## 1NC

### 1NC – OFF

#### 1] Interpretation – Affs must defend a reduction in intellectual property protections that protect the medicines.

#### Medicines are physical substances.

American Heritage Dictionary of Medicine 18 The American Heritage Dictionary of Medicine 2018 by Houghton Mifflin Harcourt Publishing Company <https://www.yourdictionary.com/medicine> //Elmer

"A **substance**, **especially a drug**, **used to treat** the signs and symptoms of a **disease**, condition, or injury."

#### For means “intended to” – the object of the IP Protection must be Medicines.

Cambridge Dictionary No Date "For" <https://dictionary.cambridge.org/us/dictionary/english/for> //Elmer

**intended to be given to:**

#### 2] Violation - Data exclusivity protects clinical trial data, NOT MEDICINE. The plan doesn’t affect the actual production of Medical Substances, just the structural factors that influence it.

Thrasher 5-25 Rachel Thrasher 5-25-2021 "Chart of the Week: How Data Exclusivity Laws Impact Drug Prices" <https://www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data-exclusivity-laws-impact-drug-prices/> //sid

Data exclusivity is a form of intellectual property protection that **applies specifically to data from** pharmaceutical **clinical trials**. While innovator firms run their own clinical trials to gain marketing approval, generic manufacturers typically rely on the innovator’s clinical trials for the same approval. Data exclusivity rules keep generic firms from relying on that data for 5 to 12 years, depending on the specific law. Data exclusivity operates independently of patent protection and can block generic manufacturers from gaining marketing approval even if the patent has expired or the original pharmaceutical product does not qualify for patent protection. Although data exclusivity laws are matters of domestic legislation, the United States, the EU and others increasingly demand in their free trade agreement (FTA) negotiations that their trading partners protect clinical trial data in this way. Data exclusivity is just one of a host of “TRIPS-plus” treaty provisions designed to raise the overall level of intellectual property protection for innovator firms. Although the WTO’s Agreement on Trade-Related Intellectual Property Rights (TRIPS) does require Member states to protect clinical trial and other data from “unfair commercial use,” it does not require exclusivity rules that block the registration of generic products.

#### [Pre-empting the We Meet] – Plan Text in a Vacuum is a useless guideline since words are contextually defined based on function – the only basis for determining Topicality should be if the implementation of the Plan as per their 1AC solvency evidence follows the directional meaning of the Topic’s intent – anything else allows the 1AR to re-contextualize what the Plan says forcing the 1NC to predict infinite 1AR spin since they’re not tied to their evidence.

#### The Aff is both Effects and Extra-T because they effect things unrelated to Medical IP like Data – both of which are voters for Limits and Ground.

#### 3] The Standard is Limits – allowing Affs that relate to the factors and structures surrounding Medicines allows treatments, drug discovery techniques, computer programs, and production techniques that all have IP protections to be topical which eviscerate a stable locus of predictability.

#### 4] Paradigm Issues –

#### a] Topicality is Drop the Debater – it’s a fundamental baseline for debate-ability.

#### b] Use Competing Interps – 1] Topicality is a yes/no question, you can’t be reasonably topical and 2] Reasonability invites arbitrary judge intervention and a race to the bottom of questionable argumentation.

#### c] No RVI’s - 1] Forces the 1NC to go all-in on Theory which kills substance education, 2] Encourages Baiting since the 1AC will purposely be abusive, and 3] Illogical – you shouldn’t win for not being abusive.

### 1NC – OFF

#### JFDA’s application of data exclusivity has encourages investment.

Obaidat 16 (, H., 2016. Hayel Obaidat Obaidat, JORDAN FOOD AND DRUG ADMINISTRATION — High-Level Panel on Access to Medicines. [online] High-Level Panel on Access to Medicines. Available at: <http://www.unsgaccessmeds.org/inbox/2016/2/28/dr-hayel-obaidat-obaidat> [Accessed 27 September 2021].)-rahulpenu

HAYEL OBAIDAT OBAIDAT, JORDAN FOOD AND DRUG ADMINISTRATION

ABSTRACT

The contribution is regarding Jordan Data Exclusivity in Pharmaceuticals Sector and their implementations at Jordan FDA, since joining World Trade Organization (WTO) in 2000, the adoption of the Unfair Competition and Trade Secrets Law, and signing a free trade agreement with the United States in 2001, **Jordan** has **strengthened** the **intellectual** **property** **protection** provides for pharmaceutical products.

JFDA is keen to bring new medications to the patients as quickly as possible to allow the worldwide therapeutic opportunities available in Jordan , so **by** **applying** the protection ( **data** **exclusivity**) this will **encourage** the international companies to **invest** **in** the **pharmaceutical** **sector** and the arrival of newer medicines, Nevertheless, JFDA has been implementing a standing operating policy and measures to accept receiving applications of generic version of an innovator during the last year protection in order to accelerate the registration of generic drugs and its affordability, also has included restricting market exclusivity to a narrow definition of “new” uses and limiting applications for data exclusivity to a short period 18 months following first market approval in worldwide..

This contribution contains some suggestion and recommendation taking in consideration human right in access to medicine

#### Especially from the US---empirics prove overwhelming investment attraction because of JUSFTA.

Chin et al. 08 (, J., Nasa’a, M., Leonard, S., Munoz, C. and Reilly, B., 2008. The Jordan-U.S. Free Trade Agreement: Eight Years Later. [online] Websites.umich.edu. Available at: <http://websites.umich.edu/~ipolicy/Policy%20Papers/jordanusfta.pdf> [Accessed 27 September 2021].)-rahulpenu

D. The Information and Communication Technology Industry

The other common effect discussed by officials when talking about the JUSFTA is a result of the agreement’s stringent IPR clauses. These officials often label the JUSFTA intellectual property rights clauses as ―TRIPS plus,‖ a reference to the fact that the agreement is stricter than the WTO’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). They argue that, in combination with Jordan’s literate, educated workforce, the JUSFTA’s IPR clauses make Jordan an attractive opportunity for companies wishing to outsource IP-heavy information and communication technology (ICT) services and also for companies wishing to base pharmaceutical R&D and manufacturing services.

While ICT is currently a small part of Jordan’s economy, the country’s officials are not shy about stating their goal to have Jordan become an ICT hub for the region. In reality, however, there is little evidence that the JUSFTA contributes to this goal. Jordan is ranked 57th overall in the World Economic Forum’s 2006-07 Global Information Technology Report’s Networked Readiness Index. Its telecommunications exports to the United States decreased over the 2001- 2005 period, the most recent for which data is available (see Table 2 below). While many argue that the JUSFTA’s ―TRIPS Plus‖ conventions will attract foreign ICT investment and contracts, this has yet to be seen. Like U.S. exports, telecommunications exports to Great Britain, another country with a well-recognized IPR commitment, also decreased over the 2001-2005 period. The major export increases during this period were to China and South Korea. However, since China is perennially on the U.S. government’s ―Special 301‖ list, which identifies countries that inadequately protect IPR, it is unlikely that Jordan’s status as a ―TRIPS Plus‖ service provider drives these exports. South Korea is also on the 2007 Special 301 list.51

Table 2: Jordanian Telecommunications Exports, 2001-2005 (SITC 764)

[Table Omitted]

Even within the MENA region, it is unlikely that Jordan’s ―TRIPS Plus‖ status drives ICT trade and significantly contributes to Jordan’s development as a regional ICT hub. Of the 15 MENA countries for which telecommunications export data is available, 6 are on the Special 301 ―Priority Watch‖ or ―Watch‖ list. Therefore, the ability of the JUSFTA’s provisions to incentivize regional ICT development also appears minimal.

E. The Pharmaceuticals Industry

U.S. and Jordanian officials commonly point to the **pharmaceuticals** **industry** **as** **another** that **benefit**s from the **JUSFTA**. While the nascent pharmaceuticals industry is directed to regional rather than U.S. markets, officials indicate that the **FTA’s** **TRIPS** Plus **provisions** **encourage** **investment** in this industry as well. Supporters point to the **successes** **of** the Arab Pharmaceutical Manufacturing Company (**APMC**), an active exporter that is listed on the Amman Stock Exchange. APMC manufactures, produces, markets and sells pharmaceuticals, compounds, and derivatives and also performs research and development activities. With almost 1000 employees and 2006 sales over $29 million, APMC is a large player in the regional and global pharmaceuticals market. International partners include the Takeda Pharmaceutical Company of Japan. 52

According to the Pharmaceutical Manufacturers Association of America (PhRMA), the **JUSFTA** **made** **Jordan's** **market** **more** **appealing** **for** **sales** **and** **licensing** **agreements**. This may be true; in 2006, the **U**nited **S**tates **export**ed $11.4 million in pharmaceutical products to Jordan, an almost **70** **percent** **increase** from 2001. Assuming that these pharmaceutical products provide real improvements over products previously offered in Jordan, this **provides** an **important** **health** **benefit** **to** the **Jordanian** **society**. However, it is less economically significant; $11.4 million in exports represented less than 2 percent of total U.S. exports to Jordan that year. Supporters who argue that the JUSFTA provides incentives for U.S. firms to contract research and development activities to Jordan face a similar challenge when trying to prove economic relevance. U.S. pharmaceutical imports from Jordan totaled only $7 million in 2006; a significant increase over 2001 numbers, but still less than one-half of one percent of Jordan’s total exports to the United States.

