## 1NC

### 1NC – OFF

#### Interpretation: medicines is a generic bare plural. The aff may not defend that member nations of the World Trade Organization reduce intellectual property protections for a subset of medicines.

Nebel 19 Jake Nebel [Jake Nebel is an assistant professor of philosophy at the University of Southern California and executive director of Victory Briefs.] , 8-12-2019, "Genericity on the Standardized Tests Resolution," Briefly, https://www.vbriefly.com/2019/08/12/genericity-on-the-standardized-tests-resolution/ SM

Both distinctions are important. Generic resolutions can’t be affirmed by specifying particular instances. But, since generics tolerate exceptions, plan-inclusive counterplans (PICs) do not negate generic resolutions. Bare plurals are typically used to express generic generalizations. But there are two important things to keep in mind. First, generic generalizations are also often expressed via other means (e.g., definite singulars, indefinite singulars, and bare singulars). Second, and more importantly for present purposes, bare plurals can also be used to express existential generalizations. For example, “Birds are singing outside my window” is true just in case there are some birds singing outside my window; it doesn’t require birds in general to be singing outside my window. So, what about “colleges and universities,” “standardized tests,” and “undergraduate admissions decisions”? Are they generic or existential bare plurals? On other topics I have taken great pains to point out that their bare plurals are generic—because, well, they are. On this topic, though, I think the answer is a bit more nuanced. Let’s see why. 1.1 “Colleges and Universities” “Colleges and universities” is a generic bare plural. I don’t think this claim should require any argument, when you think about it, but here are a few reasons. First, ask yourself, honestly, whether the following speech sounds good to you: “Eight colleges and universities—namely, those in the Ivy League—ought not consider standardized tests in undergraduate admissions decisions. Maybe other colleges and universities ought to consider them, but not the Ivies. Therefore, in the United States, colleges and universities ought not consider standardized tests in undergraduate admissions decisions.” That is obviously not a valid argument: the conclusion does not follow. Anyone who sincerely believes that it is valid argument is, to be charitable, deeply confused. But the inference above would be good if “colleges and universities” in the resolution were existential. By way of contrast: “Eight birds are singing outside my window. Maybe lots of birds aren’t singing outside my window, but eight birds are. Therefore, birds are singing outside my window.” Since the bare plural “birds” in the conclusion gets an existential reading, the conclusion follows from the premise that eight birds are singing outside my window: “eight” entails “some.” If the resolution were existential with respect to “colleges and universities,” then the Ivy League argument above would be a valid inference. Since it’s not a valid inference, “colleges and universities” must be a generic bare plural. Second, “colleges and universities” fails the upward-entailment test for existential uses of bare plurals. Consider the sentence, “Lima beans are on my plate.” This sentence expresses an existential statement that is true just in case there are some lima beans on my plate. One test of this is that it entails the more general sentence, “Beans are on my plate.” Now consider the sentence, “Colleges and universities ought not consider the SAT.” (To isolate “colleges and universities,” I’ve eliminated the other bare plurals in the resolution; it cannot plausibly be generic in the isolated case but existential in the resolution.) This sentence does not entail the more general statement that educational institutions ought not consider the SAT. This shows that “colleges and universities” is generic, because it fails the upward-entailment test for existential bare plurals. Third, “colleges and universities” fails the adverb of quantification test for existential bare plurals. Consider the sentence, “Dogs are barking outside my window.” This sentence expresses an existential statement that is true just in case there are some dogs barking outside my window. One test of this appeals to the drastic change of meaning caused by inserting any adverb of quantification (e.g., always, sometimes, generally, often, seldom, never, ever). You cannot add any such adverb into the sentence without drastically changing its meaning. To apply this test to the resolution, let’s again isolate the bare plural subject: “Colleges and universities ought not consider the SAT.” Adding generally (“Colleges and universities generally ought not consider the SAT”) or ever (“Colleges and universities ought not ever consider the SAT”) result in comparatively minor changes of meaning. (Note that this test doesn’t require there to be no change of meaning and doesn’t have to work for every adverb of quantification.) This strongly suggests what we already know: that “colleges and universities” is generic rather than existential in the resolution. Fourth, it is extremely unlikely that the topic committee would have written the resolution with the existential interpretation of “colleges and universities” in mind. If they intended the existential interpretation, they would have added explicit existential quantifiers like “some.” No such addition would be necessary or expected for the generic interpretation since generics lack explicit quantifiers by default. The topic committee’s likely intentions are not decisive, but they strongly suggest that the generic interpretation is correct, since it’s prima facie unlikely that a committee charged with writing a sentence to be debated would be so badly mistaken about what their sentence means (which they would be if they intended the existential interpretation). The committee, moreover, does not write resolutions for the 0.1 percent of debaters who debate on the national circuit; they write resolutions, at least in large part, to be debated by the vast majority of students on the vast majority of circuits, who would take the resolution to be (pretty obviously, I’d imagine) generic with respect to “colleges and universities,” given its face-value meaning and standard expectations about what LD resolutions tend to mean.

