-it-or-break it issue – failure to pass the Plan dooms the WTO BUT passage signals success that generate momentum for structural change.

Meyer 6-18 David Meyer 6-18-2021 "The WTO's survival hinges on the COVID-19 vaccine patent debate, waiver advocates warn" <https://archive.is/etPtf> (Senior Writer at Fortune Magazine; Covers mostly European Business Affairs)//Elmer

The World Trade Organization **knows all about crises**. Former U.S. President Donald Trump threw a wrench into its core function of resolving trade disputes—a blocker that President Joe Biden has not yet removed—and there is widespread dissatisfaction over the fairness of the global trade rulebook. The 164-country organization, under the fresh leadership of Nigeria's Ngozi Okonjo-Iweala, has a lot to fix. However, one crisis is **more pressing than the others**: the battle over COVID-19 vaccines, and whether the protection of their patents and other intellectual property should be temporarily lifted to boost production and end the pandemic sooner rather than later. According to some of those pushing for the waiver—which was originally proposed last year by India and South Africa—**the WTO's future rests on what happens next**. "The credibility of the WTO will depend on its **ability to find a meaningful outcome** on this issue that truly ramps-up and diversifies production," says Xolelwa Mlumbi-Peter, South Africa's ambassador to the WTO. "**Final nail in the coffin**" The Geneva-based WTO isn't an organization with power, as such—it's a framework within which countries make big decisions about trade, generally by consensus. It's supposed to be the forum where disputes get settled, because all its members have signed up to the same rules. And one of its most important rulebooks is the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS, which sprang to life alongside the WTO in 1995. The WTO's founding agreement allows for rules to be waived in exceptional circumstances, and indeed this has happened before: its members agreed in 2003 to waive TRIPS obligations that were blocking the importation of cheap, generic drugs into developing countries that lack manufacturing capacity. (That waiver was effectively made permanent in 2017.) Consensus is the key here. Although the failure to **reach consensus on a waiver could be overcome with a 75% supermajority vote by the WTO's membership, this would be an unprecedented and seismic event**. In the case of the COVID-19 vaccine IP waiver, it would mean standing up to the European Union, and Germany in particular, as well as countries such as Canada and the U.K.—the U.S. recently flipped from opposing the idea of a waiver to supporting it, as did France. It's a dispute between countries, but the result **will be on the WTO as a whole**, say waiver advocates. "If, in the face of one of humanity's greatest challenges in a century, the WTO functionally **becomes an obstacle** as in contrast to part of the solution, I think **it could be the final nail in the coffin**" for the organization, says Lori Wallach, the founder of Public Citizen's Global Trade Watch, a U.S. campaigning group that focuses on the WTO and trade agreements. "If the TRIPS waiver is successful, and people see the WTO as being part of the solution—saving lives and livelihoods—it could create goodwill and momentum to address what are still daunting structural problems."

#### Yes Link – the Plan is perceptively seen as bolstering the WTO since its by all WTO Members.

#### WTO collapse solves extinction

Hilary 15 John Hilary 2015 “Want to know how to really tackle climate change? Pull the plug on the World Trade Organisation” <http://www.independent.co.uk/voices/want-to-know-how-to-really-tackle-climate-change-pull-the-plug-on-the-world-trade-organisation-a6774391.html> (Executive Director, War on Want)//Elmer

Yet this grandiose plan soon fell victim to its own ambition. The WTO’s first summit after the launch of the Doha Round collapsed in acrimonious failure. The next was marked by pitched battles in the streets of Hong Kong as riot police fought Asian farmers desperately trying to save their livelihoods from the WTO’s free trade agenda. The WTO slipped into a coma. Government ministers must decide this week whether to turn off its life support. The answer is surely yes. It was the WTO’s poisonous cocktail of trade expansion and market deregulation that led to the economic crisis of 2008. Years of export-led growth resulted in a crisis of overproduction that could only be sustained with mountains of debt. The parallel deregulation of financial services meant that this debt soon turned out to be toxic, and the world’s banking system went into freefall. Nor is the WTO fit for purpose on ecological grounds. If last week’s climate talks in Paris taught us anything, it is that we must rethink the model of ever-expanding production and consumption in order to avoid planetary meltdown. Global capitalism may need limitless expansion in order to survive, but the planet is already at the very limits of what it can take. The choice is ours. Worst of all, it is the WTO’s ideology of unrestricted trade and corporate domination that lies behind all the bilateral trade deals that are proliferating at the moment, including the infamous Transatlantic Trade and Investment Partnership (TTIP). We need a radically different model of regulated trade and controlled investment if we are to have any chance of breaking the cycle of economic and ecological crisis. For the planet to survive, the WTO must die.

#### The WTO ensures structural poverty of the Global South – multiple warrants.

Walker 11 Aurelie Walker 11-14-2011 "The WTO has failed developing nations" <https://www.theguardian.com/global-development/poverty-matters/2011/nov/14/wto-fails-developing-countries> (trade policy advisor at the Fairtrade Foundation. Aurelie has specialised in EU trade relations with Africa, the Caribbean and the Pacific. She has worked as trade negotiator for an East African government, as advisor to business and government in Southern Africa on the Economic Partnership Agreement negotiations and for European Institutions and think tanks. Aurelie now advocates on behalf on Fairtrade producers on international trade issues)//Elmer