#### The plan would break a critical barrier for Chinese pharma investment into Jordan---strict control is key.

UNCTAD 11 (, 2011. Investment in Pharmaceutical Product ion in the Least Developed Countries A Guide for Policy Makers and Investment Promotion Agencies. [online] Unctad.org. Available at: <https://unctad.org/system/files/official-document/diaepcb2011d5\_en.pdf> [Accessed 27 September 2021].)-rahulpenu

4. Key policy determinants

The above sections indicate that there has been a clear trend towards diversification of the industry in terms of products, places of production and R&D, and target customers, in response to, inter alia, the pressures faced by the expiration of patents held by larger firms in developed countries. The landscape for pharmaceutical production has also been shaped by the policy environment, both at the international and national levels. This section examines the key policies that have demonstrably affected the pharmaceutical production and investment landscape.

Drug registration requirements. Pharmaceuticals are a heavily regulated industry, and for good reason. Products are ingested, injected, applied topically and so forth; they therefore need to be proven efficacious, safe and quality controlled. Drug regulatory authorities ensure that firms under their jurisdiction comply with these standards. They are also responsible for gauging the demand for and helping to ensure the supply of essential medicines in the country. Countries differ widely on how pharmaceuticals are regulated, however, and the scope of regulation may greatly affect the incentives for local and foreign firms. Selected examples of the impact of certain drug regulations on local production and foreign direct investment are examined below.

Drug regulatory authorities have the responsibility to register those drugs that will be allowed to be marketed in their specific countries, and depending upon the domestic law, also for export. They are also responsible for verifying compliance with good manufacturing practices by manufacturers. Those drugs that are not registered and produced in a good manufacturing practices-compliant facility cannot be distributed. Registration must satisfy certain requirements, including having met applicable laboratory, clinical and bioequivalence tests for safety, consistency, quality and the like. Good manufacturing practices approval should meet technical requirements with respect to the handling of raw materials, manufacturing and packaging processes, treatment of water for use in the production process, air-quality and quality-control equipment and systems. Changes in drug registration policies have often had a significant impact on the domestic landscape for pharmaceutical production in some developing countries. For example, the Bangladesh National Drug Policy of 1982 deregistered all medicines that had been classified as non-essential or useless, and introduced for the first time an essential medicines list. This action, however, ended up deregistering a significant part of the portfolio of products held by the R&D-based transnational corporations, relegating them to producing mainly injectable vitamins after 1982. Moreover, foreign companies that do not have their own production facility in Bangladesh are not allowed to market their products, even if they are manufactured in the country by contract manufacturing. As a result of this policy action, most of the R&D-based industry sold their factories to local investors, and local firms now control over 70 per cent of the local pharmaceutical market.44

Indonesia’s Ministry of Health issued in late 2008 Decree No. 1010, requiring every company to manufacture every one of its pharmaceutical products in Indonesia, failing which, their registrations would eventually be withdrawn. Foreign firms that are importing drugs will be classified as pharmaceutical wholesalers – they lost their registration rights for their products after a grace period of two years following the issuance of the Decree. Imported pharmaceuticals can be registered by local pharmaceutical companies with written consent from a foreign company, which must include technology transfer to allow local manufacturing within five years.45 Decree 1010 applies to all products earlier policies that required pharmaceutical firms to establish factories for local manufacture as a prerequisite for the right to distribute in Indonesia, subject to certain exceptions. The Indonesian policies have in part contributed to greater domestic investment in and the control of a predominant share of the pharmaceutical market by local firms. Given the size of Indonesia’s market and its potential for growth, however, many Western and Japanese R&D-based pharmaceutical transnational corporations have established factories in Indonesia and intend on staying in spite of the Decree.

Drug pricing. Pricing policies can have a major impact on the economic decisions of pharmaceutical firms, both in terms of trade and investment. Those prices are often determined by the drug regulatory authority, often in consultation with the industry. An interesting example of this is in **Jordan**, **where** **price** **controls** **target** certain essential **medicines**. For these medicines, the public price of imported medicines is determined according to the corresponding price at which the product is offered in the home market, plus cost and profit margins for those importers and distributors. While a profit margin has been factored into this equation, the **effect** **of** this **control**, together with a strong regulatory framework, **has** **been** generally **higher** **prices** in Jordan for pharmaceuticals. **Chinese** and Indian **manufacturers** have in large part **refrained** **from** **entering** the **Jordanian** **market**, as **they** **would** **have** **to** **meet** **strict** **Jordanian** **good** **manufacturing** **practices**, while offering their products at close to Chinese and Indian prices, respectively, **resulting** **in** **lower** **profit** **margins** than their Jordanian counterparts. 46 One should therefore be conscious about the possible effect that price controls may have, both on investment and on the competitiveness of domestic firms.

Intellectual property. With the adoption of the TRIPS Agreement in 1994 as part of the set of treaties to which aspiring WTO Members needed to adhere, most of the world became obliged to make available the possibility of obtaining a patent for pharmaceuticals. Countries that had excluded patent protection for pharmaceuticals, which included both developing countries such as India, and developed countries in the past such as Switzerland, could no longer continue not to offer the possibility of product patent protection for new chemical entities.

The TRIPS Agreement did not, however, lead to a completely uniform system of patents – nor was it designed to do so. Instead, by implementing the Agreement through national legislation, countries were allowed flexibilities to tailor the patent system to their particular needs. Additionally, developing countries that had heretofore not offered the possibility enjoyed a transition period until 1 January 2005 and LDCs, until 1 January 2006 – which has now been extended until 1 January 2016, to provide for the possibility to obtain patents for pharmaceuticals under the TRIPS Agreement. Thus, because of these disparities, patent systems remain nationally based to a large extent, and what is patentable in one country is not necessarily patentable in another.47, 48 Adding to the complexity is that R&D-based pharmaceutical firms have generally sought to seek patent protection for new chemical entities in jurisdictions where they have a potential market for good returns, but have generally not sought patent protection in other markets. The landscape for the production of generic medicines in developing countries has been heavily influenced by this complexity. India, for instance, had not offered patent protection for pharmaceutical products since the 1970 Patent Act and until the implementation of the TRIPS Agreement. It successfully nurtured a pharmaceutical industry that was home to some of the world’s largest manufacturers of generics, including giants such as Cipla, Dr. Reddy’s and Ranbaxy. In order to support the local generic industry, the Indians developed a capacity for reverse engineering. This enabled them to produce generic equivalents of even the more complex molecules produced by originator companies. They could then offer them for sale to markets where there was no patent protection for those molecules, either because protection was not available under the local patent law, the originator did not seek patent protection in that jurisdiction, or the originator filed an application for patent protection that eventually failed to obtain protection. The recent introduction of patent protection for pharmaceutical products in India is expected to change the landscape over the coming years, however. The local industry is currently in a state of flux, with the acquisition of major generic companies by R&D-based transnational corporations. Further, the development of both Argentina’s and Brazil’s generic industry is also attributable in part to the absence of pharmaceutical patents in the pre-TRIPS era.49

#### China is taking every opportunity for investment expansion---ensures US-China cold war.

Huang 9-16 (, Y., 2021. The U.S.-China Trade War Has Become a Cold War. [online] Carnegie Endowment for International Peace. Available at: <https://carnegieendowment.org/2021/09/16/u.s.-china-trade-war-has-become-cold-war-pub-85352> [Accessed 27 September 2021]. Huang is a senior fellow in the Carnegie Asia Program, where his research focuses on China’s economy and its regional and global impact.)-rahulpenu

The **U.S.-China Trade War** Has **Become** a **Cold** **War**

What began as a trade war over China’s unfair economic policies has now evolved into a so-called cold war propelled by differing ideologies. U.S.-China bilateral relations took a nosedive in 2018 when then U.S. president Donald Trump’s obsession with trade deficits led him to impose punitive tariffs on China. The tariffs were followed by restrictions on both China’s access to high-tech U.S. products and foreign investments involving security concerns and by allegations of unfair Chinese commercial practices.