#### It applies to medicines:

#### Upward entailment test – spec fails the upward entailment test because saying that nations ought to reduce IPP for one medicine does not entail that those nations ought to reduce IPP for all medicines

#### Adverb test – adding “usually” to the res doesn’t substantially change its meaning because a reduction is permanent

#### Vote neg:

#### 1] Semantics outweigh:

#### T is a constitutive rule of the activity and a basic aff burden – they agreed to debate the topic when they came here

#### Jurisdiction – you can’t vote aff if they haven’t affirmed the resolution

#### It’s the only stasis point we know before the round so it controls the internal link to engagement – there’s no way to use ground if debaters aren’t prepared to defend it

#### 2] Limits – there are countless affs accounting for thousands of medicines – unlimited topics incentivize obscure affs that negs won’t have prep on – limits are key to reciprocal prep burden – potential abuse doesn’t justify foregoing the topic and 1AR theory checks PICs

#### Paradigm Issues –

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

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

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

### 1NC – OFF

#### Counterplan Text – Member states of the World Trade Organization ought to consult the World Health Organization on whether or not to [do the Plan]. The World Health Organization ought to publicly declare that their decision on [the Plan] will represent their future decisions on all intellectual property protections on medicines.

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

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

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

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

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

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

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

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

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

#### Right to Health solves Nationalist Populism.

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

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

#### Populism is an existential threat.

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

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

### 1NC – OFF

#### Climate Patents and Innovation high now and solving Warming but waiving patents sets a dangerous precedent for appropriations – the mere threat is sufficient is enough to kill investment.

Brand 5-26, Melissa. “Trips Ip Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors.” IPWatchdog.com | Patents & Patent Law, 26 May 2021, www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/. //sid

The biotech industry is making remarkable advancestowards climate change solutions, and it is precisely for this reason that it can expect to be in the crosshairs of potential IP waiver discussions. President Biden is correct to refer to climate change as an existential crisis. Yet it does not take too much effort to connect the dots between President Biden’s focus on climate change and his Administration’s recent commitment to waive global IP rights for Covid vaccines (TRIPS IP Waiver). “This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures.” If an IP waiver is purportedly necessary to solve the COVID-19 global health crisis (and of course [we dispute this notion](https://www.ipwatchdog.com/2021/04/19/waiving-ip-rights-during-times-of-covid-a-false-good-idea/id=132399/)), can we really feel confident that this or some future Administration will not apply the same logic to the climate crisis? And, without the confidence in the underlying IP for such solutions, what does this mean for U.S. innovation and economic growth? United States Trade Representative (USTR) [Katherine Tai](https://www.ipwatchdog.com/2021/05/05/tai-says-united-states-will-back-india-southafrica-proposal-waive-ip-rights-trips/id=133224/) was subject to questioning along this very line during a recent Senate Finance Committee hearing. And while Ambassador Tai did not affirmatively state that an IP waiver would be in the future for climate change technology, she surely did not assuage the concerns of interested parties. The United States has historically supported robust IP protection. This support is one reason the United States is the center of biotechnology innovation and leading the fight against COVID-19. However, a brief review of the domestic legislation arguably most relevant to this discussion shows just how far the international campaign against IP rights has eroded our normative position. The Clean Air Act, for example, contains a provision allowing for the mandatory licensing of patents covering certain devices for reducing air pollution. Importantly, however, the patent owner is accorded due process and the statute lays out a detailed process regulating the manner in which any such license can be issued, including findings of necessity and that no reasonable alternative method to accomplish the legislated goal exists. Also of critical importance is that the statute requires compensation to the patent holder. Similarly, the Atomic Energy Act contemplates mandatory licensing of patents covering inventions of primary importance in producing or utilizing atomic energy. This statute, too, requires due process, findings of importance to the statutory goals and compensation to the rights holder. A TRIPS IP waiver would operate outside of these types of frameworks. There would be no due process, no particularized findings, no compensationand no recourse. Indeed, the fact that the World Trade Organization (WTO) already has a process under the TRIPS agreement to address public health crises, including the compulsory licensing provisions, with necessary guardrails and compensation, makes quite clear that the waiver would operate as a free for all. Forced Tech Transfer Could Be on The Table When being questioned about the scope of a potential TRIPS IP waiver, Ambassador Tai invoked the proverb “Give a man a fish and you feed him for a day. Teach a man to fish and you feed him for a lifetime.” While this answer suggests primarily that, in times of famine, the Administration would rather give away other people’s fishing rods than share its own plentiful supply of fish (here: actual COVID-19 vaccine stocks), it is apparent that in Ambassador Tai’s view waiving patent rights alone would not help lower- and middle-income countries produce their own vaccines. Rather, they would need to be taught how to make the vaccines and given the biotech industry’s manufacturing know-how, sensitive cell lines, and proprietary cell culture media in order to do so. In other words, Ambassador Tai acknowledged that the scope of the current TRIPS IP waiver discussions includes the concept of forced tech transfer. In the context of climate change, the idea would be that companies who develop successful methods for producing new seed technologies and sustainable biomass**,** reducing greenhouse gases in manufacturing and transportation, capturing and sequestering carbon in soil and products, and more, would be required to turn over their proprietaryknow-how to global competitors. While it is unclear how this concept would work in practice and under the constitutions of certain countries, the suggestion alone could be devastating to voluntary internationalcollaborations. Even if one could assume that the United States could not implement forced tech transfer on its own soil, what about the governments of our international development partners? It is not hard to understand that a U.S.-based company developing climate change technologies would be unenthusiastic about partnering with a company abroad knowing that the foreign country’s government is on track – with the assent of the U.S. government – to change its laws and seize proprietary materials and know-how that had been voluntarily transferred to the local company. Necessary Investment Could Diminish Developing climate change solutions is not an easy endeavor and bad policy positions threaten the likelihood that they will materialize. These products have long lead times from research and development to market introduction, owing not only to a high rate of failure but also rigorous regulatory oversight. Significant investment is required to sustain and drive these challenging and long-enduring endeavors. For example, synthetic biology companies critical to this area of innovation [raised over $1 billion in investment in the second quarter of 2019 alone](https://www.bio.org/sites/default/files/2021-04/Climate%20Report_FINAL.pdf). If investors cannot be confident that IP will be in place to protect important climate change technologies after their long road from bench to market, it is unlikely they will continue to investat the current and required levels**.**

