# 1N

## 1

#### Interpretation: Debaters may not specify which intellectual property or group of properties they reduce in the 1AC.

#### There were over 100,000 medical patents in 2018

WIPO ‘20

WIPO (2020). World Intellectual Property Indicators 2020. Geneva: World Intellectual Property Organization <https://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2020.pdf> // Phoenix – brackets for clarity

In 2018 – the latest year for which complete data are available due to the delay between application and publication – computer technology was the most frequently featured technology in published patent applications worldwide, with 234,667 published applications (table A29). It was followed by electrical machinery (215,828), measurement (164,255), [for] medical technology [were] (147,542) and digital communication (146,416). Together, these five fields accounted for 28.4% of all published applications globally.

#### Violation: they did

#### Standards:

#### 1] Limits – *It would literally make a case list of over 100,000* which is obviously impossible to prep for even if we had a giant coaching squad who can cut 10 case negs a day *it wouldn’t even be 1% of the case list.*

#### a) Limits outweighs – it controls the balance of prep which controls the rest of the debate since one debater could be worse than another but win on brute force of more and better cards.

#### 2] Ground – We lose all of our offense that links into general property rights or certain types of patents i.e if we read a DA to vaccines and you read a N95 aff we wouldn’t link. It also means even if we did link it would be tiny and the 1AR would always be ahead since they could leverage the specificity of the aff.

#### 3] Topic Education – Authors do not write about specific patents since there is way too many – definitely not 100,000 authors writing about Intellectual property rights – and even if there were that would mean one author per every aff creating a tiny and narrow debate.

#### a) Topic education outweighs on Timeframe since we only get 2 months to debate about the topic

#### Paradigm issues

#### 1 – Drop the debater – their abusive advocacy skewed the debate from the start and we can’t come back

#### 2 - Comes before 1AR theory — A - If we had to be abusive it’s because it was impossible to engage their aff, B – Neg abuse outweighs aff abuse because we control the depth of the debate if we can’t engage depth is impossible

#### 3 - Use competing interps on Spec – A – spec is a yes/no question, you can’t be half specify or mostly specify B - reasonability invites arbitrary judge intervention and a race to the bottom of questionable argumentation

#### 4 - No RVIs – A - Forcing the 1NC to go all in on the shell kills substance education and neg strat, B - discourages checking real abuse C - Encourages baiting – outweighs because if the shell is frivolous, they can beat it quick

## 2

#### The COVID epidemic has exposed massive flaws in biosecurity, lack of public health compliance, anti-vaxxers, and PPE shortages have shown unique vulnerabilities – the US is specifically exposed

Lyon 21 (Regan Lyon; 7/1/21; Military Medicine, Volume 186, Issue7-8, July-August 2021, Pages 193-196; *“The COVID-19 Response Has Uncovered and Increased Our Vulnerability to Biological Warfare”*; accessed 8/13/21; <https://academic.oup.com/milmed/article/186/7-8/193/6135020>; Department of Defense Analysis at the Naval Postgraduate School) HB \*We do not endorse the ableist language of the card\*