Ten years ago, a new World Trade Organisation that put developing country needs at the centre of the international trade negotiation agenda was proposed. The Ministerial Declaration adopted at the start of the Doha Development Round of trade negotiations, on 14 November 2001, was a promising response to the anti-globalisation riots of the 1990s. But the **WTO** membership **has failed to deliver** the promised **pro-development changes**. Finding "development" in the Doha Development Round today is like looking for a needle in a haystack. **Developing countries** have been **completely sidelined** **by** the **economic** **and political interests of global powers**. Here are 10 examples of how the WTO has failed the poor: 1. **Cotton**: the Fairtrade Foundation revealed last year how the $47bn in **subsidies** **paid to rich-country producers** in the past 10 years **has created barriers for** the **15 million cotton farmers across west Africa** **trying to trade their way out of poverty**, **and** how **5 million** of the **world's poorest farming families** have been **forced out of business** and into deeper poverty because of those subsidies. 2. **Agricultural subsidies**: beyond cotton, WTO members have failed even to agree how to reduce the huge subsidies **paid to rich world farmers**, whose overproduction continues to **threaten** the **livelihoods of developing world farmers**. 3. **Trade agreements**: the WTO has also failed to clarify the deliberately ambiguous rules on concluding trade agreements that allow the poorest countries to be manipulated by the rich states. In Africa, in negotiations with the EU, countries have been forced to eliminate tariffs on up to 90% of their trade because no clear rules exist to protect them. 4. Special treatment: the rules for developing countries, called "special and differential treatment" rules, were meant to be reviewed to make them more precise, effective and operational. But the WTO has failed to work through the 88 proposals that would fill the legal vacuum. 5. Medicine: the poorest in developing countries are unable to access affordable medicine because members have failed to clarify ambiguities between the need for governments to protect public health on one hand and on the other to protect the intellectual property rights of pharmaceutical companies. 6. **Legal costs**: the WTO pledged to improve access to its **expensive** and **complex legal system**, but has failed. In 15 years of dispute settlement under the WTO, 400 cases have been initiated. No African country has acted as a complainant and only one least developed country has ever filed a claim. 7. Protectionist economic policies: one of the WTO's five core functions agreed at its inception in 1995 was to achieve more coherence in global economic policy-making. Yet the **WTO** **failed to curb** the speedy **increase in** the number of **protectionist measures** applied **by G20 countries** in response to the global economic crisis over the past two years – despite G20 leaders' repeated affirmations of their "unwavering" commitment to resist all forms of protectionist measures. 8. Natural disaster: the **WTO fails to alleviate suffering** when it has the opportunity to do so. **In** the case of **natural disaster**, the **membership** will have **taken** almost **two years to** agree and **implement** temporary **trade concessions for Pakistan,** where severe flooding displaced 20 million people in 2010 and caused $10bn of damage. Those measures, according to the International Centre for Trade and Sustainable Development, would have boosted Pakistan's exports to the EU by at least €100m this year. 9. Decision-making: the WTO makes most of its decisions by consensus – and achieving consensus between 153 countries is nearly impossible. But this shows another failure of the WTO: to break the link between market size and political weight that would give small and poor countries a voice in the trade negotiations. 10. Fair trade: 10 years after the start of the Doha Development Round, governments have failed to make trade fair. As long as small and poor countries remain without a voice, the role of campaigning organisations, such as Traidcraft and Fairtrade Foundation, which are working together to eliminate cotton subsidies, will remain critical. The WTO has failed to live up to its promises over the past decade, which reveals a wider systemic problem in the global community. True and lasting solutions to global economic problems can only come when the model of global competitiveness between countries becomes one of genuine cooperation.

### 1NC – COVID Defense

#### The Plan can’t solve COVID -

#### 1] Lack of key supplies

Tepper 21 James Tepper, 4/10 [James Tepper, (James M. Tepper is an American neuroscientist currently a Board of Governors Professor of Molecular and Behavioral Neuroscience and Distinguished Professor at Rutgers University and an Elected Fellow of the American Association for the Advancement of Science.)]. "Global Covid vaccine rollout threatened by shortage of vital components." Guardian, 4-1-2021, Accessed 8-8-2021. https://www.theguardian.com/world/2021/apr/10/global-covid-vaccine-rollout-threatened-by-shortage-of-vital-components // duongie

Vaccine-makers around the world face shortages of vital components including large plastic growbags, according to the head of the firm that is manufacturing a quarter of the UK’s jab supply. Stan Erck, the chief executive of Novavax – which makes the second vaccine to be grown and bottled entirely in Britain – told the Observer that the shortage of 2,000-litre bags in which the vaccine cells were grown was a significant hurdle for global supply. His warning came as bag manufacturers revealed that some pharmaceutical firms were waiting up to 12 months for the sterile single-use disposable plastic containers, which are used to make medicines of all kinds, including the Pfizer, Moderna and Novavax Covid-19 vaccines. But Erck and his British partners said they were confident they had enough suppliers to avoid disruption to the supply of Novavax. The vaccine is waiting for approval from the Medicines and Healthcare products Regulatory Agency (MHRA) but the first of 60 million doses ordered by the government are already in production in Teesside. The Fujifilm Diosynth Biotechnologies factory began growing the first cells for the Novavax vaccine in Billingham, County Durham this month and in a few weeks they will fill the bioreactor bag, ready to be transported to GlaxoSmithKline’s plant at Barnard Castle to be put into vials for distribution. “The first hurdle is showing it works and we don’t have that hurdle any more,” Erck said. But he added there were others still to overcome. “There’s the media that the cells have to grow in,” Erck said. “You grow them in these 2,000-litre bags, which are in short supply. Then you pour it out and you have to filter it, and the filters are in short supply. The little things count.” Novavax almost ran out of bags at one of its 20 factories earlier this year, but there had been no delays for the UK operation, according to Martin Meeson, global chief executive of Fujifilm Diosynth. “We started working on our part of the supply chain in summer last year,” he said. “We had to accelerate some of the investment here, but the commitment we made last summer to start manufacturing in February has been fulfilled.” Production of coronavirus vaccines is being ramped up. Production of coronavirus vaccines is being ramped up. Photograph: Christophe Archambault/AP Both Meeson and Erck said the UK’s vaccine taskforce had been helpful in sorting out supply issues so far, but other countries and other medical supplies might be affected. ABEC makes bioreactor bags at two plants in the US and two in Fermoy and Kells in Ireland, and delivered six 4,000-litre bags to the Serum Institute in India last year for its Covid vaccines. Brady Cole, vice-president of equipment solutions at ABEC, said: “We are hearing from our customer base of lead times that are pushing out to nine, 10, even 12 months to get bioreactor bags. We typically run out at 16 weeks to get a custom bioreactor bag out to a customer.” He said ABEC was still managing to fulfil orders at roughly that rate. “The bag manufacturing capacity can’t meet demand right now,” he added. “And on the component side, the tubes and the instruments and so forth that also go into the bag assembly – those lead times are also starting to get stretched as well. But the biggest problem we see is it really is just the ability to get bags in a reasonable amount of time.” ABEC expanded its factories last year and has now started making 6,000-litre bags, which are roughly the size of a minibus. Other firms including MilliporeSigma, part of German company Merck, have also been expanding their manufacturing facilities. American firm Thermo Fisher Scientific expects it will finish doubling its capacity this year. The US government has also blocked exports of bags, filters and other components so it can supply more Pfizer vaccines for Americans. Adar Poonawalla, the chief executive of the Serum Institute of India, said the restrictions were likely to cause serious bottlenecks. Novavax is hoping to avoid delays and “vaccine nationalism” by operating on four continents, with 20 facilities in nine countries. “One year ago, we had exactly zero manufacturing capacity,” Erck said. “We’re self-sufficient. The two main things we need to do are done in the UK. And in the EU we have plants in Spain and the Czech Republic and fill-and-finish in Germany and the Netherlands.” There was no need for vaccines to cross borders to fulfil contracts, he said. The Oxford/AstraZeneca vaccine was hit by a delay to a delivery of 5 million doses from India and a problem with a batch made in Britain, and the company has been dragged into a lengthy row between the UK and the EU over vaccine exports.

