# 1NC

## 1

### 1NC – T

#### Interp: Reduce excludes eliminations

Michigan District Court 11 “SAGINAW OFFICE SERVICE, INC., Plaintiff, v. BANK OF AMERICA, N.A., Defendant. Civil Action No. 09-CV-13889 UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MICHIGAN, SOUTHERN DIVISION,” Lexis

In determining whether the words "reduce" and "adjust" are ambiguous, the Court is directed to consider the ordinary meanings of the words, Rory, 703 N.W.2d at 28, and to harmonize [\*11] the disputed terms with other parts of the contract, Royal, 706 N.W.2d at 432 ("construction should be avoided that would render any part of the contract surplusage or nugatory"). "When determining the common, ordinary meaning of a word or phrase, consulting a dictionary is appropriate." Stanton v. City of Battle Creek, 466 Mich. 611, 647 N.W.2d 508 (Mich. 2002). The Court finds that the plain meanings of these terms do not unambiguously support the Bank's position. The dictionary definition of "adjust" is to "adapt" or "to bring to a more satisfactory state." Webster's Third New Int'l Dictionary 27 (2002) ("Webster's"). This is a fairly broad definition, which may be subject to, alternatively, narrower or more expansive scope. To say that the complete elimination of a schedule brings it to a more satisfactory state is undoubtedly an expansive viewof adjustment. It is the Court's duty to determine the intent of the contracting parties from the language of the contract itself, Rory, 703 N.W.2d at 30 ("the intent of the contracting parties is best discerned by the language actually used in the contract"), and in this case, it cannot unambiguously be said that the sense in which the parties used these [\*12] terms embraces the Bank's more expansive definition. Likewise, "reduce" means "to diminish in size, amount, extent, or number," Webster's, at 1905, but the term does not, in the context of the TSA, unambiguously embody an expansive scope that views complete deletion as a subset of diminution.

#### Standards:

#### 1] Limits and Ground – letting the aff eliminate medicines explodes the topic to tons of random fringe affs and gives the aff tons of extra-T power. That’s a voter cuz it kills access to the ballot.

#### 2] Extra T is a voter – means the res is no longer a stable basis and they can defend whatever they want. Also means you don’t have jurisdiction to vote for them cuz they haven’t affirmed the res.

#### Drop the debater:

#### 1] The abuse already occurred and shifted my time allocation

#### 2] It’s the same as DTA since we indict your whole aff

#### Use Competing Interps:

#### 1] There’s no way to be “reasonably” topical, it’s a yes/no binary

#### 2] Reasonability collapses since we use offense defense to determine what’s reasonable

## 2

### 1NC – DA

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

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

Saudi Arabia remains on the Priority Watch List in 2021.

Ongoing Challenges and Concerns

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## 3

### 1NC – CP

#### Text: the member nations of the World Trade Organization should engage in binding prior consultation with the World Health Organization over [the aff].

#### The WHO has authority and solves

WTO et al 20 [World Trade Organization, World Health Organization and World Intellectual Property Organization, 2020 “Promoting Access to Medical Technologies and Innovation Intersections between public health, intellectual property and trade 2nd Edition” WTO, WIPO, WHO, Accessed 8-8-2021, <https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e.pdf> ww