INTRODUCTION Biological warfare has been an unlikely, but serious, concern for military operations and national security. The 2018 National Biodefense Strategy (NBS) articulated a collaborative plan to prevent, detect, and respond to biological threats to the USA.1 The NBS highlights recent, isolated outbreaks of Systemic Acute Respiratory Syndrome (SARS), Ebola, and Zika viruses as warnings to nation states and justification for enhanced biological threat responses. Although these events are not considered deliberate threats, clandestine bioweapon programs and terrorist groups seeking such programs are known to exist and capitalize on such natural outbreaks.1 The NBS’s emphasis on prevention and response drives the requirement to enhance biological weapon deterrence and defense strategies to avert the employment of biological weapons on U.S. civilians or military personnel.1 The public health crisis that ensued with SARS-associated coronavirus-2 (SARS-CoV-2) has highlighted our nation’s bioweapon vulnerabilities on the international stage and has the potential for disastrous effects on national security. Previous questions regarding how the USA would respond to a large biological outbreak (or biological weapon) have now been answered for potential adversaries across the world. The ambiguity of both our capabilities and weaknesses, which provided deterrence to adversarial employment of biological weapons before the pandemic, no longer exists. This article will provide an overview on biological weapons and the concepts of deterrence and defense in the context of bioterrorism. Then, it will analyze how the national personal protective equipment (PPE) shortage, public resistance to public health measures, the anti-vaccination movement, and USNS (United States Navy Ship) Comfort deployment to New York City have increased our vulnerability to bioterror attack by impacting our deterrence and defense measures. Finally, it will offer recommendations to restore our bioterrorism security after the detrimental effects from the events unfolding in the USA. BIOLOGICAL WEAPONS REGULATIONS, DETERRENCE, AND DEFENSE Even though biological warfare is considered a “weapon of mass destruction” and is prohibited by a treaty drafted by the 1972 United Nations Biological Weapons Convention (BWC), not all adversaries adhere to these standards. Terrorist groups and covert operations have utilized biological weapons for small operations because the actors, by nature, are either non-eligible to ratify the treaty or would not do so if they could. Although there have been no intentional large-scale attacks, especially by adversarial nation states, this is not guaranteed to be the case in the future.2 The BWC does not prohibit ratified nations from having pathogens or toxins for peaceful purposes, such as the development of vaccines. After the natural outbreak of smallpox and its subsequent eradication accomplished by the World Health Organization in 1980, less virulent poxviruses have continued to be used in a variety of laboratories for research and development of vaccines for a variety of diseases.3 The original, more deadly strain of smallpox has been retained at two facilities in Russia and Atlanta.4 Because smallpox’s virology makes it an ideal biological weapon, the samples in Atlanta and Russia offer defense through researching countermeasures should an attack occur and simultaneously provide a repository from which a biological weapon can be acquired. “Deterrence” and “defense” are two concepts which are typically described in terms of nuclear warfare, but they can also be applied to national security from a biological attack.5 Deterrence is the ability to prevent an adversary from taking some action during peacetime.5 For biological warfare deterrence, vaccines and preventative medicine measures prevent susceptibility to a microbe. For a largely vaccinated and/or health-conscious population, the costs of production, storage, and dissemination of a bioweapon greatly outweighs the rare chance of the target contracting the disease. New Zealand’s robust public health measures, citizen compliance, and continued efforts to sustain a caseload under 20 since April is a strong deterrent for biological attack.6 Defense mechanisms decrease the effectiveness of the attack, putting a high cost-to-benefit burden on the adversary.5 A defense measure for bioterrorism would be an adequate medical treatment response to casualties of the bioweapon, decreasing mortality and the overall effectiveness of the weapon. COVID-19 PANDEMIC ANALYSIS The novel SARS-CoV-2 has several characteristics of an ideal biological weapon, including high transmission rate, long incubation period, airborne transmission, and significant morbidity/mortality.7 In fact, early in the pandemic, suspicion was cast that the virus was being developed as a biological weapon by a laboratory in Wuhan, China.8 Although these allegations have been deemed conspiracy theories as a result of misinformation operations, the resulting pandemic and the panicked public share similarities to a bioterror attack. The events occurring within the USA during the coronavirus disease 2019 (COVID-19) pandemic create a global narrative on how we respond to a biological crisis. The 2018 NBS emphasized the continued threat of biological weapons to national security and identified the need to deter and defend against bioterrorism acts.1 This section will analyze events in the USA during the pandemic, how they bolstered or negated our current bioterrorism deterrence or defense strategies, and offer areas for improvement to restore our bioterror security. Personal Protective Equipment Shortage The 2018 NBS mandates having a robust mobilization of PPE for frontline healthcare workers and an adequate communication plan on preventative health measures for the general public in the event of an attack.1 The ability to provide sufficient quantities of PPE for medical personnel is a vital defense tactic as it increases the efficiency of the healthcare system to treat casualties in response to a biological outbreak. Having the ability to mobilize these resources to hospitals strengthens bioterror deterrence by demonstrating to a potential adversary that a bioterror attack would have a limited effect on a population given the healthcare preparedness. As conflicting information was published across multiple media platforms from January to March, panic spread that the virus was more dangerous than originally believed. Citizens flooded stores in town and online, buying “essential items” in preparation for a lockdown. Items such as masks, gloves, and sanitizers were out of stock everywhere, including healthcare supply chains. More importantly, citizens heard N95 masks could prevent contracting the virus, suddenly increasing N95 demand.9 Demand exceeded supply quickly, and healthcare workers began complaining of the nation-wide shortage of appropriate PPE required to care for infected patients.10 The inability to acquire necessary PPE supplies due to crippled supply chains and general public hoarding caused a ripple effect within the healthcare system. As a result, hospitals began to institute resource conservation measures, attempting to extend the life of supplies intended for one-time use. These PPE conservation measures, however, were interpreted by some healthcare workers as putting their lives in jeopardy and instigated lobbying and campaigning for government involvement. News reports flourished of disgruntled healthcare workers who were at risk of infection due to a lack of PPE. Such reports of general public hoarding, inadequate PPE logistical chains, and inappropriate PPE conservation measures by hospitals demonstrate the USA’s poor public health response. The NBS calls for an extensive mobilization of adequate PPE in response to a biological outbreak to decrease the pathogen spread, minimize its effects, and improve our resiliency.1 The capability to decrease the pathogen’s effects increases an attacker’s “sunk costs” should they choose to release a biological weapon. An impaired, or presumably impaired, capability adversely affects our defense strategy. In addition, the decrease in cost-to-risk ratio impairs our deterrence measures by showing worsened biological denial. The rapid healthcare PPE disappearance secondary to pandemic panic demonstrated a critical vulnerability in one of the most important defense strategies for a bioterror attack. To improve our defense capability, our healthcare workers must have an adequate supply of PPE, which can be mobilized expeditiously. Bioweapons have a high transmission rate and are easily disseminated, which make airborne and droplet transmission favorable. Public health experts should retrospectively analyze the types and amounts of PPE utilized in areas highly impacted by SARS-CoV-2. With these data, models can be created to make recommendations for phase-based mobilization of PPE and to determine the size of stockpile needed for immediate release. Government agencies need to establish agreements with PPE manufacturers to prioritize production in declared biological emergencies. Anti-Vaccination Movements Non-compliance with recommended public health and protective measures, including vaccines, also cripples our nation’s biodefense. Public health measures such as social distancing, aggressive sanitation, and mask mandates are examples of defense tactics for the COVID-19 pandemic. The individualistic U.S. culture fueled widespread non-compliance with these measures and has had significant effect on our ability to “flatten the curve” compared to other countries.11 The preference for “freedom…without interference from the state” is present in 58% of U.S. citizens, compared to 30-38% of European countries.11 The USA’s inability to uniformly employ these measures and decrease the virus spread compared to other countries signals to adversaries a weakness in our defense to decrease the effects of a biological outbreak. Furthermore, the speculation and conspiracy theories surrounding COVID-19 vaccines suggest an inevitable resistance to receiving the vaccine when available. Resistance to vaccinations is nothing new and caused challenges for vaccination against smallpox in the 19th-century U.K. epidemic.12 Then in 2019, the U.S. measles outbreak was amplified by anti-vaxxer campaigns.13 Since early in the COVID-19 pandemic, social media posts have warned that future coronavirus vaccines contain either tracking devices for the U.S. government or toxic chemicals.13,14 This unopposed and contagious anti-vax movement directly affects future biological deterrence because our adversaries know that the population will not be universally compliant with vaccination and will be susceptible to certain pathogens. Recent polls indicate that one-third of U.S. citizens,14 compared to 14% of U.K. citizens,12 would avoid receiving a SARS-CoV-2 vaccine, even if available and affordable. A poor vaccination rate increases a population’s disease susceptibility and decreases biological weapon deterrence by denial. The anti-vaccination movement has caught traction from massive information operations and propaganda on multiple media platforms. Since May 2020, anti-vaxxers have been propagating lies about the side effects of the coronavirus vaccine, but as of June, the Centers for Disease Control, which is responsible for vaccine education, had only a “plan” to counter such anti-vaccine campaigns.14 When the first vaccines were being administered to healthcare workers in the USA in December 2020, multiple social media efforts were started to promote the vaccine.15 Hashtags such as #vaxup, #IGotTheShot, #vaccineswork, and many more were used with social media posts of doctors, nurses, and other medical personnel receiving their vaccine.16 Some posts continued with threads of updates on any side effects encountered to quell public concerns. Information operations such as these may be more effective to counter the anti-vaccination propaganda than government-sponsored campaigns and require further research by public health officials.