Despite pleas from the U.S. business community to ease tensions, U.S. President Joe Biden so far has amplified his predecessor’s policies by strengthening anti-China alliances and implementing additional sanctions. **Biden** now **characterizes** the **U.S.-China conflict** **as** “a **battle** **between** the utility of **democracies** in the twenty-first century **and** **autocracies**.”

But the logic underpinning the U.S. trade war was flawed, and the more recent, politically driven restrictions are counterproductive given the damaging long-term economic consequences for both sides. Nonetheless, there have been few signs to date that Biden is likely to change course. In the meantime, then, Europeans may be in a better position for productive give-and-take discussions with China on economic policymaking.

MISGUIDED U.S. TRADE POLICY

The Trump administration’s initial mistake in launching a trade war was to assume that U.S. trade deficits—which occur when a country imports more than it exports—were inherently bad and that China was to blame.

However, trade deficits are not a good indicator of the state of the economy, and U.S. trade balances largely are driven by soaring U.S. federal budget deficits, which have little to do with China. The irony is that three years after Trump’s tariffs were initiated to fix the U.S. trade deficit, bilateral trade between the United States and China has now rebounded to all-time highs, China’s trade surplus has increased, and the U.S. deficit has gotten worse.

Trump also echoed popular but misguided sentiments that U.S. firms had been overinvesting in China, resulting in a loss in competitiveness. But over the past two decades, only 1–2 percent of annual U.S. foreign investment has gone to China. By contrast, the EU, which is comparable to the United States in its economic size, has invested roughly twice as much as the United States has annually. The concern should be why the United States invests so little in China rather than so much.

CHINA’S INTELLECTUAL PROPERTY SAFEGUARDS

China’s alleged failure to protect intellectual property rights is also mischaracterized. At the extreme, **China** is **accused** **of** **stealing** **foreign** **i**ntellectual **p**roperty, especially technology. But after accounting for the size of China’s foreign transactions and research activities, such events may not occur unusually often or are possibly exaggerated.

Further, China’s patent courts have matured in dealing with this problem—foreign plaintiffs are now more likely to win their cases than domestic firms. In addition, theft is becoming less of a concern as payments for royalties and licenses by Chinese firms, according to one think tank scholar, have grown almost by a factor of four in the past ten years, making China the second-largest payer of such royalties globally.

The reality is that it takes **generations** **to** **develop** a **sound** **regime** **for** **i**ntellectual **p**roperty **rights**, as was the case for the United States. The foundation of China’s system was laid only two decades ago with reforms that accompanied China’s 2001 accession to the World Trade Organization. Progress has been notable in recent years as evidenced by the findings of the “2020 Business Climate Survey” by the American Chamber of Commerce in China; the survey indicated that nearly 70 percent of surveyed U.S. firms in China felt that China’s enforcement of intellectual property rights had improved, compared with only 47 percent in 2015.

CHINA’S PROTECTIONIST POLICIES

But there are also credible concerns that **China’s** **investment** **policies** **treat** **foreign** **firms** **unfairly**. One complaint is China’s use of subsidies. All countries provide subsidies to domestic companies and households, such as U.S. support to farmers, tax deductions to households to encourage clean energy use, and incentives to companies like Amazon to relocate. But in China, subsidies tend to be more focused on using the country’s banks and equity markets to support high-tech firms and strategic industries.

The U.S. government could choose to pressure China to better align its subsidy policies with Western norms, but instead, the Biden administration is copying China’s playbook by proposing its own subsidies to promote strategic industries.

China’s protectionist tendencies are also evident from the requirement that foreign firms form joint ventures with domestic Chinese firms as a condition for market entry in some economic sectors. This stipulation has been widely cited as a means of promoting so-called forced technology transfer, where foreign firms pass new technology on to their Chinese partners as a condition for being able to invest and produce in China.

But these Chinese requirements, too, have seemed to get less stringent in recent years, as exemplified by major foreign investments in chemical manufacturing (BASF), auto manufacturing (Tesla), and finance (BlackRock). These foreign companies have been allowed for the first time to enter key sectors without a Chinese partner.

China’s willingness to drop the joint venture requirement featured prominently in the EU-China Comprehensive Agreement on Investment negotiated in December 2020 (which has not yet been ratified). This experience suggests that policy differences can be addressed through consultations if both sides are willing to compromise.

#### US-China trade war causes nuclear war --- escalates and causes miscalc.

Kazianis 18 [Harry, director of defense studies at the Center for the National Interest, Fellow for National Security Affairs at the Potomac Foundation and a non-resident Senior Fellow at the University of Nottingham. "The US-China trade war has begun - a shooting war could be next." 7/6. http://www.foxnews.com/opinion/2018/07/06/us-china-trade-war-has-begun-shooting-war-could-be-next.html]

A trade war broke out Friday between the U.S. and China, when the U.S. imposed tariffs on $34 billion in Chinese products and China slapped tariffs on and equal amount of U.S. products. President Trump has said that would prompt the U.S. to impose up to $500 billion in Chinese products. But things could get worse. The deterioration in U.S.-China relations could escalate and turn into a shooting war between two nuclear armed superpowers. In the worst-case scenario, this could result in massive casualties on both sides that could even lead to nuclear war. Some will call such a statement pure hype – and I wish it was. But the facts lead us to a dark place when it comes to our relationship with China, which is becoming less of a partnership and more like a fight between mortal enemies looking to gain any advantage they can over the other. We are all rightly concerned over North Korea’s nuclear weapons, Iran’s penchant for backing terror, and a rogue Russia that can’t seem to stop causing trouble all over the world. But these problems are nothing when compared to the China challenge. No other nation is as able to challenge American power on the world stage in the coming years. Just look over the current state of affairs in the U.S.-China relationship. We see trade and military stand-offs, territorial disputes, and allies and partners of both nations squaring off or cybersecurity challenges. We see two nations on a collision course that seems more like the Cold War than the 21st century. But before we stare war with China in the eye, let’s consider the budding trade battle between Washington and Beijing. The Trump administration new duties on $34 billion in on Chinese goods amount to a 25 percent tariff. The duties impact items such as X-ray machine parts, water boilers, airplane tires and industrial parts. China slapped its tariffs on $34 billion worth of U.S. products such as soybeans, electric cars, pork and other products. But the Trump administration is not ready to back down, and, in fact, seems itching for a scrap. A senior Trump administration official told me Friday: “We are ready for a trade war. If they want it we are ready to fight it. They need to remember America would win that so-called war, hands-down. Our market is bigger, our consumers richer – we are the global innovator. All we ask is for an even playing field from the Chinese. If they won’t agree to that, then they will have to deal with the consequences.” When I asked what those consequences were, the official was quite clear: “China will pay a price. We will impose costs on them. They need to be ready for that. We are.” And one thing is quite clear: Washington does hold an advantage in a trade fight – the numbers don’t lie. America imports much more from China than China imports from the U.S. And while U.S. consumers and businesses would be hurt in a full-blown trade war, China stands to lose out on a big portion of the $462 billion in goods and services America imports from that nation. Considering the fact that the Chinese economy is already slowing down, Chinese President Xi Jinping would be wise to back off. But something bigger is afoot here – a seismic shift in international affairs that has been dormant, until now. As I have explained in these very digital pages, the U.S.-China relationship was bound to become adversarial as soon the Soviet Union collapsed in 1991. The Soviet threat was the one thing that brought both China and the U.S. together in the 1970s. Beijing saw the confrontation with America coming, and was already beginning to modernize its armed forces and recalibrate its military posture to take on the looming challenge from across the Pacific. While China certainly did prepare for what it felt was an inevitable encounter with America, time and circumstances seems to put any sort of showdown. Beijing’s ascension to the World Trade Organization in 2001 meant economic ties would grow between both nations quickly – and geopolitical tensions are not good for business. The Sept. 11, 2001 terrorist attacks also meant Washington was forced to shift its attention from Asia and back into the Middle East for over a decade. A true showdown with China was averted – at least for a while. Unfortunately, it seems the chances of a real clash with China – and even a military confrontation – are now spiking. With America less involved in the daily squabbles of the Middle East and no longer keen on letting Beijing take us to the cleaners on trade, any number of issues could see these two superpowers exchange blows. For example, China over the last few years has been pushing absurd claims that seek to turn the waters around its coasts into its own sovereign territory. From the East China Sea all the way to South China Sea, Beijing is determined to ensure that is the master of the seas – and push Washington out of the region for good. To support such claims, Beijing has made some key investments in its military to win a war with America. The centerpiece of this is a missile arsenal that is second to none, and is of such a size that U.S. missile defenses would be overwhelmed many times over. Firing from shore, China would hope to destroy most of America’s military bases around the region as well as sink any warships as far out as Guam. The worst part of all – thanks to treaty commitments with Russia – is that Washington is unable to counter Beijing’s missile weaponry on land. And from there it gets even worse. Backed by a massive militia that is nearly impossible to match, a growing navy armed with aircraft carriers and an air force that is producing fighter planes that strangely look like our very own stealth aircraft – because China stole the technology – Beijing’s claims in Asia are only growing more outrageous. At one point a few years ago, it seemed China was even making veiled claims to Okinawa, a clear part of Japanese territory that is home to a massive U.S. military presence. Such claims have even fostered parody articles saying that China has claimed most of the Pacific and Hawaii, almost fooling an entire conference at Yale University a few years ago. History tells us that nations with divergent interests and competing geopolitical goals with enough proximity tend to clash. In fact, as Harvard Professor Graham Allison reminds us, in 12 out of 16 cases studies where a rising power competed with an established power – think China vs. America – war was the result. Therefore, when talk of a trade war with China heats up, I think of a very different type of war. And you should too.