1. World Health Organization¶ The WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends.¶ Monitoring the impact of trade and intellectual property rights (IPRs) on public health is one of the strategic areas of the work of the WHO. Following the adoption of the TRIPS Agreement, the Forty-ninth World Health Assembly (WHA), in May 1996, adopted the first mandate of the WHO to work on the interface between public health and IP.11 In subsequent years, many more resolutions were adopted, continually broadening and reinforcing the WHO mandate to work on issues related to public health, IP and trade.¶ In May 2003, WHO member states decided to establish the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) to examine the interface between IPRs, innovation and public health.12 Its 2006 report (WHO, 2006a) contained 60 recommendations aimed at fostering innovation and improving access to medicines. It concluded that: “Intellectual property rights have an important role to play in stimulating innovation in health-care products in countries where financial and technological capacities exist, and in relation to products for which there are profitable markets. In developing countries, the fact that a patent can be obtained may contribute nothing or little to innovation if the market is too small or scientific and technological capability inadequate. [...] Where most consumers of health products are poor, as are the great majority in developing countries, the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding.”¶ Following CIPIH recommendations, WHO member states adopted in 2008 and 2009 the GSPA-PHI, which was a major step forward in the process of achieving global consensus on practical action on public health, innovation and IP. The GSPA-PHI reaffirmed and extended the mandate of the WHO to work at the interface of public health and IP. A comprehensive evaluation and an overall programme review of the GSPA-PHI were published in 2016 and 2017, respectively (Capra International, 2016; WHO, 2017e).¶ In 2019, the WHO Secretariat developed a new, comprehensive Access Roadmap, which outlines the programming of the WHO’s work on access to medicines and vaccines for the period 2019–2023, covering implementation of the GSPA-PHI as well as other relevant strategic documents, such as the WHO Global Strategy on Human Resources for Health: Workforce 2030.13 The WHO has produced a large body of material to provide evidence-based guidance to its member states in order to support them during the process of shaping their policies on public health and IP. Examples of such guidance include patent landscape analyses for key hepatitis C medicines (WHO, 2016d), a range of detailed analyses of opportunities and challenges in local production14 and a technical background document on intersections in trade and health (WHO, 2015d). The WHO also fulfils technical functions outside the scope of the GSPA-PHI that are of significant relevance to the intersection of medicines, IP and trade. For example, the Model List of Essential Medicines (EML),15 reviewed every two years, comprises the medicines that satisfy the priority health-care needs of the population,16 and is used by many countries as a basis for developing national formularies (lists) to guide procurement, among other purposes. As another example, the WHO provides a quality assurance mechanism through its Prequalification platform.17 Hundreds of medicines and other health products have been quality assured through WHO prequalification, without which, in many cases, quality assurance would have been difficult or impossible (see Chapter IV, section A.11(a)).

#### WHO says yes – it supports increasing the availability of generics and limiting TRIPS

Hoen 03 [(Ellen T., researcher at the University Medical Centre at the University of Groningen, The Netherlands who has been listed as one of the 50 most influential people in intellectual property by the journal Managing Intellectual Property, PhD from the University of Groningen) “TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond,” Chicago Journal of International Law, 2003] JL

However, subsequent resolutions of the World Health Assembly have strengthened the WHO’s mandate in the trade arena. In 2001, the World Health Assembly adopted two resolutions in particular that had a bearing on the debate over TRIPS [30]. The resolutions addressed:

– the need to strengthen policies to increase the availability of generic drugs;

– and the need to evaluate the impact of TRIPS on access to drugs, local manufacturing capacity, and the development of new drugs

#### Consultation displays strong leadership, authority, and cohesion among member states which are key to WHO legitimacy

Gostin et al 15 [(Lawrence O., Linda D. & Timothy J. O’Neill Professor of Global Health Law at Georgetown University, Faculty Director of the O’Neill Institute for National & Global Health Law, Director of the World Health Organization Collaborating Center on Public Health Law & Human Rights, JD from Duke University) “The Normative Authority of the World Health Organization,” Georgetown University Law Center, 5/2/2015] JL

Members want the WHO to exert leadership, harmonize disparate activities, and set priorities. Yet they resist intrusions into their sovereignty, and want to exert control. In other words, ‘everyone desires coordination, but no one wants to be coordinated.’ States often ardently defend their geostrategic interests. As the Indonesian virus-sharing episode illustrates, the WHO is pulled between power blocs, with North America and Europe (the primary funders) on one side and emerging economies such as Brazil, China, and India on the other. An inherent tension exists between richer ‘net contributor’ states and poorer ‘net recipient’ states, with the former seeking smaller WHO budgets and the latter larger budgets.

Overall, national politics drive self-interest, with states resisting externally imposed obligations for funding and action. Some political leaders express antipathy to, even distrust of, UN institutions, viewing them as bureaucratic and inefficient. In this political environment, it is unsurprising that members fail to act as shareholders. Ebola placed into stark relief the failure of the international community to increase capacities as required by the IHR. Guinea, Liberia and Sierra Leone had some of the world's weakest health systems, with little capacity to either monitor or respond to the Ebola epidemic.20 This caused enormous suffering in West Africa and placed countries throughout the region e and the world e at risk. Member states should recognize that the health of their citizens depends on strengthening others' capacity. The WHO has a central role in creating systems to facilitate and encourage such cooperation.

The WHO cannot succeed unless members act as shareholders, foregoing a measure of sovereignty for the global common good. It is in all states' interests to have a strong global health leader, safeguarding health security, building health systems, and reducing health inequalities. But that will not happen unless members fund the Organization generously, grant it authority and flexibility, and hold it accountable.