#### **Patents are the key to preventing bioweapon development – they prevent technology from being accessible to hostile state and non-state actors**

Finlay 10 (Brian Finlay; Summer 2010; The Fletcher Forum of World Affairs, *“The Bioterror Pipeline: Big Pharma, Patent Expirations, and New Challenges to Global Security”*; accessed 8/13/21; Brian Finlay is a senior associate at the Stimson Center in Washington, DC, where he directs the Managing Across Boundaries Program. He has worked at the Brookings Institution, the Century Foundation, and Canadas Laboratory Center for Disease Control/Health Canada; pages 54-58; ask me for the pdf) HB

NEW CHALLENGES: THE BIOTECH REVOLUTION AND THE ROLE OF THE PRIVATE SECTOR Myriad private sector actors, ranging from single-employee enterprises to major multinational pharmaceutical giants dominate today's biopharmaceutical marketplace. Privately owned companies not only develop, produce, and operate the lion's share of biological industrial equipment, but carry out the greatest share of the scientific research and development for the relevant technologies, goods, and methods of application. University and other non-profit research is often commercially-funded, and many governments around the globe have built public-private partnerships, even in some of the most sensitive areas of biotechnology, to capitalize on cost reductions and innovation. According to a recent Ernest and Young study of the industry, today more than 80 percent of biotechnology firms-and, thus, the technologies they innovate-are in the hands of the private sector." In the United States, the industry's compound annual growth rate has historically hovered around 15 percent, yielding aggregate revenues of more than $70 billion in 2008.18 With fortunes to be made, unprecedented new applications to be discovered, and practically unlimited possibilities for growth, the biopharmaceutical industry has swelled dramatically over the past decade. It is estimated that the biotech sector supports about 3.2 million jobs across the U.S. economy-a little more than one job for every 100 Americans.' 9 In Europe, publicly traded biotech companies' revenues increased 17 percent in one year, from f9.6 billion in 2007 to £11.2 billion in 2008. And although the recent global financial crisis had a negative impact, the product pipelines of European industry are growing across all phases of clinical development.20 By virtually any measure, the United States and Europe remain unmatched global hubs for biotechnological investment and innovation. For national security analysts, this reality has long provided some measure of comfort. Although the system of security assurances mandated by technologically advanced (principally Western) governments is far from a panacea against biothreats, the absence of similarly robust legal barriers in many countries raises serious international security concerns. 2' For instance, although the United States, Canada, the United Kingdom, Germany, and Singapore have all introduced strict regulations on pathogenic agents that may be of interest to committed bioterrorists, most countries have not. Similarly, export controls and enforcement over many sensitive technologies are often extremely lax, particularly in countries of the Global South.22 And because terrorists and proliferant states may shop for pathogens and dual-use production technologies where controls are the weakest, this uneven patchwork of regulations leaves open a significant gap in global biosecurity standards.23 It was in this porous regulatory environment that President Obama released his National Strategy for Countering Biological Threats in November 2009. His plan cited both unparalleled innovations in the life sciences and imperfections in existing control regimes as the principle motivations for a new strategy that seeks to prevent biotechnology products from being used for harmful purposes.24 However, while the President's plan presented a more forward-leaning agenda to counter the rising risk of proliferation by explicitly leveraging public health in support of international security, at its root, the strategy extends the traditional state-centric approaches to a problem that is increasingly one of the private sector. A proper approach to the issue-and its solution set-must place industry at its epicenter. In short, the Obama strategy exemplifies the continued mismatch between governments' near singular focus on regulation of the industry on the one hand, and the elusive nature of privately-driven biotech innovation on the other. Beyond encouraging the industry to adopt more stringent security standards in the public interest, governments have generally proven bereft of innovative ideas that more directly link these measures to the private sector's enlightened self-interest. This mismatch is aggravated by the reality that the biotech and pharmaceutical community stands on the brink of yet another grand transformation that will render traditional control efforts, however effective they may have proven in the past, even more anachronistic. Over the course of the coming decade, the traditional drug development strategies employed so successfully by Western biopharmaceutical companies in the past will run headlong into two realities that will fundamentally alter biopharmaceuticals' business model: continued and rampant globalization of the life sciences and big pharma's patent expiration challenges. These forces will have profound implications on the future of drug development and the internationalization of intellectual property. Further, it threatens to open a new era of biological weapons proliferation by pushing bio-innovation into regions that are ill-prepared to manage the leakage of sensitive knowledge and equipment to those intent on developing biological weapons. Accelerating Globalization of the Life Sciences As globalization began to take firm root in the 1980s, virtually every industrial sector across the Western world sought to capitalize upon its underlying forces to promote efficiency and financial gain. Conceptions of tightly integrated firms whose product development was bound by national borders gave way to an internationalization of R&D, production, and supply chains. Expedited global trade, hastened by advances in everything from information to transportation technologies, allowed profit and efficiency to be maximized through outsourcing, off-shoring, supply-chaining, and other activities that drove intellectual and manufacturing capacity far beyond Western shores. The corresponding transfer of information, processes, and technology generated new local enterprises, including subsidiary operations that collaborated with or competed for global market share. This dynamic, in turn, created a virtuous cycle that accelerated the biotechnological competencies of these new markets. Soon, states that were seen to have lacked the indigenous expertise to perform complex R&D and manufacturing operations began to develop advanced, competitive industrial sectors.25 By the late 1990s, the spread of biotechnological knowledge and equipment allowed even more companies, universities, and research institutes around the world to benefit from advances in the life sciences. Today, developing countries nurture competitive industrial sectors that challenge traditional suppliers in Western Europe. According to the United Nations, many developing countries, including Argentina, Brazil, China, Cuba, Egypt, India, Mexico, and South Africa are already approaching the leading edge of biotechnological applications and have "significant" research capacity in the biosciences.26 In aggregate, this can only be seen as a significant boon to global development. As in the North, the developing South is putting these biotech capacities to work for peaceful purposes. Recent technological breakthroughs are indicative of this new geographic diversity of biological talent: the first vaccine against meningitis B was developed in Cuba; South Africa was the first country involved in HIV-C strain preventive treatment; India is the world's largest producer of the hepatitis B vaccine; and China was the first country to license gene therapy.27 Meanwhile, biotechnology is providing an infusion of high-skilled, stable, and lucrative jobs, and endowing struggling economies with critical growth and diversification. For the security conscious, however, the globalization of biotechnology has also expanded the locus of the bioproliferation challenge from technologically advanced countries of the North into far-flung places around the globe.28 Thus, even as humankind reaps the benefits of the biotech revolution, governments around the world are increasingly challenged by the confluence of rapidly advancing science and technology and by globalization itself. High technical hurdles to isolation and weaponization of dangerous pathogens once confined fears about the development and use of biological weapons to advanced industrial states. But now, the spread of dual-use biotechnologies means that a growing number of countries-and even terrorist groups-may gain access to the capacities necessary to develop a bioweapon.