### 1NC – OFF

#### Text – States ought to

#### individually domestically establish single-payer national health insurance.

#### Solves the aff while avoiding the turns

Narayanan 19 Srivats Narayanan 8-15-2019 "Medicare for All and Evergreening" <https://medium.com/@srivats.narayanan/medicare-for-all-and-evergreening-cb84c930e0ea> (UMKC School of Medicine)//Elmer

Drug companies rake in massive profits. The pharmaceutical industry has some of the largest profit margins among American industries. Unfortunately, pharmaceutical giants don’t always have patients’ best interests in mind — they make a big portion of their money by exploiting the patent process instead of making breakthrough drugs that would meaningfully improve patients’ lives. Pharmaceutical corporations aren’t as innovative as one might expect. Although the Food and Drug Administration (FDA) has been consistently approving new (and expensive) drugs every year, most of these drugs aren’t impacting healthcare much. Many studies have revealed that a whopping 85–90% of new drugs since the mid-1990s “provide few or no clinical advantages.” This is because pharmaceutical firms are spending their time and money on a technique known as “evergreening.” Evergreening is when drug companies produce redundant drugs that are nothing but minor modifications of old drugs. By making slight alterations to their medicines, biotech companies continue to hold patents for drugs with minimal spending on research and development (R&D). Pharmaceutical companies then use those patents to prevent competitors from selling generic versions of their drugs. Without any competition, these corporations get away with ridiculously high drug pricing and can thus make big profits on their drugs. The companies simultaneously justify their absurd drug prices by pointing to the inflated R&D costs of producing new drugs. This excuse has been used time and again by the profit-hungry pharmaceutical industry, and it’s coming at the expense of patients who struggle to afford their medicines. A well-known example of evergreening pertains to the anticonvulsant medication gabapentin, which was first sold by Pfizer under the brand name Neurontin. When the drug became available as a generic medication over a decade ago, Pfizer created a very similar medicine, pregabalin (Lyrica), that didn’t have any significant benefits over the original drug. As a result, Pfizer has kept a control over the market for anticonvulsant drugs with negligible innovation. The drug industry’s reliance on evergreening is undoubtedly stifling innovation. This is where Medicare for All, which would impose the government as the only health insurer, would be useful. In our current system, there are many insurers and they each have little market power and consequently little negotiating power to reduce treatment prices. Since the government would have consolidated control over healthcare financing under Medicare for All, its stronger bargaining power would force drug companies to charge lower prices for their products. In addition, prescription drugs would be paid for by the government and not by patients under Medicare for All. Medicare for All would prevent evergreening. National healthcare financing would align how much the government pays a drug company with how much patients benefit from the company’s drugs. If a new drug had more clinical benefits than an older version, the government would pay more for it. If a new drug produced the same results as an older version, the government wouldn’t pay more for the new drug. So, Medicare for All would encourage pharmaceutical companies to pursue truly innovative drugs because such drugs would be more profitable. The policy would incentivize companies to invest in R&D for more useful drugs, instead of just producing redundant and expensive medications. A national healthcare plan would prioritize “patient and community needs” and match up pharmaceutical companies’ interests with actually improving public health. Evergreening has become the name of the game for the pharmaceutical industry. A major solution to the evergreening problem is Medicare for All. A single-payer system like Medicare for All would sharply curtail evergreening, since drug companies wouldn’t be able to profit from it. Medicare for All would usher in a new era of medical innovation.

### 1NC – OFF

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

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

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

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

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

#### WHO says yes

Kimball 21 [(Spencer, news editor with CNBC.com) “WHO chief urges world to follow U.S. lead and support waiving Covid vaccine patent protections,” CNBC, 5/7/2021] JL

World Health Organization Director General-Tedros Adhanom Ghebreyesus on Friday urged other countries, particularly the Group of Seven industrialized nations, to follow the U.S. example and support a World Trade Organization motion to temporarily waive Covid-19 vaccine patent protections. “Wednesday’s announcement by the U.S. that it will support a temporary waiver of intellectual property protections for Covid-19 vaccines is a significant statement of solidarity and support for vaccine equity,” Tedros said at a press briefing. “I know that this is not a politically easy thing to do, so I very much appreciate the leadership of the U.S. and we urge other countries to follow their example.”

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

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

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

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

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

#### Right to Health solves Nationalist Populism.

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

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

#### Populism is an existential threat.

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

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

## Case

### 1NC – AT: Advantage 1

#### Strong current IP guarantees causes massive Pharma innovation.

* Answers Evergreening/Me-Too Drugs

Stevens and Ezell 20 Philip Stevens and Stephen Ezell 2-3-2020 "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" <https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work> (Philip founded Geneva Network in 2015. His main research interests are the intersection of intellectual property, trade, and health policy. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division on a range of IP and health issues. Prior to his time with WIPO, Philip worked as director of policy for International Policy Network, a UK-based think tank, as well as holding research positions with the Adam Smith Institute and Reform, both in London. He has also worked as a political risk consultant and a management consultant. He is a regular columnist in a wide range of international newspapers and has published a number of academic studies. He holds degrees from the London School of Economics and Durham University (UK).)//Elmer