#### 2] Hurts Innovation

**Value Ingenuity 20** [Value Ingenuity, (The Value Ingenuity project is telling the story of innovation, its roots, its impact, its social and moral imperatives, and the public policy prescriptions that will assure a continued upward trajectory for the generations to follow. Our objective is to advance globally a shared purpose of mutual investment in sustainable innovation.)]. "WTO IP Waiver Would Undermine Covid Innovation." 10-2-2020, Accessed 8-5-2021. https://www.valueingenuity.com/2021/05/18/wto-ip-waiver-would-undermine-covid-innovation/ // duongie

A TRIPS waiver for vaccines would do nothing to help — and could in fact hurt — the effort to produce billions of vaccine doses and get them in arms. Supply of these high-tech products is ramping up quickly, with about 10 billion doses projected to be produced by the end of 2021 — we shouldn’t distract attention away from that all-important goal. IP is not a barrier to vaccine access. It already enabled the creation of three vaccines, in record-breaking time, that have received FDA authorization. IP is also safely facilitating international partnerships (275+ to date) to share technology and information more easily with trusted partners across borders. An IP waiver could lead to untested and unregulated copycats. Some nations are looking to manufacture sophisticated vaccines without permission, exacerbating the shortage of the critical materials (raw materials, tubing, vials etc.) and increasing vaccine hesitancy due to the development of unsafe products and medicines. The proposal jeopardizes U.S. manufacturing & jobs. Allowing other countries to take and commercialize American-made technologies conflicts with President Biden’s goal to build up American infrastructure and create manufacturing jobs. In the U.S. alone, biopharmaceutical companies support 4 million jobs across all 50 states, with many more across innovation ecosystems in labs, finance, and SMEs. Waiving IP undermines America’s leadership in the life sciences. We should not be forfeiting IP to countries looking to undermine America’s global leadership in biomedical technology and innovation. IP protections enabled decades of R&D by biopharmaceutical research companies, allowing them to move quickly and effectively against COVID-19. Business welcomes the Biden Administration’s support for the global vaccine program, COVAX. This type of program can have a significant positive, practical impact on global rollout of vaccines and therapies without disrupting the incredible IP-enabled progress that has been made to date to defeat the pandemic. Its effects will be even more effective as trade barriers are removed and all countries allow vaccines to be exported internationally. GOOD TO KNOW: Today 57% of all new medicines globally come from the United States with its world-class IP ecosystem, and private companies in the life sciences community make up more than 80% of the investment in the research and development of those new drugs. The U.S. biopharmaceutical industry directly and indirectly supports over 4 million American jobs. SCIENTISTS, ACADEMICS, ADVOCATES AND POLITICAL LEADERS SKEPTICAL OF WAIVING IP RIGHTS “The goal is noble, but the demand [for an IP waiver] is more slogan than solution … patents on vaccines are not the central bottleneck, and even if turned over to other nations, would not quickly result in more shots. This is because vaccine manufacturing is exacting and time-consuming. Look at the production difficulties encountered by Emergent BioSolutions, a vaccine manufacturer in Baltimore, where 15 million doses were contaminated. That was caught before the shots were distributed, but one can imagine the horrific consequences of a failure to maintain quality control elsewhere in the world.” WASHINGTON POST EDITORIAL BOARD, May 4, 2021 “The goal is noble, but the demand [for an IP waiver] is more slogan than solution … patents on vaccines are not the central bottleneck, and even if turned over to other nations, would not quickly result in more shots. This is because vaccine manufacturing is exacting and time-consuming. Look at the production difficulties encountered by Emergent BioSolutions, a vaccine manufacturer in Baltimore, where 15 million doses were contaminated. That was caught before the shots were distributed, but one can imagine the horrific consequences of a failure to maintain quality control elsewhere in the world.” WALL STREET JOURNAL EDITORIAL BOARD, May 6, 2021 “The U.S. decision to support a temporary waiver of intellectual-property protections for Covid-19 vaccines won’t end debate on the issue, much less end the pandemic. Reaching a formal agreement could take months and even then may not accelerate vaccine production; opposition from countries such as Germany could yet doom any compromise.” BLOOMBERG EDITORIAL BOARD, May 12, 2021 “The collaboration that’s happened in the midst of this pandemic I think points to the ways in which IP has actually not been a barrier, but a facilitator of critical, cutting-edge innovation […] I don’t think that waiving IP rights will suddenly enable other countries to ramp up the manufacturing of complex vaccines.” SEN. CHRIS COONS (D-DE), CSIS: April 22, 2021 “There are only so many vaccine manufacturers in the world […] people are very careful about the safety of vaccines […] The thing that is holding us back is not IP. There is no idle factory with regulatory approval that makes magically safe vaccines […] we have all the rights from the vaccine companies and the work is going at full speed” BILL GATES, Sky News: April 25, 2021 “There are enough manufacturers, it just takes time to scale up. And by the way, I have been blown away by the cooperation between the public and private sectors in the last year, in developing these vaccines.” ADAR POONAWALLA, CEO SERUM INSTITUTE OF INDIA, February 14, 2021 “These [vaccines] are complex to make so just waiving IP and patents isn’t going to help […] you can only get trade secrets and knowhow with the cooperation of the originator companies, and they don’t have the bandwidth to do this in every part of the world … the only immediate solution is for rich countries to donate or sell their surplus vaccine to COVAX or other countries.” JAYASHREE WATAL, GEORGETOWN LAW PROFESSOR & FORMER WTO IP COUNSELOR, April 22, 2021 “It is also unclear whether a waiver of IP rights will make a difference […] Furthermore, as others have pointed out, IP rights are only a piece of what is needed to produce vaccines. There is currently a global shortage of raw materials and proper manufacturing facilities.” SAPAN KUMAR, LAW FOUNDATION PROFESSOR OF LAW AT THE UNIVERSITY OF HOUSTON LAW CENTER, May 9, 2021 “This is technology that’s every bit as critical as munitions and encryption codes […] It’s a platform technology that can be used to make all manner of treatments going forward, including vaccines.” DAVID KAPPOS, FORMER U.S. PATENT AND TRADEMARK OFFICE FOR PRESIDENT OBAMA, April 22, 2021 “The notion that we would then turn around and go to the World Trade Organization and basically endorse a policy of DARPA-funded technology transfer to China is just inconceivable. You’re basically aiding and abetting China’s ‘Made in China 2025’ plans for technological dominance.” CLETE WILLEMS, FORMER SPECIAL ASSISTANT TO THE PRESIDENT FOR INTERNATIONAL TRADE, INVESTMENT, AND DEVELOPMENT, April 22, 2021.