#### **Any reduction in bioweapons threat is key – 1ar impact defense doesn’t account for future technology developments that make them a existential threat**

Millett and Snyder-Beattie 17 (Piers Millett and Andrew Snyder-Beattie; 2017; Health Security, Volume 15, Number 4; *“Existential Risk and Cost-Effective Biosecurity”*; accessed 8/13/21; <https://www.liebertpub.com/doi/pdf/10.1089/hs.2017.0028>; Piers Millett, PhD, is a Senior Research Fellow, and Andrew Snyder-Beattie, MS, is Director of Research; both at the University of Oxford, Future of Humanity Institute, Oxford, England.; page 378) HB

Why Uncertainty Is Not Cause for Reassurance Each of our estimates rely to some extent on guesswork and remain highly uncertain. Technological breakthroughs in areas such as diagnostics, vaccines, and therapeutics, as well as vastly improved surveillance, or even eventual space colonization, could reduce the chance of disease-related extinction by many orders of magnitude. Other breakthroughs such as highly distributed DNA synthesis or improved understanding of how to construct and modify diseases could increase or decrease the risks. Destabilizing political forces, the breakdown of the Biological Weapons Convention, or warfare between major world powers could vastly increase the amount of investment in bioweapons and create the incentives to actively use knowledge and biotechnology in destructive ways. Each of these factors suggests that our wide estimates could still be many orders of magnitude off from the true risk in this century. But uncertainty is not cause for reassurance. In instances where the probability of a catastrophe is thought to be extremely low (eg, human extinction from bioweapons), greater uncertainty around the estimates will typically imply greater risk of the catastrophe, as we have reduced confidence that the risk is actually at a low level.48 xxx Given that our conservative models are based on historical data, they fail to account for the primary source of future risk: technological development that could radically democratize the ability to build advanced bioweapons. If the cost and required expertise of developing bioweapons falls far enough, the world might enter a phase where offensive capabilities dominate defensive ones. Some scholars, such as Martin Rees, think that humanity has about a 50% chance of going extinct due in large part to such technologies.49 However, incorporating these intuitions and technological conjectures would mean relying on qualitative arguments that would be far more contentious than our conservative estimates. We therefore proceed to assess the cost-effectiveness on the basis of our conservative models, until superior models of the risk emerge.

#### **Bioweapon usage causes extinction – increasing development of lethality and spread proves that the threat is increasing – action now to bolster infrastructure is key**

Millett and Snyder-Beattie 17 (Piers Millett and Andrew Snyder-Beattie; 2017; Health Security, Volume 15, Number 4; *“Existential Risk and Cost-Effective Biosecurity”*; accessed 8/13/21; <https://www.liebertpub.com/doi/pdf/10.1089/hs.2017.0028>; Piers Millett, PhD, is a Senior Research Fellow, and Andrew Snyder-Beattie, MS, is Director of Research; both at the University of Oxford, Future of Humanity Institute, Oxford, England.; page 374) HB

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a long historical track record of state-run bioweapon research applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of staterun bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and mutually assured destruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25The possibility of a war between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27 Non-state actors may also pose a risk, especially those with explicitly omnicidal aims. While rare, there are examples. The Aum Shinrikyo cult in Japan sought biological weapons for the express purpose of causing extinction.28 Environmental groups, such as the Gaia Liberation Front, have argued that ‘‘we can ensure Gaia’s survival only through the extinction of the Humans as a species. we now have the specific technology for doing the job. several different [genetically engineered] viruses could be released’’(quoted in ref. 29). Groups such as R.I.S.E. also sought to protect nature by destroying most of humanity with bioweapons.30 Fortunately, to date, non-state actors have lacked the capabilities needed to pose a catastrophic bioweapons threat, but this could change in future decades as biotechnology becomes more accessible and the pool of experienced users grows.31,32

## Case

### No Solvency

#### They use the WTO – trasher is an indict – TRIPS plus is not the WTO and domestic – conceded in cross

#### Data exclusivity ramps up drug prices – best empirics prove TRIPS-plus rules create a monopoly over drug prices

**1AC Thrasher 21**, Rachel JD, MA IR @ BU, co-editor of The Future of South-South Economic Relations, Researcher at BU (May 25, 2021, "Chart of the Week: How Data Exclusivity Laws Impact Drug Prices," BU Global Development Policy Center, <https://www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data-exclusivity-laws-impact-drug-prices/>) KD

**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. “**TRIPS-plus”** rules, more severe protections that go beyond what is required in the TRIPS Agreement

### AMR

#### AMR is non-uq and no impact – the argument has no correlation to the affirmative reducing – literally read Farrah 20 its talking about bugs and even if you buy the impact – in no fashion does the aff reduce AMR as resistance is independent of the aff.