The **Current System** Has **Produced a Tremendous Amount of Life-Sciences Innovation** The frontier for biomedical innovation is seemingly limitless, and the challenges remain numerous—whether it comes to diseases that afflict millions, such as cancer or malaria, or the estimated 7,000 rare diseases that afflict fewer than 200,000 patients.24 And while certainly citizens in developed and developing nations confront differing health challenges, those challenges are increasingly converging. For instance, as of this year, analysts expect that **noncommunicable** diseases such as cardiovascular disease and diabetes will account for 70 percent of natural fatalities **in developing countries**.25 Citizens of low- and middle-income countries bear 80 percent of the world’s death burden from cardiovascular disease.26 Forty-six percent of Africans over 25 suffer from hypertension, more than anywhere else in the world. Similarly, 85 percent of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.27 To develop treatments or cures for these conditions, novel biomedical innovation **will be needed from everywhere**. Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over **$1.36 trillion in R&D** in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach $181 billion by 2022.28 In no small part due to that investment, **943 new active substances have been introduced** globally over the prior 25 years.29 The U.S. Food and Drug Administration (FDA) has approved more than **500 new medicines since 2000** alone. And these medicines are getting to more individuals: Global medicine use **in 2020 will reach 4.5 trillion doses**, up 24 percent from 2015.30 Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.31 In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).32 And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the **world’s most intractable diseases**, **including cancer and Alzheimer’s**.33 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved **41 new medicines** (at that point, the most since 1996) many of which were first-in-class medicines.34 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.35 Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through **enhanced clinical efficacy** (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, **or better treatment** for some individuals who don’t respond well to the original drug) and by generating competition that exerts downward price pressures. For example, a patient needing a cholesterol drug has a host of statins from which to choose, which is important because some statins produce harmful side effects for some patients. Similarly, patients with osteoporosis can choose from Actonel, Boniva, or Fosomax. Or take for example Hepatitis C, which until recently was an incurable disease eventually requiring a liver transplant for many patients. In 2013, a revolutionary new treatment called Solvadi was released that boosted cure rates to 90 percent. This was followed in 2014 by an improved treatment called Harvoni, which cures the Hepatitis C variant left untouched by Solvadi. Since then, an astonishing six new treatments for the disease have received FDA approval, opening up a wide range of treatment options that take into account patients’ liver and kidney status, co-infections, potential drug interactions, previous treatment failures, and the genotype of HCV virus.36 “If you have to have Hepatitis C, now is the time to have it,” as Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York, told the Financial Times. “We have these marvellous drugs we can treat you with right now, without side effects,” he added. “And this time next year, we’ll have another round of drugs available.”37 Moreover, the financial potential of this new product category has led to multiple competing products entering the market in quick succession, in turn placing downward pressure on prices.38 As Geoffrey Dusheiko and Charles Gore write in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”39 As noted previously, opponents of the current market- and IP-based system contend patents enable their holders to exploit a (temporary) market monopoly by inflating prices many multiples beyond the marginal cost of production. But rather than a conventional neoclassical analysis, an analysis based on “innovation economics” finds it is exactly this “distortion” that is required for innovation to progress. As William Baumol has pointed out, “Prices above marginal costs and price discrimination become the norm rather than the exception because … without such deviations from behaviour in the perfectly competitive model, innovation outlays and other unavoidable and repeated sunk outlays cannot be recouped.”40 Or, as the U.S. Congressional Office of Technology Assessment found, “Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary **to induce companies to invest** in researching new chemical entities.”41 This is also why, in 2018, the U.S. Congressional Budget Office estimated that because of high failure rates, biopharmaceutical **companies would need to earn a 61.8 percent rate of return on their successful new drug R&D projects in order to match a 4.8 percent after-tax rate of return on their investment**s.42 Indeed, **it’s the ability to recoup fixed costs, not just marginal** costs, through mechanisms such as patent protection that lies at the heart of all innovation-based industries and indeed all innovation and related economic progress. If companies could not find a way to pay for their R&D costs, and could only charge for the costs of producing the compound, **there would be no new drugs developed**, just as there would be no new products developed in any industry. Innovating in the life sciences remains expensive, risky, difficult, and uncertain. Just 1 in 5,000 drug candidates make it all the way from discovery to market.43 A 2018 study by the Deloitte Center for Health Solutions, “Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018,” found that “the average cost to develop an asset [an innovative life-sciences drug] including the cost of failure, has increased in six out of eight years,” and that the average cost to create a new drug has risen to $2.8 billion.44 Related research has found the development of new drugs requires years of painstaking, risky, and expensive research that, for a new pharmaceutical compound, takes an average of 11.5 to 15 years of research, development, and clinical trials, at a cost of $1.7 billion to $**3.2 billion**.45 IP rights—including patents, copyrights, and data exclusivity protections—give innovators, whether in the life sciences or other sectors, the **confidence** to undertake the risky and expensive process of innovation, secure in the knowledge they’ll be able to capture a share of the gains from their efforts. And these gains are often only a small fraction of the true value created. For instance, Yale University economist William Nordhaus estimated inventors capture just 4 percent of the total social gains from their innovations; the rest spill over to other companies and society as a whole.46 Without adequate IP protection, private investors would never find it viable to fund advanced research because lower-cost copiers would be in a position to undercut the legitimate prices (and profits) of innovators, even while still generating substantial profits on their own.47 As the report “Wealth, Health and International Trade in the 21st Century” concludes, “Conferring robust intellectual property rights is, in the pharmaceutical and other technological-development contexts, **in the global public’s long-term interests.** Without adequate mechanisms for directly and indirectly securing the private and public funding of medicines and vaccines, research and development communities across the world will lose future benefits that would far outweigh the development costs involved.”48 Put simply, the current market- and IP-based life-sciences innovation system is producing life-changing biomedical innovation. As Jack Scannell, a senior fellow at Oxford University’s Center for the Advancement of Sustainable Medical Innovation has explained, “I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995.” He continued, “Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good.”49 For example, on September 14, 2017, the FDA approved Mvasi, the first biosimilar for Roche’s Avastin, a breakthrough anticancer drug when it came out in the mid-1990s for lung, cervical, and colorectal cancer.50 In other words, a medicine to treat forms of cancer that barely existed 20 years ago is now available as a generic drug today. It’s this dynamic that enables us to imagine a situation wherein drugs to treat diseases that aren’t available anywhere at any price today (for instance, treatments for Alzheimer’s or Parkinson’s) might be available as generics in 20 years. But that will only be the case if we preserve (and improve where possible) a life-sciences innovation system that is generally working. The current system does not require wholesale replacement by a prize-based system that—notwithstanding a meaningful success here or there—has produced nowhere near a similar level of novel biomedical innovation.

#### **Reducing IP protections chills future investment – even the perception of wavering commitment scares off companies.**

Grabowski et al. ’15 (Harry; Professor Emeritus of Economics at Duke, and a specialist in the intersection of the pharmaceutical industry and government regulation of business; February 2015; “The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation”; Health Affairs; <https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047>; Accessed: 8-31-2021; AU)

Patents and other forms of **intellectual property** **protection** play **essential roles** in encouraging innovation in biopharmaceuticals. As part of the “21st Century Cures” initiative, Congress is reviewing the policy mechanisms designed to accelerate the discovery, development, and delivery of new treatments. Debate continues about how best to balance patent and intellectual property incentives to encourage innovation, on the one hand, and generic utilization and price competition, on the other hand. We review the current framework for accomplishing these dual objectives and the important role of patents and regulatory exclusivity (together, the patent-based system), given the lengthy, costly, and risky biopharmaceutical research and development process. We summarize existing targeted incentives, such as for orphan drugs and neglected diseases, and we consider the pros and cons of proposed voluntary or mandatory alternatives to the patent-based system, such as prizes and government research and development contracting. We conclude that patents and regulatory exclusivity provisions are likely to remain the core approach to providing incentives for biopharmaceutical research and development. However, prizes and other voluntary supplements could play a useful role in addressing unmet needs and gaps in specific circumstances. Technological innovation is widely recognized as a key determinant of economic and public health progress. 1,2 Patents and other forms of intellectual property protection are generally thought to play essential roles in encouraging innovation in biopharmaceuticals. This is because the process of developing a new drug and bringing it to market is **long, costly, and risky**, and the costs of imitation are low. After a new drug has been approved and is being marketed, its **patents protect it** from competition from chemically identical entrants (or entrants infringing on other patents) for a period of time. **For firms** to have an **incentive** to **continue to invest** in innovative development efforts, they must have an **expectation** that they can **charge enough** during this period to **recoup** costs and make a profit. After a drug’s patent or patents expire, **generic rivals** can enter the market at **greatly reduced development cost** and prices, providing added consumer benefit but **eroding** the **innovator drug** company’s revenues. The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) was designed to balance innovation incentives and generic price competition for new drugs (generally small-molecule chemical drugs, with some large-molecule biologic exceptions) by extending the period of a drug’s marketing exclusivity while providing a regulatory framework for generic drug approval. This framework was later changed to encompass so-called biosimilars for large-molecule (biologic) drugs through the separate Biologics Price Competition and Innovation Act of 2009. Other measures have been enacted to provide research and development (R&D) incentives for antibiotics and drugs to treat orphan diseases and neglected tropical diseases. Discussion continues about whether current innovation incentives are optimal or even adequate, given evolving public health needs and scientific knowledge. For instance, the House Energy and Commerce Committee recently embarked on the “21st Century Cures” initiative, 3 following earlier recommendations by the President’s Council of Advisors on Science and Technology on responding to challenges in “propelling innovation in drug discovery, development, and evaluation.” 4 In this context, we discuss the importance of patents and other forms of intellectual property protection to biopharmaceutical innovation, given the unique economic characteristics of drug research and development. We also review the R&D incentives that complement patents in certain circumstances. Finally, we consider the pros and cons of selected voluntary (“opt-in”) or mandatory alternatives to the current patent- and regulatory exclusivity–based system (such as prizes or government-contracted drug development) and whether they could better achieve the dual goals of innovation incentives and price competition. The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term. Several economic characteristics make patents and intellectual property protection **particularly important** to **innovation incentives** for the biopharmaceutical industry. 5 The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a **billion** dollars in out-of-pocket costs. 6 Only approximately one in eight drug candidates survive clinical testing. 6 As a result of the high risks of failure and the high costs, research and development must be funded by the **few successful, on-market products** (the top quintile of marketed products provide the dominant share of R&D returns). 7,8 Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. **Absent intellectual property protections** that allow marketing exclusivity, innovative firms would be **unlikely** to make the costly and risky investments needed to bring a new drug to market. Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, **they do not guarantee demand**, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents. New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment. Patents play an **essential role** in the economic “ecosystem” of **discovery and investment** that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. 11 The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the **strength of intellectual property protection** plays a **key role** in funding and partnership opportunities for such firms. Universities also play a key role in the R&D ecosystem because they conduct basic biomedical research supported by sponsored research grants from the National Institutes of Health (NIH) and the National Science Foundation (NSF). The Patent and Trademark Law Amendments Act of 1980 (commonly known as the Bayh-Dole Act) gave universities the right to retain title to patents and discoveries made through federally funded research. This change was designed to encourage technology transfer through industry licensing and the creation of start-up companies. Universities received only 390 patents for their discoveries in 1980, 12 compared to 4,296 in 2011, with biotechnology and pharmaceuticals being the top two technology areas (accounting for 36 percent of all university patent awards in 2012). 13