#### 3] Skill Disparities and Trade Secrets – 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.

#### 4] A vaccine waiver greenlights counterfeit medicine – independently turns Case by increasing vaccine hesitancy.

Conrad 5-18 John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.

### 1NC – Disease Turn

#### Forcing factory production results in unsafe manufacturing and forces trade-offs with medicines for other infectious diseases.

Szabo et. Al 21 Liz Szabo et. Al 21 [Liz Szabo (Liz Szabo, a senior correspondent and enterprise reporter who focuses on the quality of patient care, has covered medicine for two decades.)]. "Why Even Presidential Pressure Might Not Get More Vaccine to Market Faster." Kaiser Health News, 1-26-2021, Accessed 8-5-2021. https://khn.org/news/article/ramping-up-covid-vaccine-production-could-take-months-even-with-bidens-best-tool-to-pressure-companies/ // duongie

Americans are dying of covid-19 by the thousands, but efforts to ramp up production of potentially lifesaving vaccines are hitting a brick wall. Vaccine makers Moderna and Pfizer-BioNTech are **running their factories full ti**lt and are under enormous pressure to expand production or collaborate with other drug companies to set up additional assembly lines. That pressure is only growing as new viral variants of the virus threaten to launch the country into a deadlier phase of the pandemic. President Joe Biden has said he plans to invoke the Cold War-era authority of the Defense Production Act to provide more vaccines to millions of Americans. Consumer advocates — who had called for Donald Trump to use the Defense Production Act more aggressively as president — are now asking Biden to do the same. But even forcing companies to gear up production won’t **provide much-needed doses anytime soon**. Expanding production lines takes time. Establishing lines in repurposed facilities can take months. “The big problem is that even if you can get the raw material and get the infrastructure set up, how do you get a company that is already producing at maximum capacity to go beyond that maximum capacity?” said Lawrence Gostin, a professor of global health law at Georgetown University. Ordering the companies to work 24/7 “would be a naïve solution,” said Dr. Nicole Lurie, a senior adviser to the CEO of the Coalition for Epidemic Preparedness Innovations, an international group that finances vaccines for emerging diseases. “They’re probably already doing that to the extent they have the raw materials.” Lurie added, “If you completely wear people out, mistakes happen. You **have to balance speed with quality and safety.”** The technological challenges involved are daunting, and the companies haven’t been forthcoming about what’s needed to overcome any supply shortfalls. “We don’t know what the holdup is. Is it capacity? Raw materials? People? Glass vials? We just don’t know what the bottleneck is,” said Erin Fox, senior director of drug information and support services at the University of Utah Health Hospitals. Forcing other companies to start making the vaccines might not work either, Gostin said. “I’m not sure if Biden could require a private company to transfer its technology to another company,” Gostin said. “That is highly questionable legally. … President Biden’s room for maneuvering isn’t as great as people think.” Drug companies define “trade secrets” broadly, Fox said. “In general, drug companies don’t have to tell me who is making their product, where it’s made, the location of the factory. … That’s considered proprietary.” Part of the challenge relates to how these vaccines are made. The first two authorized products use lipid nanoparticles to deliver a snippet of the coronavirus’s genetic material — called messenger RNA, or mRNA — into cells. The viral genes teach our cells how to make proteins that stimulate an immune response to the novel coronavirus. Messenger RNA is fragile and breaks down easily, so it needs to be handled with care, with specific temperatures and humidity levels. The vaccines “are not widgets,” said Lurie, who served as assistant secretary for preparedness and response at the Department of Health and Human Services during the Obama administration. Every step, experts say, to get vaccines to market has its complexities: obtaining raw materials; building facilities to precise specifications; buying single-use products, such as tubing and plastic bags to line stainless steel bioreactors; and hiring employees with the requisite training and expertise. Companies also must pass safety and quality inspections and arrange for transportation. The Defense Production Act, for instance, would allow the government to commandeer a plant that already has a fermenter — there are plenty in the biotech industry — to expand production. But that’s just the first stage in making an mRNA vaccine and, even then, it would take about a year to get going, said Dr. George Siber, a vaccine expert who is on the advisory board of CureVac, a German mRNA vaccine company. Companies would first have to do a breathtakingly thorough cleaning to prevent cross-contamination, Siber said. Next, they would need to set up, calibrate and test equipment, and train scientists and engineers to run it. Finally, Siber said, unlike a drug, whose components can be tested for purity, there’s no way to be sure a vaccine produced in a new facility is what it claims to be without testing it on animals and people. “Making vaccines is not like making cars, and quality control is paramount,” said Dr. Stanley Plotkin, a vaccine industry consultant credited with inventing the rubella vaccine. “We are expecting other vaccines in a matter of weeks, so it might be faster to bring them into use.” However, even that will require patience. Johnson & Johnson, expected to announce clinical trial results this month, has said that it won’t be able to deliver as many shots as planned because of manufacturing delays. The company did not confirm a manufacturing delay and declined to respond to questions. AstraZeneca’s vaccine, also funded in part by U.S. taxpayers, is in use already in the United Kingdom and India, but the Food and Drug Administration has raised questions about its late-stage trial, so it may not be available here until the spring. Novavax, another U.S.-funded vaccine maker, has been plagued by delays and only recently began recruiting volunteers for its big trial. Merck, the most recent company to get federal support for covid vaccines, announced Monday it was scrapping its two candidates after they failed to produce adequate immune response in early tests. “None of the vaccine makers are manufacturing at the volume they ultimately want to be at,” Lurie said. “They all have manufacturing delays.” Pfizer, which has committed 200 million doses to the U.S. government by the end of July, said last week it expected “no interruptions” in shipments from its primary U.S. covid manufacturing plant in Kalamazoo, Michigan. Pfizer spokesperson Sharon Castillo said the company has expanded manufacturing facilities and added more suppliers and contract manufacturers. Those efforts, and the company’s announcement that its five-dose vials actually contain an extra dose, mean “we can potentially deliver approximately 2 billion doses worldwide by the end of 2021.” The U.S. government also has an option to acquire another 400 million doses of the Pfizer-BioNTech vaccine, though the company declined to provide details on that option when asked. But countries around the world are competing for the same supplies and raw materials, Gostin said. Biden could use the Defense Production Act “to force Pfizer to prioritize U.S. contracts, but that would be politically risky,” given that other countries could retaliate by hoarding supplies. Although Pfizer is an American company, it has partnered with BioNTech, of Germany, to make its covid vaccine. “That would lead to a global mess.” Trying to corner the world market on vaccine ingredients or supplies would look bad, experts say, given that the United States just this week joined Covax, an international venture to source and distribute vaccines, in an effort to ensure poor countries aren’t left behind. Paradoxically, the rush to get vaccines to market may have resulted in a less efficient manufacturing process. Vaccine companies typically spend months making their factories run as efficiently as possible, as well as finding an ideal dose and the most effective interval between doses, Lurie said. Given the urgency of the pandemic, however, they delayed parts of this process and launched straight into mass production. Pfizer angered European countries last week when it paused vaccine production at a Belgian plant to upgrade its capacity. Pfizer said the weeklong closure would decrease vaccine deliveries to Europe for three to four weeks before boosting supplies in February. The move doesn’t affect U.S. vaccine supplies. “The U.S can’t necessarily readily access stuff that’s being held for vaccines in other countries,” Lurie said. And forcing other companies to make covid vaccines could jeopardize production of **other important shots,** such as measles, said Dr. Amesh Adalja, a senior scholar at the Johns Hopkins Center for Health Security. Routine childhood immunization rates have fallen during the pandemic, raising the risk of epidemics. Using the act to prioritize covid vaccine manufacturing has already disrupted supplies of at least one drug, Fox noted. In December, Horizon Therapeutics warned doctors and patients to expect a shortage of a drug called Tepezza, used to treat thyroid-related eye disease, because its manufacturer was ordered to prioritize covid shots. Lawmakers and consumer advocates such as Public Citizen called on the government to use the Defense Production Act more aggressively. In a letter sent earlier this month, Sen. Elizabeth Warren (D-Mass.) and Rep. Katie Porter (D-Calif.) said Moderna should share its technique for stabilizing its vaccine at normal refrigerator temperatures, without “ultracold” freezers. Moderna officials have said the intrinsic differences in the two companies’ mRNA material make that technology hard to share. Besides, they say, Pfizer has declined to share data with Moderna. Pfizer has declined to comment on the issue. Since Moderna’s effort is federally funded, the government presumably has march-in rights and could take over production, said Mike Watson, former president of Moderna subsidiary Valera, in an email. “The reality is that however far you push production capacity, you sooner or later reach a bottleneck.” Experts say it’s not as simple as demanding that glassmaker Corning step up and make glass vials, for example. Of course, the vials will need to meet rigorous requirements. But there’s also this: The U.S. is facing a shortage of mined sand, the main component needed to make glass vials.