### Inequality Defense

#### IPR is not the cause of medicine inequality. Multiple alternative causes exist

Haugen 2021 [Hans Morten, Professor of International Diakonia at the VID Specialized University, Oslo, Norway, The Journal of World Intellectual Property, "Does TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) prevent COVID-19 vaccines as a global public good?" March 18, https://onlinelibrary.wiley.com/doi/10.1111/jwip.12187

This article analyzes the context for the allegation that IP is among the crucial factors in promoting health innovation globally, and not preventing the universal and equitable access to vaccines, even if supply of medicines is held by developed countries to be “difficult” (WTO Secretariat, 2020a). Biotechnology actors expressed criticism of the UN High-level Panel on Access to Medicines (2016), arguing that IP tends to be overemphasized in debates over access to medicines, ignoring the wider context of what impedes such access (International Council of Biotech Associations [ICBA], 2016; Biotechnology Innovation Organization [BIO], 2016). Hence, developed countries and biotech associations concur in identifying weak funding of health care and lack of manufacturing capacity as constituting the core of the problem of access (WTO Secretariat, 2020a; see also U.S. Department of State, 2016), as well as regulatory inefficiencies, trade policies and inadequate health insurance (ICBA, 2016).

### Innovation Turn

#### Data exclusivity is necessary to ensure effective clinical research

Bing 21

Dr. Han Bing (senior research fellow at the Institute of World Economics and Politics of Chinese Academy of Social Sciences). “TRIPS-plus Rules in International Trade Agreements and Access to Medicines: Chinese Perspectives and Practices.” Global Development Policy Center, Global Economic Governance Iniative. GEGI Working Paper 049, April 2021. JDN. https://www.bu.edu/gdp/files/2021/04/GEGI\_WP\_\_Bing\_FIN.pdf

Undisclosed test or other data refer to the data obtained in the entire medicine development process to demonstrate the medicine’s safety, efficacy and quality. The medicines and healthcare products regulatory agencies in various countries analyze and evaluate whether to approve the marketing of a new medicine based on such data. Since it is obtained from scientific studies, undisclosed test or other data are unable to satisfy the requirements of patent grant and cannot be protected by patent rights. However, the cost of obtaining marketing approval is expensive and the first registrant needs to be significant to overcome the negative price effects of competition from pharmaceutical manufacturers that free ride on the initial registrant’s marketing approval. Therefore, it is argued that, without a period of monopoly, the new drug developers will have no incentive to “conduct the costly clinical research and trials necessary to obtain marketing approval” (Chow and Lee 2018). Given its importance to the pharmaceutical industry, the United States is a strong proponent of adding such a provision in the TRIPS Agreement (Chow and Lee 2018). However, since the TRIPS Agreement was formally implemented 25 years ago, WTO members had not yet unified their opinions on the application of this provision. The United States, the European Union, and some members argue that, taking into account the considerable amount of efforts and costs for generating the necessary data, unless permitted by the originator, undisclosed test or other data should be granted exclusive rights against disclosure for a specific period of time (UNCTAD & ICTSD 2013, 613-615). During the period, government agencies shall not only protect such data against disclosure, but also prevent generic drug manufacturers from relying upon the data to obtain marketing approval. Developing countries such as Argentina, Brazil, India, and Thailand provide a non-exclusive protection on undisclosed test or other data, that is, such data are protected against unfair commercial use, but not granted exclusive rights, which allows government agencies to rely on such data to approve the marketing of generic medicines (UNCTAD & ICTSD 2013, 615-616). Developing countries believe that if the US and European practices were adopted, the marketing of generic medicines would be delayed, thereby unreasonably restricting the public access to medicines (UNCTAD & ICTSD 2013, 621). Prior to accession to the WTO in 2001, there were no data exclusivity provisions in China. After joining the WTO, China has assumed the obligation to protect such data in compliance with the TRIPS Agreement. Unlike most WTO members, as a condition for accession to the WTO, China agreed to provide data exclusivity protection for a period of six years (Feng 2010). Included in the Part V “Trade-Related Intellectual Property System” of the Report of the Working Party on the Accession of China (World Trade Organization 2001), China reiterated the content of and added what is not stipulated in Article 39(3) of the TRIPS Agreement. That is, during the period of six years, China does not allow approval of marketing for generic medicines, in order to provide exclusive protection for undisclosed test or other data of new chemical entities (World Trade Organization 2001, 284). Moreover, such protection is independent of patent protection, which means such data are protected whether a medicine is granted patent or not. The period of six years exclusive protection for undisclosed test or other data is longer than the period of 5 years of protection in the US and a number of bilateral free trade agreements.