#### Data exclusivity is key to prevent freerider production of new biologics which is necessary for innovation.

Gangil, J, et al 10. “Do Intellectual Property Rights and Data Exclusivity Encourage Innovation in the Pharmaceutical World?” Systematic Reviews in Pharmacy, vol. 1, no. 2, 22 Dec. 2010, p. 190., doi:10.4103/0975-8453.75088. //sid

The purpose of data exclusivity is to ensure that the initial registrants of a new drug can recover the costs of testing the drug for efficacy and safety. Extensive testing directly translates into considerable costs for generating the data necessary to obtain approval of each new active ingredient. Drug developers challenge that they cannot afford to bring drugs to market without data exclusivity because later registrants, who did not have to invest in the high cost of obtaining marketing approval, can free-ride on the initial registrant’s approval and sell the same or similar drug at a lower price.[7] Experts argue that data exclusivity offers benefits to domestic innovators in developing countries and, in particular, that it provides incentives for research to identify new uses for the existing unpatented product. Data exclusivity is likely to have the largest effect in countries where for historical or other reasons there are many products with no current patent protection that may gain rights to exclusivity. Today in many developing countries, there are numerous medicines that are not patented. This is often the case in developing countries where TRIPS-based laws have only recently been introduced. In addition, even where there are patent laws, companies may not have considered the market sufficiently valuable to justify the expense and administrative cost of securing patents. In that case, the introduction of data exclusivity laws may bring into exclusivity drugs that would otherwise be open to generic competition. The perceived absence of strong patent protection in India, even after the law was revised in 2005, and the presence of a large number of products without patent protection due to the absence of product patent protection before 2005, is a major reason why the international pharmaceutical industry lobbied very hard for a strong data exclusivity regime in India. In contrast, Indian companies focusing principally on generics argued for a weaker data protection regime.[8] In certain cases it is observed that “data exclusivity” helps innovator companies to recover investments made on discovering and developing a new drug; for example, according to a published article, Aventis’s innovative drug Leflunomide for rheumatoid arthritis took 17 years from discovery to commercialization.[9] Data Exclusivity Plays a Key Role for Biologics New Economics Research supports 13–16 years of data exclusivity for biologics. A new working paper by Duke University economist Dr. Henry Grabowski, “Data Exclusivity for New Biological Entities,” identifies 12.9–16.2 years or about 13–16 years of data exclusivity as necessary to sustain investment in the research and development (R and D) of new biologics in any approach to creating an abbreviated pathway for follow-on biologics (FOBs). The Duke University working paper states that without sufficient data exclusivity, there would be little incentive to develop and market new biologics with uncertain or few remaining years of patent protection. Under this scenario, innovators would be less likely to pursue the development of a molecule if there were uncertainty regarding the possibility of recouping their investments and achieving a positive return.[10]

#### Data exclusivity ­does not prevent competitive products.

GaBi Online 11 “Data Exclusivity Is Not the Same as Market Exclusivity.” GaBi Online, 26 Jan. 2011, www.gabionline.net/policies-legislation/Data-exclusivity-is-not-the-same-as-market-exclusivity. //sid

Furthermore, Mr Quinn states that it is fiction that 12 years of data exclusivity would extend innovators’ monopoly power. “Data exclusivity does not give it any sort of monopoly”, he writes. “You would be hard pressed to find a term that is used more and understood less than the term ‘monopoly’. “Patents don’t give monopolies, and neither would data exclusivity. If patents gave monopolies then how is it possible that anyone other than Apple could sell a portable MP3 player? Apple has the iPod and iPhone locked up tight, but not so tight that other companies are prohibited from selling similar products. Look at all the iPhone wanna-bes that are on the market now. Seriously! You have to stop thinking that patents grant monopolies. What they do is make it difficult for others to copy an innovation, but if you can make something that does the same thing that isn’t a copy, then patent law does not prevent that”. He explains that similarly, products that compete with innovative biologicals can still be introduced during the period of data exclusivity. A period of data exclusivity merely means that those who do not innovate cannot piggyback off the hard work of innovators and rely on the research conducted by the innovator company. They must conduct their own safety and efficacy research and testing to obtain FDA approval and, obviously, not infringe the patents owned by the innovator. “So can we please stop using the world ‘monopoly’? No matter how many times it is used it will never accurately describe the protections provided. If you doubt that do a patent search and you will see in every industry numerous patents that all purport to cover similar things. How else, for example, could Microsoft and Apple both have patent portfolios? How else could Motorola and Nokia have patent portfolios? How else could AMD and IBM have patent portfolios? And so on” Mr Quinn states. (see also [Minimal 12 years of biologicals data exclusivity required](http://www.gabionline.net/Biosimilars/News/Minimal-12-years-of-biologicals-data-exclusivity-required), [12 years exclusivity workable for patients; not anticompetitive](http://www.gabionline.net/Generics/General/12-years-exclusivity-workable-for-patients-not-anticompetitive) and [Innovative biologicals development must be preserved](http://www.gabionline.net/Pharma-News/Innovative-biologicals-development-must-be-preserved))

#### 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.

#### 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.

#### Otherwise, 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.

#### Non-Unique – Health diplomacy is non-unique – COVID proves that Export Bans and Nationalism thump.

Vijay 21 Svĕt Lustig Vijay 2-22-2021 "Global Health Diplomacy In The COVID-19 Era – Can Failure Usher In A New Era of Success?" <https://healthpolicy-watch.news/global-health-diplomacy-in-the-covid-19-era-can-failure-usher-in-a-new-era-of-success/> (Reporter for Health Policy Watch)//Elmer

**More than a year into the world’s largest global health emergency**, **health diplomats** have **fought hard to** **ensure** that every country across the globe secures **access to** lifesaving coronavirus **health products**, including vaccines, treatments, and diagnostics. **That has not happened** yet, given that **80% of countries** that are now **rolling out vaccines are** either **high-income or upper middle-income countries**. **Export bans** on essential health products **in 80 countries**, ranging from personal protective equipment to ventilators, **have not helped** either. And in the absence of clear global guidance, up to 130 countries have imposed an uneven patchwork of travel restrictions in an attempt to keep more contagious variants at bay – mostly to no avail.

#### Alt cause to pandemics —billions of livestock use more antibiotics than humans

#### Your Farrah evidence just says that non adherence causes death not extinction

#### No evidence post-plan innovations are aimed at AMR or quick enough to solve

#### Disease doesn’t cause extinction

Adalja 16 [Amesh Adalja is an infectious-disease physician at the University of Pittsburgh. Why Hasn't Disease Wiped out the Human Race? June 17, 2016. https://www.theatlantic.com/health/archive/2016/06/infectious-diseases-extinction/487514/]

But when people ask me if I’m worried about infectious diseases, they’re often not asking about the threat to human lives; they’re asking about the threat to human life. With each outbreak of a headline-grabbing emerging infectious disease comes a fear of extinction itself. The fear envisions a large proportion of humans succumbing to infection, leaving no survivors or so few that the species can’t be sustained.

I’m not afraid of this apocalyptic scenario, but I do understand the impulse. Worry about the end is a quintessentially human trait. Thankfully, so is our resilience.

For most of mankind’s history, infectious diseases were the existential threat to humanity—and for good reason. They were quite successful at killing people: The 6th century’s Plague of Justinian knocked out an estimated 17 percent of the world’s population; the 14th century Black Death decimated a third of Europe; the 1918 influenza pandemic killed 5 percent of the world; malaria is estimated to have killed half of all humans who have ever lived.

Any yet, of course, humanity continued to flourish. Our species’ recent explosion in lifespan is almost exclusively the result of the control of infectious diseases through sanitation, vaccination, and antimicrobial therapies. Only in the modern era, in which many infectious diseases have been tamed in the industrial world, do people have the luxury of death from cancer, heart disease, or stroke in the 8th decade of life. Childhoods are free from watching siblings and friends die from outbreaks of typhoid, scarlet fever, smallpox, measles, and the like.

So what would it take for a disease to wipe out humanity now?