#### That turns the Case – limited care and medicine for other infectious diseases will go to white, privileged populations leaving minorities and those in the global south vulnerable to unnecessary deaths.

### 1NC Contention 1

#### LBL

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### 1NC – Women’s Health

#### Removing Patents won’t make Cancer more accessible – multiple warrants.

Chalkidou and Sullivan 19 Kalipso Chalkidou and Richard Sullivan 7-31-2019 "Removing cancer drug patents will not benefit the poorest" <https://www.ft.com/content/0527ce98-b2ec-11e9-8cb2-799a3a8cf37b> (Director of Global Health Policy and a Senior Fellow at the Center for Global Development.)//Elmer rec sr

We write in response to “ Essential cancer drugs must be more affordable” (July 22). Though addressing the cancer burden in poorer countries deserves more attention and more investment, removing patents for the latest metastatic cancer drugs is not going to help improve cancer outcomes for the poorest. First, many of the new cancer medicines launched in high income economies are of questionable clinical value. More than half of the new drugs entering the German healthcare system were shown to add no clinical benefit; in the UK, fewer than one in five of the cancer drug/clinical indication pairs covered under the now-reformed Cancer Drugs Fund were shown to offer a survival benefit of, on average, slightly more than three months, at a total cost to the British taxpayer of £1.3bn. Second, even these mostly marginal benefits are realised only if patients receive appropriate and timely pathways of care, including screening programmes, early diagnosis and radiology, pathology, surgery and radiotherapy, as the UK experience has shown. All of these are in serious deficit across most low and middle-income countries. Third, even at zero acquisition cost, some cancer drugs may be cost-ineffective because they need to be given with other drugs or treatment modalities, as recent experience in the National Health Service has shown. High-tech tertiary-care hospital infrastructure to monitor progression and deal with side effects as well as specialist personnel all cost money that poor healthcare systems would have to divert away from other uses such as treating children with diarrhoea or pregnant women attending community clinics. Further, the cost of launching a drug even after it has been voluntarily licensed is not negligible. Fourth, innovative medicines are expensive to develop and commercialise. Yes, Big Pharma’s priorities are wrong and the market for on-patent drugs is dysfunctional, with escalating costs and deteriorating access even in the wealthiest of countries. However, to address the health needs of the poorest in the world, most of whom live in emerging economies, there is a dire need for private investment in research and development. Without middle-income countries stepping up and paying for innovation in treating diseases that affect their own populations, the plight of the poorest is likely to remain unaddressed. If anything, we need more incentives for private investment in R&D for the diseases of the poor, not less. Removing patents is not likely to entice such investment. Finally, more than 90 per cent by value of the pharmaceutical market in sub-Saharan Africa and south Asia, where the world’s poorest live, is made up of generic medications that are generally overpriced. In French West Africa almost 80 per cent of expenditure on drugs goes on products more than 20 years old. Fixing the market for generics through swifter regulation, better quality control, and more patent and price information to empower payers to get a better deal must be the top priority for national governments, development partners and the World Health Organization. Removing the patents of new cancer drugs and even making them free throughout LMICs will not improve cancer outcomes for the world’s poorest.