### High Drug Prices – Defense

#### Drug prices are not escalating and wouldn’t have an impact even if they were

IBD ‘18

Investor’s Business Daily, 2-16, 18, <https://www.investors.com/politics/editorials/drug-prices-trump-budget-medicare-price-controls/> Trump Is, In Fact, Taking On High Drug Prices // Phoenix

Concern about high drug prices are legion. But these stories often lack any context. The Los Angeles Times, for example, reported last week that prescription drug prices are slated to climb 6.3% a year, on average, over the next decade, which is faster than overall health spending. It goes on to say that drug prices are one of the "biggest drivers" of health costs and this, in turn, has sparked "growing calls by Democrats for more government regulation of prices." But a look at the data the Times used actually tells a much different story. Despite all of the hue and cry about drug prices, prescription drugs account for slightly less than 10% of national health spending. That share is almost identical to where it was in 1960, when the array of drugs available was far more limited. And in 2016 — the last year for which the government has data — drug spending as a share of overall health spending actually dropped slightly. Because drugs constitute a small share of the nation's health budget, holding down costs won't make much of a difference. For example, if drug spending were to climb at just 4% a year, instead of 6.3% a year, over the next decade, it would shave just 2% off the nation's health care bill in 2026.

#### Squo solves - Competition lowering prices now – new FDA regulation proves

IBD ‘16

Investor’s Business Daily, 2-16, 18, <https://www.investors.com/politics/editorials/drug-prices-trump-budget-medicare-price-controls/> Trump Is, In Fact, Taking On High Drug Prices // Phoenix

But Trump is tackling high drug prices. Trump's FDA **administrator**, Scott **Gottlieb, is focused on increasing price-lowering market competition**. Gottlieb understands that the more choices there are, the more price competition there will be. **So he's pushed the agency to shorten approval times for generics, particularly when there's only one generic alternative on the market. He's also working to streamline the FDA's approval process for new drugs, and lifting the FDA's prejudice against so-called me-too drugs**. This sort of competition is already working. A few years ago, price-control advocates pointed to Sovaldi, a breakthrough drug that can cure hepatitis C but cost $80,000 to administer, as the poster child for price controls. Instead, the FDA last year fast-tracked approval of a second hepatitis C drug — Mavyret — which cost less than a third of Sovaldi. Suddenly, there was a price war for Hep C treatments. Competition, not price controls, cut costs overnight. By boosting competition, Trump will be far more effective at lowering dug costs than any regime of federal price controls could ever hope to be.

### Intl Coop

#### This is just false – if intl coop was real then why do countries make nukes? Why do we impose sanctions? The real answer is because we all hate each other –

#### History proves interdependence does not deter conflict

Spaniel and Malone 3/5/**19** [William Spaniel, Department of Political Science, University of Pittsburgh. Iris Malone, Department of Political Science, Stanford. The Uncertainty Tradeoff: Re-Examining Opportunity Costs and War. March 5, 2019. <https://wjspaniel.files.wordpress.com/2019/03/uncertainty-tradeoff-final.pdf>] **Italics in original**

However, not all scholars believe opportunity costs are a panacea for war.2 The historical record contains empirical inconsistencies in this relationship. At times, conflicts have arisen despite increased economic interdependence between parties, fueling concerns over when and whether opportunity costs reduce conflict. We therefore ask a simple question: holding all else equal, does increasing opportunity costs for war decrease the probability of conflict?3

#### Interdependence is bad – better and more recent studies -

#### As economic costs of war grow, they incentivize more aggressive negotiation strategies that exploit leverage – that makes conflicts more likely

Spaniel and Malone 3/5/19 [William Spaniel, Department of Political Science, University of Pittsburgh. Iris Malone, Department of Political Science, Stanford. The Uncertainty Tradeoff: Re-Examining Opportunity Costs and War. March 5, 2019. <https://wjspaniel.files.wordpress.com/2019/03/uncertainty-tradeoff-final.pdf>]

In this paper, we develop a model that reconciles this puzzle by showing both proponents and skeptics of the opportunity cost mechanism are right. Instruments like trade have competing effects on the probability of war. How is this true? Despite raising the price of war, opportunity costs also have an indirect, second-order effect of exacerbating uncertainty about a state’s resolve, which is among the most popular mechanisms that explain war.4 Which effect is stronger? We show that the latter effect can dominate in equilibrium—that is, the probability of war increases despite raising opportunity costs.

The intuition falls back on screening models where a proposer is uncertain about its opponent’s willingness to fight. Broadly, the uninformed state can pursue two strategies under these conditions. First, it can offer a generous amount that resolved types would accept. This has the benefit of avoiding the costs of war. Alternatively, it can propose a stingy settlement and screen the opponent’s willingness to fight, causing unresolved types to accept while inducing resolved types to reject. The latter benefits the proposer by giving it a large share of the settlement when the opponent accepts, but also forces it to pay the costs of war if its screening offer backfires.

#### Interdependence can just as easily cause more war even between nuclear states

Spaniel and Malone 3/5/19 [William Spaniel, Department of Political Science, University of Pittsburgh. Iris Malone, Department of Political Science, Stanford. The Uncertainty Tradeoff: Re-Examining Opportunity Costs and War. March 5, 2019. <https://wjspaniel.files.wordpress.com/2019/03/uncertainty-tradeoff-final.pdf>]

This paper has more general implications for trade-conflict research. It complements growing calls to disaggregate the effects of instruments like trade (Martin et al. 2008). Empirical analyses must carefully trace what precisely parties do not know about each other to draw the correct inference. It also suggests states should be careful in interpreting how other states value or benefit from mutual trade flows. A free trade agreement championed by one state may be perceived as relatively less beneficial in another state. This uncertainty may undermine the credibility to abide by the agreement in the long-run.

We also highlight the need for future research to consider screening incentives in trade deals themselves. Although the proposer benefits from greater trade—both from the direct economic benefit and indirect ability to steal more surplus from the receiver— trade can harm unresolved receivers and incentivize screening. This could generate some constraints in the deals a state is willing to sign, in fear that the rearranged incentives under uncertainty could hurt its ability to effectively bluff later. A more unified approach to trade and crisis negotiations would yield additional interesting insights.