#### The WHO plays a key role in responses to pandemics and disease outbreaks

Kuznetsova 20 [Lidia Kuznetsova “COVID-19: The World Community Expects the World Health Organization to Play a Stronger Leadership and Coordination Role in Pandemics Control” Published: Public Health, September 8, 2020] [https://doi.org/10.3389/fpubh.2020.00470] [Kuznetsova: Faculty of Medicine, Barcelona Institute for Global Health, University of Barcelona, Barcelona, Spain.] || SM

The coronavirus disease 2019 (COVID-19) pandemic and other recent and ongoing infectious disease outbreaks, emerging, re-emerging, and neglected infectious diseases, as well as bioterrorism, posing a threat to health security, suggest the necessity and significance of pandemics-related research. The control of pandemics is impossible without international cooperation, due to their transboundary nature, and intergovernmental organizations are to play an important role in pandemic preparedness and response. The World Health Organization (WHO) is the only source of legally binding international regulations for pandemic response, the importance of which is growing, and a provider of technical assistance and standard guidelines to the states (1). Strong national health systems are the foundation for effective pandemics prevention and control, and their strengthening is crucial, especially in low-income countries. The international system of mechanisms of response to pandemics is currently in the process of formation, and it is a dynamic process. The challenge for such system is to ensure the existence of supranational legal authority and make it function. The authority and the capacity of the WHO to lead the international response have been questioned during the Ebola outbreak and the COVID-19 pandemic. The crises also revealed the lack of resources of the WHO to effectively prevent and respond to pandemics (2). At the same time, the role of emerging influential and resourceful actors in pandemic control has been growing, including the World Bank Group, the Bill and Melinda Gates Foundation, Médecins Sans Frontières, and other organizations. One of the central issues in international efforts to prevent and control pandemics is the aid to the poorest countries to develop health systems and ensure availability and accessibility to the basic health services by their population (3).¶ The Role of the WHO in Pandemic Prevention and Control¶ The role of international mechanisms advanced significantly from adopting the WHO International Health Regulations (IHR) in 1969, focusing on just three diseases (cholera, plague, and yellow fever), to approving the current version of the IHR in 2005 and to creating the WHO Contingency Fund for Emergencies (CFE) in 2015 (4, 5).¶ During the SARS outbreak in 2003, the problem of coordinating response actions in different countries already became obvious. The existing response mechanisms were rather slow and disorganized. The outbreak revealed the necessity to modify the IHR. The revision of the IHR in 2005 allowed the WHO to declare Public Health Emergency of International Concern (PHEIC) and required the Member States to strengthen national emergency response capacity. The revised version of the IHR was tested by H1N1 influenza outbreak in 2009, when weaknesses in the global response to influenza pandemic were revealed again. The WHO issued recommendations to the Member States to create more extensive reserve global health workforce and establish $100 million contingency fund for future pandemics. However, these recommendations were not implemented until 2014 (6). The Ebola crisis revealed the importance of legal instruments and raised legal and ethical issues, due to, for example, introduction by some governments of trade and travel restrictions. This outbreak questioned the WHO credibility and the effectiveness of the IHR (7).¶ The WHO plays a key role among all intergovernmental organizations involved in tackling pandemics, and it is the only source of legal authority. The core functions of the WHO related to pandemics prevention and control include the following: support Member States in developing national capacity to respond to pandemics, support training programs, coordinate Member States for pandemic and seasonal influenza preparedness and response, develop guidelines, and strengthen biosafety and biosecurity (8).¶ The main instruments used by the WHO for pandemic prevention and control include the IHR, the Global Outbreak Alert and Response Network (GOARN), the Public Health Emergency Operations Centre Network (EOC-NET), the Contingency Fund for Emergencies, and the Pandemic Influenza Preparedness (PIP) Framework. At the strategic level in pandemic control, the WHO focuses on reinforcing national public health systems, One Health approach, and strengthening global partnership.¶ The IHR is a legally binding regime for protection and management of disease threats. It is a framework for collective response to the threats, involving one or more countries, or to public health events of global significance. The current version of the IHR entered into force on 15 June 2007, and they are binding on 196 countries across the globe, including all WHO Member States (1).

#### Causes Extinction

Piers Millett 17, Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization.

A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6

While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and theWestern Abenaki (which suffered a staggering 98% loss of population).

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.19-2

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### 1NC – CP

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

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

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

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

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

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

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