#### Patents for Women’s Medicine are overwhelmingly done by Women – o/ws their ev on specificity to the medicine in their impacts

Koning 21, Rembrand, Sampsa Samila, and John-Paul Ferguson. "Who do we invent for? Patents by women focus more on women’s health, but few women get to invent." Science 372.6548 (2021): 1345-1348. (Harvard Business School)//Elmer

We **measured the gender of inventors** **and the sex focus of their inventions** **for** all U.S. **biomedical patents filed between 1976 and 2010**. We found that in this field, **inventions by women are more likely to focus on the medical needs of women**. This pattern is **strongest for all-female invention teams**, **holds over** **decades**, **and is present even within narrow areas of invention**. This last finding suggests that the female inventor-invention link is both the result of women working in more female-focused research areas and female inventors identifying opportunities to invent for women regardless of the area in which they work. We also analyzed biomedical research articles between 2002 and 2020 and found that **female-discovered ideas are** also **more likely to be female-focused**. That upstream research ideas also exhibit a female inventorinvention link further suggests that the gender gap in who commercializes their ideas has contributed to the sex gap in what types of ideas become inventions. The starting point for our analysis was a new measure for a patent’s focus on the medical needs of men and/or women. We extracted the title, abstract, and start of the summary text from the 441,504 “Drugs and Medical” patents in the PatentsView-NBER (National Bureau of Economic Research) dataset. We then fed this text through the National Library of Medicine’s Medical Text Indexer (MTI) (21).

#### IP protections are specifically key to incentivize Female Inventors.

Osei-Tutu 18 J. Janewa Osei-Tutu March/April 2018 "Using Intellectual Property Law to Promote Human Flourishing for “Market Women”" <https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/march-april/using-intellectual-property-law-promote-human-flourishing-market-women/> (Professor Osei-Tutu holds an LL.M., with distinction, in International and Comparative Law from McGill University)//Elmer

The “Market Woman”: **Using IP to Promote Human Development** **Women entrepreneurs who are aware of the possibilities that IP rights create will be better able to protect and distinguish their products in the marketplace**. Patents, for example, protect new, useful, and nonobvious inventions. However, this protection is not automatic, but rather requires one to complete an application and examination process. This requires the entrepreneur to have sufficient awareness of the possibility of obtaining patent protection and the means to do so. Women entrepreneurs may create innovations that could be protected by patents, which, as discussed above, create a period of market exclusivity. Obtaining a patent can be an expensive and complicated process, but the rewards can be significant. The first step is for the African market woman to recognize that she may have created something of value that she could protect, market, and sell. Due to the application process, patents are probably the most complicated of all the forms of intellectual property and the least likely to be used by the African market woman. Copyright and trademarks are less costly and less involved than obtaining patent protection. Both these forms of **i**ntellectual **p**roperty **can** also **help to advance women’s social, cultural, and economic progress**. For example, market women may create cultural artworks that are protectable by copyright. Because copyright protection arises upon creation, no application process is required. Some nations, however, may require registration before the rights can be enforced. African market women and other female entrepreneurs, including Abena, Akua, and Charity, whose businesses were described at the beginning of this article, would benefit from creating logos and verbal trademarks that could serve as indications of source for their products or services. By using trademarks in association with their goods or services, these market women would have effective tools to communicate something about their enterprises, while distinguishing their products and services from those of other enterprises. These women could grow their businesses, thereby increasing their opportunities, which can have positive impacts on their economic progress. This improves their ability to obtain health care and access to educational resources for themselves and their families. Certainly, the full picture is much more complex, and IP rights play a small role in supporting human development. However, IP rights are significant in the world economy, and these female entrepreneurs may be better able to enjoy their small part if they are aware of the advantages intellectual property can provide them. For example, a United States Patent and Trademark Office (USPTO) report estimates that in the United States, “IP-intensive industries directly and indirectly supported 45.5 million jobs, about thirty percent of all employment.”25 According to the report, trademark-intensive industries are more numerous than copyright and patent industries and contribute the most to employment in the United States.26 Thus while intellectual property may not be the most important factor in promoting human flourishing and human development for women entrepreneurs, it is one factor that should be incorporated into the overall development framework.

#### That’s key to Female Empowerment.

Montanari 18 Lorenzo Montanari 4-26-2018 "How IP Rights Empower Women" <https://www.forbes.com/sites/lorenzomontanari/2018/04/26/how-ip-rights-empower-women/?sh=552c71296e73> (I am also executive director of Property Rights Alliance, an advocacy policy group in charge of publishing the International Property Rights Index. I analyze the crossroads on how rule of law, intellectual property rights and international relations impact the global economy.)//Elmer