Moving forward, the results speak to other lines of research in international relations theory predicated on changing costs of conflict. We couched our results in the interdependence literature due its clear application. However, the comparative static speaks to cases where the receiver’s costs increase more generally.23 Framed this way, the results have clear implications for other literatures. For example, standard nuclear deterrence theory argues that possessing nuclear weapons increases the costs of war for potential challengers due to the risk of a retaliatory nuclear response (Morgenthau 1961, 280; Gilpin 1983, 213-219). The logic of alliance formation similarly relies on the assumption that entering these pacts induces peace by raising an opponent’s costs of conflict (Morrow 1994). Together, these mechanisms assume raising the costs of war should decrease conflict. Our results demonstrate this effect is likely more conditional than previously realized. We find increased costs of conflict can exacerbate issues with uncertainty over resolve even if both states possess destructive weaponry. This promises to shed new insights into how raising costs affects deterrence and coercive bargaining in other contexts.

### WTO Cred Defense

#### No uniqueness and no impact – the WTO has had hundreds of disputes within the last few decades and protectionism has no impact

Nebehay ‘18

Nebehay, Stephanie. “WTO's Credibility, Survival at Risk as Trade War Looms: Experts Report.” Reuters, Thomson Reuters, 17 July 2018, [www.reuters.com/article/us-trade-wto/wtos-credibility-survival-at-risk-as-trade-war-looms-experts-report-idUSKBN1K7295. //](http://www.reuters.com/article/us-trade-wto/wtos-credibility-survival-at-risk-as-trade-war-looms-experts-report-idUSKBN1K7295.%20//) Phoenix

GENEVA (Reuters) - The credibility and survival of the World Trade Organization (WTO) is under “serious threat” as major economies put up protectionist barriers, independent experts warned on Tuesday.

The report issued by the Bertelsmann Foundation comes amid a deepening trade dispute between China and the United States which has engulfed other major trading partners.

U.S. President Donald Trump has warned he may ultimately impose tariffs on more than $500 billion worth of Chinese goods - nearly the total amount of U.S. imports from China last year – to combat what Washington says are Beijing’s trade abuses.

China has sworn to retaliate at each step.

The 14 experts, led by Bernard Hoekman, urged WTO’s 164 member states to agree on a new work program that will address trade-distorting policies and preserve the multilateral rule-based trading system.

“Sticking to status quo modes of operating is a recipe for the institution’s gradual demise,” they said in the report, “Revitalizing Multilateral Governance at the World Trade Organization”.

It is urgent to avoid “further erosion of the WTO’s credibility”, they said, adding: “This includes preventing backsliding by WTO members towards unilateral use of protectionist trade policies and ensuring that disputes are resolved effectively and efficiently.”

In a statement, WTO director general Roberto Azevedo welcomed the “very timely” report.

The United States told the WTO last week that a “reckoning” over China’s unfair trade policies is urgent and is too big for the WTO to handle.

The experts said that problems go beyond the failure to conclude the WTO’s stalled Doha round, launched in 2001, with some national policies distorting trade and threatening to undermine the system.

The report cited the U.S. invoking national security concerns to impose tariffs and quotas on imports of selected products as a prime example.

“Such measures create systemic risks given the prospect of tit-for-tat imposition of trade-distorting measures and greater use of national security justifications by WTO members for the imposition of protectionist measures,” it said.

China and India also feel that the WTO is unbalanced and treats them unfairly, the report said.

Failure to clinch new WTO agreements has led states to set up more than 400 preferential trade agreements since 2000, it said.

“Care must be taken that the baby is not thrown out with the bathwater,” it said. “All countries, large and small, have a major stake in an effective, rules-based multilateral trading system.”

More than 500 disputes have been brought to the WTO since 1995, the report said.

Under Trump, the United States has demanded that the WTO’s dispute system is changed to stop Washington getting what he regards as an “unfair deal”.

Trump has also blocked appointments to the WTO’s appeals chamber to replace judges as their terms expire.

“If this matter is not resolved, the Appellate Body will be down to 3 members in September 2018, the minimum needed to consider an appeal, and will cease to be operational at the end of 2019 when two more vacancies arise,” the report said.

### Bioterror

#### No risk of bioterror – even weaponized pathogens can’t be dispersed

Kolssak 15

12 October 2015 Spencer Kolssak writes about domestic and international terror threats for the Patrick Henry Inteligencer. The Intelligencer‘s mission is to expand public understanding of crucial matters in national security, intelligence, and international relations. The Intelligencer is a student-led special project sponsored by Patrick Henry College’s Strategic Intelligence (SI) program. http://phcintelligencer.com/2015/10/12/bioterrorism-neither-likely-nor-practical/