In Michael Crichton’s The Andromeda Strain, the canonical book in the disease-outbreak genre, an alien microbe threatens the human race with extinction, and humanity’s best minds are marshaled to combat the enemy organism. Fortunately, outside of fiction, there’s no reason to expect alien pathogens to wage war on the human race any time soon, and my analysis suggests that any real-life domestic microbe reaching an extinction level of threat probably is just as unlikely.

Any apocalyptic pathogen would need to possess a very special combination of two attributes. First, it would have to be so unfamiliar that no existing therapy or vaccine could be applied to it. Second, it would need to have a high and surreptitious transmissibility before symptoms occur. The first is essential because any microbe from a known class of pathogens would, by definition, have family members that could serve as models for containment and countermeasures. The second would allow the hypothetical disease to spread without being detected by even the most astute clinicians.

The three infectious diseases most likely to be considered extinction-level threats in the world today—influenza, HIV, and Ebola—don’t meet these two requirements. Influenza, for instance, despite its well-established ability to kill on a large scale, its contagiousness, and its unrivaled ability to shift and drift away from our vaccines, is still what I would call a “known unknown.” While there are many mysteries about how new flu strains emerge, from at least the time of Hippocrates, humans have been attuned to its risk. And in the modern era, a full-fledged industry of influenza preparedness exists, with effective vaccine strategies and antiviral therapies.

HIV, which has killed 39 million people over several decades, is similarly limited due to several factors. Most importantly, HIV’s dependency on blood and body fluid for transmission (similar to Ebola) requires intimate human-to-human contact, which limits contagion. Highly potent antiviral therapy allows most people to live normally with the disease, and a substantial group of the population has genetic mutations that render them impervious to infection in the first place. Lastly, simple prevention strategies such as needle exchange for injection drug users and barrier contraceptives—when available—can curtail transmission risk.

Ebola, for many of the same reasons as HIV as well as several others, also falls short of the mark. This is especially due to the fact that it spreads almost exclusively through people with easily recognizable symptoms, plus the taming of its once unfathomable 90 percent mortality rate by simple supportive care.

Beyond those three, every other known disease falls short of what seems required to wipe out humans—which is, of course, why we’re still here. And it’s not that diseases are ineffective. On the contrary, diseases’ failure to knock us out is a testament to just how resilient humans are. Part of our evolutionary heritage is our immune system, one of the most complex on the planet, even without the benefit of vaccines or the helping hand of antimicrobial drugs. This system, when viewed at a species level, can adapt to almost any enemy imaginable. Coupled to genetic variations amongst humans—which open up the possibility for a range of advantages, from imperviousness to infection to a tendency for mild symptoms—this adaptability ensures that almost any infectious disease onslaught will leave a large proportion of the population alive to rebuild, in contrast to the fictional Hollywood versions.

#### No extinction from pandemics

* Death rates as high as 50% didn’t collapse civilization
* Fossil fuel record caps risk at .1% per century
* health, sanitation, medicine, science, public health bodies, solve
* viruses can’t survive in all locations
* refugee populations like tribes, remote researchers, submarine crews, solve

Ord 20 Ord, Toby. Toby David Godfrey Ord (born 18 July 1979) is an Australian philosopher. He founded Giving What We Can, an international society whose members pledge to donate at least 10% of their income to effective charities and is a key figure in the effective altruism movement, which promotes using reason and evidence to help the lives of others as much as possible.[3] He is a Senior Research Fellow at the University of Oxford's Future of Humanity Institute, where his work is focused on existential risk. BA in Phil and Comp Sci from Melbourne, BPhil in Phil from Oxford, PhD in Phil from Oxford. The precipice: existential risk and the future of humanity. Hachette Books, 2020.

Are we safe now from events like this? Or are we more vulnerable? Could a pandemic threaten humanity’s future?10 The Black Death was not the only biological disaster to scar human history. It was not even the only great bubonic plague. In 541 CE the Plague of Justinian struck the Byzantine Empire. Over three years it took the lives of roughly 3 percent of the world’s people.11 When Europeans reached the Americas in 1492, the two populations exposed each other to completely novel diseases. Over thousands of years each population had built up resistance to their own set of diseases, but were extremely susceptible to the others. The American peoples got by far the worse end of exchange, through diseases such as measles, influenza and especially smallpox. During the next hundred years a combination of invasion and disease took an immense toll—one whose scale may never be known, due to great uncertainty about the size of the pre-existing population. We can’t rule out the loss of more than 90 percent of the population of the Americas during that century, though the number could also be much lower.12 And it is very difficult to tease out how much of this should be attributed to war and occupation, rather than disease. As a rough upper bound, the Columbian exchange may have killed as many as 10 percent of the world’s people.13 Centuries later, the world had become so interconnected that a truly global pandemic was possible. Near the end of the First World War, a devastating strain of influenza (known as the 1918 flu or Spanish Flu) spread to six continents, and even remote Pacific islands. At least a third of the world’s population were infected and 3 to 6 percent were killed.14 This death toll outstripped that of the First World War, and possibly both World Wars combined. Yet even events like these fall short of being a threat to humanity’s longterm potential.15 In the great bubonic plagues we saw civilization in the affected areas falter, but recover. The regional 25 to 50 percent death rate was not enough to precipitate a continent-wide collapse of civilization. It changed the relative fortunes of empires, and may have altered the course of history substantially, but if anything, it gives us reason to believe that human civilization is likely to make it through future events with similar death rates, even if they were global in scale. The 1918 flu pandemic was remarkable in having very little apparent effect on the world’s development despite its global reach. It looks like it was lost in the wake of the First World War, which despite a smaller death toll, seems to have had a much larger effect on the course of history.16 It is less clear what lesson to draw from the Columbian exchange due to our lack of good records and its mix of causes. Pandemics were clearly a part of what led to a regional collapse of civilization, but we don’t know whether this would have occurred had it not been for the accompanying violence and imperial rule. The strongest case against existential risk from natural pandemics is the fossil record argument from Chapter 3. Extinction risk from natural causes above 0.1 percent per century is incompatible with the evidence of how long humanity and similar species have lasted. But this argument only works where the risk to humanity now is similar or lower than the longterm levels. For most risks this is clearly true, but not for pandemics. We have done many things to exacerbate the risk: some that could make pandemics more likely to occur, and some that could increase their damage. Thus even “natural” pandemics should be seen as a partly anthropogenic risk. Our population now is a thousand times greater than over most of human history, so there are vastly more opportunities for new human diseases to originate.17 And our farming practices have created vast numbers of animals living in unhealthy conditions within close proximity to humans. This increases the risk, as many major diseases originate in animals before crossing over to humans. Examples include HIV (chimpanzees), Ebola (bats), SARS (probably bats) and influenza (usually pigs or birds).18 Evidence suggests that diseases are crossing over into human populations from animals at an increasing rate.19 Modern civilization may also make it much easier for a pandemic to spread. The higher density of people living together in cities increases the number of people each of us may infect. Rapid long-distance transport greatly increases the distance pathogens can spread, reducing the degrees of separation between any two people. Moreover, we are no longer divided into isolated populations as we were for most of the last 10,000 years.20 Together these effects suggest that we might expect more new pandemics, for them to spread more quickly, and to reach a higher percentage of the world’s people. But we have also changed the world in ways that offer protection. We have a healthier population; improved sanitation and hygiene; preventative and curative medicine; and a scientific understanding of disease. Perhaps most importantly, we have public health bodies to facilitate global communication and coordination in the face of new outbreaks. We have seen the benefits of this protection through the dramatic decline of endemic infectious disease over the last century (though we can’t be sure pandemics will obey the same trend). Finally, we have spread to a range of locations and environments unprecedented for any mammalian species. This offers special protection from extinction events, because it requires the pathogen to be able to flourish in a vast range of environments and to reach exceptionally isolated populations such as uncontacted tribes, Antarctic researchers and nuclear submarine crews. 21 It is hard to know whether these combined effects have increased or decreased the existential risk from pandemics. This uncertainty is ultimately bad news: we were previously sitting on a powerful argument that the risk was tiny; now we are not. But note that we are not merely interested in the direction of the change, but also in the size of the change. If we take the fossil record as evidence that the risk was less than one in 2,000 per century, then to reach 1 percent per century the pandemic risk would need to be at least 20 times larger. This seems unlikely. In my view, the fossil record still provides a strong case against there being a high extinction risk from “natural” pandemics. So most of the remaining existential risk would come from the threat of permanent collapse: a pandemic severe enough to collapse civilization globally, combined with civilization turning out to be hard to re-establish or bad luck in our attempts to do so.