In many parts of the world, women are not treated equal to men under the law. From owning land to obtaining inheritance, women are at a disadvantage. Stronger intellectual property protections can help alleviate this discrepancy. When IP rights are strongly protected, the rights of women are protected as well. For example, the countries with the strongest protection of copyrights also tend to have the highest paid actresses and female artists. April 26 is commemorated as World IP Day by WIPO, the World Intellectual Property Organization. Celebrated internationally, the goal of World IP Day is to promote knowledge about intellectual property (patents, copyright, trademarks) and their role in promoting innovation and creativity. This year, World IP Day’s theme “Powering change: Women in innovation and creativity” will celebrate women and their role in shaping the future of society. The protection of intellectual property rights is vital for economic growth. Intellectual property rights are so important that they are enshrined in Article 27 of the Universal Declaration of Human Rights of 1948, which states “everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.” Elena Panaritis, author of Prosperity Unbound, founder and CEO of Thought 4 Action, explains that practice shows that women become more civically involved in the politics of their community and country, as well as and powerful market players, leaders of innovation and middle class once they are given secure ownership of their property rights. Women's involvement increases over 53% in such countries. The protection of IP rights restores this financial incentive to create and innovate, by giving owners and content creators exclusive power over their creations. For women, this is of huge importance. Statistics have shown that countries with stronger IP rights tend to have stronger measures of gender equality. “Women in the economy are a powerful force for change and leadership. Intellectual property rights when used correctly can advance entrepreneurship by enabling women who develop innovative ideas and products to secure financing, signal their innovation, and negotiate access to the IPRs held by others. IP systems should recognize and protect creativity in all its forms, including contributions from traditional and indigenous knowledge developed by women,” said Prof. Walter G. Park, of American University and author of the Patent Index. The focus on the protection of intellectual property comes at a time when IP rights are both of their highest importance to the global economy and the most at risk. IP-intensive firms account for more than 38% of GDP and 45.5 million in the U.S., and 42% of GDP and 82 million jobs in the EU. These industries not only support jobs, but high-paying jobs. In the EU and U.S., workers earn 46% more in IP-intensive sectors than workers in other sectors. Without strong rights protections, innovation is stifled as content creators lose a large portion of their incentive to create – profit. In the absence of effective IP laws, creative works can be infringed upon, reproduced without needing the creator’s permission, and sold without compensating the creator. In the developing world, weak IP regimes and unreliable enforceability of the rule of law have allowed the growth of counterfeit products to reach alarming rates: 2.5% of global trade is now thought to be in counterfeit products. While produced in lesser developed countries, 80% of these counterfeits infringe on the rights of EU and U.S. businesses. The EU is estimated to lose €83 billion and 790,000 jobs every year due to counterfeiting and piracy. To make matters worse, these counterfeits are not just in consumer goods such as sports jerseys or sneakers. 10% of the global pharmaceutical trade is thought to be counterfeit. These "medicines" have been found in legitimate supply chains in a third of the world’s countries, jeopardizing life-saving treatments and resulting in serious health consequences, even death. This increased trade in counterfeit pharmaceuticals worsens an already costly and risky process to manufacture medicines. New medicines require research, countless trials, on average $2.8 billion in investments, and up to 12 years of time. Less than 10% of medicines in development make it through these trials. Strong IP rights incentivize commitment and collaboration to produce pioneering work. Because of this governments worldwide increasingly use tax incentives like the patent box to encourage innovation and economic growth. Weak IP regimes in these developing countries, some of the world’s most populated, can exacerbate already disparate living conditions for women. Developing countries tend to have higher levels of female unemployment, higher infant mortality rates, and lower female education rates. Investments into these countries that can raise GDP per capita and improve the standard of living for all are limited when rampant rights abuses disincentivize major companies from entering the market. Protecting IP can change this - the country that protects IP rights the most is also the country with best entrepreneurial environment for women. However, while these developed countries generally have stronger IP protections than developing countries, there is still room to grow in IP for women even in developed nations. According to the Women’s Institute for Policy Research, while women have quintupled their representation among patent holders since 1977, less than one in five patents in the United States have at least one woman inventor named. The study also found that women only make up 7.7 of primary inventors who hold patents. Based on this rate, women won’t reach parity in patenting until 2092. This discrepancy between the genders is even more discouraging given the important role women inventors have played in history. Women are to thank for some of today’s most common-place items, such as the windshield wiper patented by Mary Anderson and frequency hopping technology patented by Hedy Lamarr, which laid the groundwork for Bluetooth and WiFi technology. Developed countries are also no safe haven for the strong protection of intellectual property rights. The World Health Organization sponsored push for plain packaging is robbing companies of their trademark rights in developed countries such as Australia and the U.K. This has costly economic, security, and health consequences. Plain packaging has been linked to a rise in the illicit tobacco trade in Australia, funneling money into the black market, while subjecting consumers to unregulated, unsafe tobacco. If implemented in the U.S. to alcohol and sugary drinks, plain packaging could cost the beverage industry $300 billion, larger than the GDP of some countries. According to different indexes which are important scorecards for how well countries around the world protect intellectual property rights among women, countries that do a better job of protecting property rights tend to have better measures of gender equality, including in areas such as access to land, access to credit, and equal inheritance rights. "Empowering women is a solution for poverty. A way to empower women is giving them property rights." said Prof. Sary Levy-Carciente of Universidad Central de Venezuela. This measure shows us that protecting intellectual property rights is a win-win for all societies. By protecting these rights, economic incentives exist to innovate and invest. This results in economic growth and prosperity. Protecting these rights also elevates the position of women in society to one of more equality with men, resulting in even more long term economic growth. This World IP Day, an international coalition of organizations celebrate the role of women in IP not only through celebrating past achievements, but also encouraging further growth and advancement.

#### LBL

#### 1] They can’t solve any of their impacts – their evidence critiques broader structures of inequality like wage gap and drug prices – Cross-app our turns from the first contention – drug prices

#### 2] Hay is about inequality the healthcare system writ-large which they can’t solve simply by reducing IP – your card says that inequality happens because of flawed models but passing the plan doesn’

### 1NC – IP not Key

#### Alt Causes to lack of generics thump Aff solvency to zero – pay-for-delay, citizen petitions, authorized generics, and testing sample access – this is terminal since they’d just shift tactics to non-patent strategies.

Fox 17, Erin. "How pharma companies game the system to keep drugs expensive." Harvard Business Review (April 6, 2017), https://hbr. org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive (last visited on November 22, 2019) (2017). (director of Drug Information at University of Utah Health)//Elmer

The ways companies stop generics One of the ways branded drug manufacturers prevent competition is simple: cash. In so-called “pay for delay” agreements, a brand drug company simply pays a generic company not to launch a version of a drug. The Federal Trade Commission estimates these pacts cost U.S. consumers and taxpayers $3.5 billion in higher drug costs each year. “Citizen petitions” offer drug companies another way to delay generics from being approved. These ask the Food and Drug Administration to delay action on a pending generic drug application. By law, the FDA is required to prioritize these petitions. However, the citizens filing concerns are not individuals, they’re corporations. The FDA recently said branded drug manufacturers submitted 92% of all citizen petitions. Many of these petitions are filed near the date of patent expiration, effectively limiting potential competition for another 150 days. “Authorized generics” are another tactic to limit competition. These aren’t really generic products at all; they are the same product sold under a generic name by the company that sells the branded drug. Why? By law, the first generic company to market a drug gets an exclusivity period of 180 days. During this time, no other companies can market a generic product. But the company with the expiring patent is not barred from launching an “authorized generic.” By selling a drug they’re already making under a different name, pharmaceutical firms are effectively extending their monopoly for another six months. Another way pharmaceutical firms are thwarting generics is by restricting access to samples for testing. Generic drug makers need to be able to purchase a sample of a brand-name product to conduct bioequivalence testing. That’s because they have to prove they can make a bioequivalent product following the current good manufacturing practices (CGMP) standard. These manufacturers don’t need to conduct clinical trials like the original drug company did. But the original drug developer often declines to sell drug samples to generics manufacturers by citing “FDA requirements,” by which they mean the agency’s Risk Evaluation and Mitigation Strategies program. The idea behind this program is a good one: give access to patients who will benefit from these personalized medicines, and bar access for patients who won’t benefit and could be seriously harmed. However, brand drug makers are citing these requirements for the sole purpose of keeping generics from coming to market.