Past Bioterrorism Attempts The record of attempted use of biological weapons is very limited. Most nations ended their offensive biological weapons programs with the ratification of the Biological Weapons Convention in 1972. The United States ceased its programs in 1970, but continued biological weapons research for defensive purposes. In April 1979, 68 people died in Sverdlovsk, Russia, as a result of an anthrax leak from a Soviet bioweapons facility. In 1995, the Iraqi government admitted that it had a program to research and produce weaponized anthrax.7 The anthrax attacks of 2001, dubbed “Amerithrax”, are the most famous example of a biological weapons attack.1 Letters sent through the mail laden with dried anthrax spores killed five people and sickened seventeen.1 The genetic strain used in the attack was specially engineered, demonstrating that the perpetrator had access to US bioweapons research facilities.7 The investigation eventually centered on Bruce Ivans, a US scientist. Ivans took his own life before federal investigators could bring formal charges.8 Perhaps even more relevant are the failed bioterror attacks by the Japanese cultist group, Aum Sinrikyo. In the late 1980s, Aum spent millions of dollars and employed a team of trained scientists to engineer advanced biological agents. They experimented with botulinum toxin, anthrax, cholera, and even Q fever in hopes of producing enough biological agent to trigger a global Armageddon.9 Aum had access to **far more scientific resources** than any modern Islamist terror group. In April 1990, the group used a fleet of trucks equipped with aerosol sprayers to disperse liquid botulinum on the Imperial Palace, the National Diet of Japan, the US Embassy in Tokyo, and two US naval bases in Narita. No casualties resulted; no one outside the cult even knew that the terrorist attacks had taken place.9 Three years later, in June and August of 1993, Aum decided to switch to anthrax as its biological agent. This time, in addition to its fleet of trucks, the group used aerosol sprayers mounted on its headquarters building to create a cloud of anthrax over Tokyo. Again, the attacks were unsuccessful and went unnoticed. It was only after a successful 1995 subway attack using Sarin nerve gas (a chemical agent) that investigations discovered the 1990 and 1993 attacks.9 Hollywood Has it Wrong The historical record demonstrates that weaponized biological agents have been used infrequently and ineffectually. Terrorists want to spread destruction by any means they can. **If bioterrorism really was effective, more terrorist groups likely would have used pathogens as weapons by now**. The absence of widespread bioterrorism helps to show the gap between current misconceptions and reality. One gram of anthrax contained within one of the letters in 2001 had enough spores to kill thousands of people. Combined, the amount of anthrax used in the attacks could have killed millions.10 Yet the attacks only killed five. Even though the anthrax terrorist had enough biological agent to kill millions, he did not have the capability to distribute his weapon effectively. As the Aum Shinrikyo biological attacks demonstrated, even a sophisticated group of scientists working to incite global Armageddon can find it difficult to actually execute biological attacks. Terrorists have to overcome a number of challenges in order to effectively convert biological agents into weapons of mass destruction. The use of a pathogen as a biological agent depends on the group’s ability to isolate a virulent strain, weaponize it, and then distribute it. If the group could successfully isolate a dangerous genetic strain, it would then turn to two possible methods of distribution: aerosolized spray and human carriers.11 Most non-state actors do not possess the technology necessary to refine the aerosol method. Wind patterns and humidity can render such an attack ineffective. The human carrier method is less expensive but also has a number of problems. It requires the pathogen to be a contagion. Once the carrier is infected, he must be mobile while contagious and cannot be visibly ill—a situation that is unlikely with serious diseases like Ebola.11 All other possible means of delivering a biological agent are fraught with even more problems. Each potential biological agent also has individual reasons why it would not make an effective weapon of terror. Ebola is only transmitted through direct contact with the bodily fluids of someone infected with the disease.12 Anthrax is not easily transmitted across individuals and is unlikely to spark an epidemic. Anthrax can also be treated by readily available antibiotics if noticed in time.9 Even incredibly deadly biological agents like ricin and botulinum are hard to use in mass attacks due to the difficulty in converting them into a weaponized form that can be readily dispersed.

#### Assembling gene fragments into a virus is impossible

Catherine Jefferson 14, researcher in the Department of Social Science, Health, and Medicine at King’s College London, et al., 9/18/14, “The myths (and realities) of synthetic bioweapons,” <http://thebulletin.org/myths-and-realities-synthetic-bioweapons7626>

Building a dangerous virus from scratch is hard. DNA synthesis is one of the key enabling technologies of synthetic biology. There are now a number of commercial companies that provide DNA synthesis services, so the process can be out-sourced: A client can order a DNA sequence online and receive the synthesized DNA material by post within days or weeks. The price charged by these companies has greatly reduced over the last 20 years and is now around 3 cents a base pair, which puts the cost within reach of a broad range of actors. This has led to routine statements suggesting that it is now cheap and easy to obtain a synthesized version of any desired DNA sequence. There are however several challenges that need to be taken into account when assessing the potential for misuse that inexpensive DNA sequencing might enable.

Even specialized DNA synthesis companies cannot easily synthesize, de novo, any desired DNA sequence. Several commercial companies provide routine gene synthesis services for sequences of less than 3,000 base pairs, but length is a crucial factor; the process is error prone, and some sequences are resistant to chemical synthesis. A number of entirely new synthesized DNA fragments would have to be assembled to produce a full genome, and, even if doing so were not already regulated by guidelines, simply ordering the full-length genome sequence of a small virus online is not possible.

Ordering short DNA sequences and assembling them into a genome requires specialist expertise, experience, and equipment available in academic laboratories but not easily accessible to an amateur working from home.

#### Lack of expertise, knowledge, infrastructure prove no bioterror – but even if it happens safeguards check

Seitz 16 (Sam, Director of Nuclear Security Studies @ the Global Intelligence Trust, “Why WMD Terrorism Isn’t as Scary as it Seems” https://politicstheorypractice.wordpress.com/2016/08/26/why-wmd-terrorism-isnt-as-scary-as-it-seems/)

Biological attacks are equally unlikely to occur for many of the same reasons. There simply aren’t many biological weapons programs because the use of these kinds of systems is prohibited by international law. Thus, few individuals have the requisite knowledge to engineer and produce effective bio-agents. Without proper expertise and infrastructure, it is unlikely that terrorist networks will ever possess the knowledge or means to produce weapons grade biological agents (7). Like chemical weapons, biological weapons also have a poor track record when it comes to inflicting serious damage. As Alan Dove explains, “Terrorist groups have… deployed biological weapons twice… The first was [in] 1984… [when] a cult in Oregon inoculated restaurant salad bars with Salmonella… 751 people got sick, but nobody died.” The second biological terrorist attack was conducted by another cult, the same one that launched the chemical attack in Tokyo; its bio-attack was even less effective than its chemical attack. Despite the cult being “well-financed, and [having] many highly educated members… Nobody got sick or died” (8). Finally, it’s important to remember that the United States and other Western countries have impressively modern and well-funded public health institutions. Thus, even if terrorists are able to execute a potent biological attack against metropolitan areas in North America or Europe, it is unlikely that casualties would be high, as well-stocked hospitals and emergency response units would be able to mitigate the impact and prevent worst case scenarios.