#### Tech capabilities prevent DIY biotech

**Jefferson et al 14** [Catherine Jefferson, Filippa Lentzos, and Claire Marris, Department of Social Science, Health and Medicine, King’s College London, London, UK 8-21-2014, accessed on 9-11-2021, Frontiers, "Synthetic Biology and Biosecurity: Challenging the “Myths”" <https://www.frontiersin.org/articles/10.3389/fpubh.2014.00115/full>] Adam

These concerns are based on the assumption that synthetic biology already has made it, or shortly will make it, easy for anybody to “engineer biology.” The underlying vision is one where well-characterized biological “parts” can be easily obtained from open-source online registries and then easily assembled, by people with no specialist training and working outside professional scientific institutions, into genetic “circuits,” “devices,” and “systems” that will reliably perform desired functions in live organisms ([1](https://www.frontiersin.org/articles/10.3389/fpubh.2014.00115/full#B1), [2](https://www.frontiersin.org/articles/10.3389/fpubh.2014.00115/full#B2)). However, this does not even reflect current realities in academic or commercial science laboratories, where researchers are still struggling with every stage of this process ([19](https://www.frontiersin.org/articles/10.3389/fpubh.2014.00115/full#B19), [20](https://www.frontiersin.org/articles/10.3389/fpubh.2014.00115/full#B20)).

Moreover, synthetic biologists who participated in our recent workshop ([11](https://www.frontiersin.org/articles/10.3389/fpubh.2014.00115/full#B11)) argued that although historical experience with other forms of (non-biological) engineering demonstrate that dependence on the craft skills of a small number of highly trained individuals is reduced for some parts of the production process, usually by standardization and mechanization, this does not mean that skills become irrelevant or that all aspects of the work become easier. Specialized expertise, teamwork, large infrastructures, complicated machinery, advanced technology, trouble-shooting, and organizational factors continue to be required when a design and engineering approach develops. Thus, even though the engineering approach of synthetic biology aims to make processes more systematic and more reproducible, this will not make it easier for anybody to engineer biology. Indeed, some aspects of the work may become more complex, and new skills may be required.

#### Synthetic Vaccines solve.

**Jain 12** [Kewal K. Jain, Consultant in biotechnology and pharmaceutical medicine. Research in cell/gene therapy, neuroprotection, and nanobiotechnology. Reviewer, research grant applications for government agencies in Canada, USA (US Army) and Europe (European Commission, the Netherlands, Austria, Finland, Estonia and UK). Chairman of the Scientific Advisory Board, Genometrica Ltd, Lugano, Switzerland. Member of Board of Managers of Progenitor Cell Therapy 2006-2010, until takeover of the company by NeoStem Inc. Member Editorial Board, Nanomedicine, published by Future Medicine. Member Editorial Board, Technology in Cancer Research and Treatment, Adenine Press. Member International Advisory Board, Medical Principles & Practice, Karger. Consultant in Neurology Senior Associate editor, MedLink Corporation, San Diego, California. 08-16-2012, accessed on 9-11-2021, PubMed Central (PMC), "Synthetic Biology and Personalized Medicine", <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5586729/>] Adam

Conventional vaccine strategies mainly focus on live-attenuated vaccines, inactivated microorganisms, and subunits thereof comprising purified components or recombinant proteins formulated with adjuvants. The development of new vaccines is limited by several drawbacks, including risks associated with the use of attenuated pathogens, along with difficulties altering vaccine target specificity. Synthetic biology-based vaccines aim to overcome some of these drawbacks and enable economic and rapid chemical synthesis of DNA encoding the immunogens designed in silico as well as their efficient assembly with delivery systems to obtain vectored vaccines [[30](https://www.karger.com/Article/Fulltext/341794#ref30)]. Altogether, synthetic biology can help develop improved vaccine candidates in considerably less time compared to conventional approaches. Some examples are given in the following sections.

Peptide Nanoparticle-Based Vaccines

A biocompatible as well as biodegradable nanoparticle has been designed by computer modeling, which self-assembles from single polypeptide chains to produce a structure with isohedral symmetry and a diameter of ∼16 nm [[31](https://www.karger.com/Article/Fulltext/341794#ref31)]. These peptide nanoparticles are multifunctional with high binding affinity and specificity. They can be customized to a high functional density. This platform was used to design and produce a prototypic malaria vaccine that can repetitively display a tandem repeat of the B cell immunodominant repeat epitope of the circumsporozoite protein of rodent malaria parasite Plasmodium berghei [[32](https://www.karger.com/Article/Fulltext/341794#ref32)]. Administered without an adjuvant, this vaccine conferred a long-lasting antibody response against B cell epitope and protected mice against malarial parasite for up to 6 months.

Liposome-Based Synthetic Vaccines

The use of liposomes has been proposed as artificial microbes for vaccination as they can be genetically programmed to produce specific antigens at will [[33](https://www.karger.com/Article/Fulltext/341794#ref33)]. Studies in mice with such vaccines showed that antigen-expressing immunostimulatory liposomes (AnExILs) elicited higher specific humoral immune responses against the produced antigens than control vaccines. AnExILs can be used as a synthetic biology platform to construct DNA-based vaccines, which combines antigen production, adjuvants and delivery in one system, offering several advantages over existing vaccine formulations. This system can be easily altered for other antigens by simply changing the DNA template and carries no risk of infection by attenuated pathogens.

Reverse Vaccines against Microbial Pathogens

Availability of complete genome sequences, high throughput technologies and synthetic biology has enabled reverse vaccinology (RV). Availability of sequence data from different specimens of the same species of a pathogen provides an opportunity to select novel vaccine candidates. Thus the empiric approach to vaccine development is being replaced by vaccine design. The RV approach is one of the most powerful examples of biotechnology applied to the field of vaccinology for identifying new protein-based vaccines.

RV combines the availability of genomic data, the analyzing capabilities of new bioinformatic tools and the application of high throughput expression. Purification systems can be combined with serological screening assays for a coordinated screening process of the entire genomic repertoire of bacterial, viral or parasitic pathogens. The application of RV to Neisseria meningitidis serogroup B represents the first success of this novel approach. This approach can be easily applied to any pathogen [[34](https://www.karger.com/Article/Fulltext/341794#ref34)].

#### Low prices independently cause AMR.

Babu and Suma 6 Babu, Varsha, and C. Suma. "Antibiotic pricing: when cheaper may not be better." Clinical infectious diseases 43.8 (2006): 1085-1086. (Government Primary Health Center)//Elmer

To The Editor—Antibiotics in India have always been cheaper in absolute terms thanks to weak patent laws that have been in effect until recently. Because a direct translation of drug prices from US dollars to Indian rupees (INR) would have rendered most new antibiotics inaccessible to the vast majority of Indians, such patent violations were subtly encouraged. Even despite this, we were caught unaware when pharmaceutical representatives approached our primary care center in rural India, claiming that a 5-day course of levofloxacin would henceforth cost the patient ∼INR 20 (<$0.50). Reluctant to accept such a statement at face value, we consulted the CIMS Updated Prescriber's Handbook [1], a popular index of pharmaceutical drugs available in India. Here, we discovered that a 5-day course of oral levofloxacin (500 mg once daily) cost anywhere from INR 19.5 to INR 475 ($0.50–$10.50), with most companies pricing their brand at <$1 for a full course. The same course in the United States would cost >$100. Intrigued, we did some more research and came up with the following results. The cheapest 5-day courses of first-line antibiotics, such as oral amoxicillin (500 mg thrice daily) or oral erythromycin (500 mg 4 times daily), cost INR 45 ($1) and INR 90 ($2), respectively. On the other hand, the cost of a 3-day course of oral azithromycin (500 mg daily) was one-half that of a course of erythromycin. Despite the obvious price advantage to the patients, we find this trend troubling. **Lower prices** often **lead to wider prescription of a given drug**, especially in resource-limited settings. **If** second-line **antibiotics**—such as levofloxacin and azithromycin—**are made available at lower prices** than first-line antibiotics, **there is a high probability of their overuse and subsequent development of resistance**. In the face of **very low costs of medication**, patients are unlikely to complain of escalating medical expenses. The issue assumes more gravity when one considers the fact that levofloxacin is an important second-line drug for the treatment of tuberculosis [2]. Its widespread use in the community **is likely to lead to emergence of resistance** **among** **mycobacteria** **and** delayed diagnosis of **tuberculosis** [3]—an occurrence that India, with its large population of tuberculosis-affected patients, cannot afford. We believe we have encountered a situation where **low prices of antibiotics are likely to cause more harm than good**. In the post World Trade Organization treaty scenario, governments in resource-limited countries should use their privileges of essential drug control to ensure that the costs of first-line antibiotics remain lower than those of second-line drugs. Such a government-instituted ladder in antibiotic pricing is essential to prevent the misuse of antibiotics in the community and to ensure that antibiotic resistance is kept at low levels.