#### Petitions to the FDA swamp and deter generics.

Feldman 17 Robin Feldman 6-16-2017 "Pharma companies fight behind-the-scenes wars over generic drugs" <https://www.statnews.com/2017/06/16/generic-drugs-biosimilars-pharma/> (Arthur J. Goldberg Distinguished Professor of Law and Director of the Center for Innovation.)//Elmer

One tactic that my colleague Evan Frondorf and I describe in our book, “Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market,” involves petitions to the Food and Drug Administration asking that the agency not give the green light to generic versions of a drug. Our research on 12 years of FDA data shows that in some years nearly 1 out of every 5 petitions filed on any topic — including food, tobacco, dietary supplements, and devices — was related to delaying generic entry. The FDA denies 80 percent of these petitions, but the process takes time, even for silly petitions, such as one asking the FDA to declare that a generic must provide information that the regulations already require. The time it takes to respond to these petitions delays the entry of the generic.

#### Authorized Generics decimate competition.

Sipkoff 4 Martin Sipkoff 8-4-2004 "Big Pharma uses effective strategies to battle generic competitors" <https://www.drugtopics.com/view/big-pharma-uses-effective-strategies-battle-generic-competitors> (Healthcare Writer)//Elmer

But, according to Cutting Edge, brand-name pharmaceutical companies have begun flanking generics in an inventive way: They enter into manufacturing and distribution agreements with a generic company before a patent is about to expire, attempting to preempt market share. "A typical agreement specifies that the generic company will serve as a distributor of the nonbranded, generic form of the drug, which will continue to be produced in the branded drug company's manufacturing facilities," said Hess. "It's an increasingly popular strategy, often stemming from out-of-court patent lawsuit settlements." A successful flanking strategy can be beneficial to a generic manufacturer because it saves on capital outlay by not having to build or modify manufacturing facilities. "The brand-name pharmaceutical company benefits because the partnership enables it to continue to operate its manufacturing lines and turn a profit, thereby recouping more of its R&D investment in the drug and more of its capital investment in the manufacturing plant," said Hess. Here's an example of effective flanking: Generic drugmaker Apotex launched a version of GlaxoSmithKline's blockbuster drug Paxil in September 2003, threatening to significantly dent GSK's $3.2 billion-a-year bestseller. In response to Apotex's entry into the market, GSK struck a licensing agreement with another generic drugmaker, Par Pharmaceutical, in April 2003. The agreement specifies that GSK will supply Par with generic Paxil, in immediate-release form. The tablets are made by a GSK subsidiary, and Parwhich pays a royalty to GSK on salesdistributes them in the United States. "The royalty payments help GSK capture a small segment of the generic Paxil market, which offsets the losses of its branded Paxil sales following the drug's patent expiration," said Hess. Flanking is very controversial because it virtually derails competition. In fact, some generic manufacturers say it's illegal. It's very similar to what the Generic Pharmaceutical Association and others regard as the illegitimate strategy of "authorized generics." "It's an easy concept to describe," said Robert Reznick, a partner with the national law firm Hughes Hubbard & Reed. He chairs the firm's Pharmaceutical and Healthcare Practice Group and has written about the legality of authorized generics. "An authorized generic is like any other generic in that it is deemed equivalent to a brand-name drug," he said. "But rather than being made by an independent generic drug manufacturer pursuant to an Abbreviated New Drug Application, it is either made by or under a license from the New Drug Application holder itself. It may be marketed by an affiliate of the brand-name manufacturer or by a third party." In a white paper titled "Are Authorized Generics Lawful?" Reznick and his colleagues recently concluded that agreements between brand and generic manufacturers to create authorized generics may be legal under antitrust law, but the issue has yet to be fully settled.

#### Generic companies are just incompetent – means even without patents, they wouldn’t be able to produce.

Fox 17, Erin. "How pharma companies game the system to keep drugs expensive." Harvard Business Review (April 6, 2017), https://hbr. org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive (last visited on November 22, 2019) (2017). (director of Drug Information at University of Utah Health)//Elmer

Problems with generic drug makers Although makers of a branded drug are using a variety of tactics to create barriers to healthy competition, generic drug companies are often not helping their own case. In 2015, there were 267 recalls of generic drug products—more than one every other day. These recalls are for quality issues such as products not dissolving properly, becoming contaminated, or even being outright counterfeits. A few high-profile recalls have shaken the belief that generic drugs are truly the same. In 2014, the FDA withdrew approval of Budeprion XL 300 — Teva’s generic version of GlaxoSmithKline’s Wellbutrin XL. Testing showed the drug did not properly release its key ingredient, substantiating consumers’ claims that the generic was not equivalent. In addition, concerns about contaminated generic Lipitor caused the FDA to launch a $20 million initiative to test generic products to ensure they are truly therapeutically equivalent. In some cases, patent law also collides with the FDA’s manufacturing rules. For example, the Novartis patent for Diovan expired in 2012. Ranbaxy received exclusivity for 180 days for the first generic product. However, due to poor quality manufacturing, Ranbaxy couldn’t obtain final FDA approval for its generic version. The FDA banned shipments of Ranbaxy products to the United States. Ranbaxy ended up paying a $500 million fine, the largest penalty paid by a generic firm for violations. Due to these protracted problems with the company that had won exclusivity, a generic product did not become available until 2014. The two-year delay cost Medicare and Medicaid at least $900 million. Ranbaxy’s poor-quality manufacturing also delayed other key generic products like Valcyte and Nexium. Ironically, it was Mylan—involved in its own drug pricing scandal over its EpiPen allergy-reaction injector—that filed the first lawsuit to have the FDA strip Ranbaxy of its exclusivity. Mylan made multiple attempts to produce generic products but was overruled in the courts.