#### Climate change destroys the world.

Specktor 19 [Brandon writes about the science of everyday life for Live Science, and previously for Reader's Digest magazine, where he served as an editor for five years] 6-4-2019, "Human Civilization Will Crumble by 2050 If We Don't Stop Climate Change Now, New Paper Claims," livescience, <https://www.livescience.com/65633-climate-change-dooms-humans-by-2050.html> Justin

The current climate crisis, they say, is larger and more complex than any humans have ever dealt with before. General climate models — like the one that the [United Nations' Panel on Climate Change](https://www.ipcc.ch/sr15/) (IPCC) used in 2018 to predict that a global temperature increase of 3.6 degrees Fahrenheit (2 degrees Celsius) could put hundreds of millions of people at risk — fail to account for the **sheer complexity of Earth's many interlinked geological processes**; as such, they fail to adequately predict the scale of the potential consequences. The truth, the authors wrote, is probably far worse than any models can fathom. How the world ends What might an accurate worst-case picture of the planet's climate-addled future actually look like, then? The authors provide one particularly grim scenario that begins with world governments "politely ignoring" the advice of scientists and the will of the public to decarbonize the economy (finding alternative energy sources), resulting in a global temperature increase 5.4 F (3 C) by the year 2050. At this point, the world's ice sheets vanish; brutal droughts kill many of the trees in the [Amazon rainforest](https://www.livescience.com/57266-amazon-river.html) (removing one of the world's largest carbon offsets); and the planet plunges into a feedback loop of ever-hotter, ever-deadlier conditions. "Thirty-five percent of the global land area, and **55 percent of the global population, are subject to more than 20 days a year of** [**lethal heat conditions**](https://www.livescience.com/55129-how-heat-waves-kill-so-quickly.html), beyond the threshold of human survivability," the authors hypothesized. Meanwhile, droughts, floods and wildfires regularly ravage the land. Nearly **one-third of the world's land surface turns to desert**. Entire **ecosystems collapse**, beginning with the **planet's coral reefs**, the **rainforest and the Arctic ice sheets.** The world's tropics are hit hardest by these new climate extremes, destroying the region's agriculture and turning more than 1 billion people into refugees. This mass movement of refugees — coupled with [shrinking coastlines](https://www.livescience.com/51990-sea-level-rise-unknowns.html) and severe drops in food and water availability — begin to **stress the fabric of the world's largest nations**, including the United States. Armed conflicts over resources, perhaps culminating in **nuclear war, are likely**. The result, according to the new paper, is "outright chaos" and perhaps "the end of human global civilization as we know it."

### 1NC – OFF

#### Text: The member nations of the World Trade Organization ought to appoint an international panel of scientists including National Academies and corresponding organizations to decide if they should [reduce intellectual property protections by implementing a one and done approach to patent protections] and manage similar conflicts of interest between intellectual property. The panel should say yes to the proposal and member states must abide by that ruling.

#### International panel of science diplomats can rule over IP---that’s key to science diplomacy.

Hajjar and Greenbaum 18 [David; Dean Emeritus and University Distinguished Professor, and Professor of Biochemistry and Pathology at Weill Cornell Medicine, Cornell University. He is a Fellow of the American Academy of Arts and Sciences, Fellow of the American Association for the Advancement of Sciences, a Jefferson Science Fellow of the National Academies at the U.S. Department of State, and a recent Senior Fellow in Science Policy at the Brookings Institute; Steven; Professor and Chair of the Department of Physics and Astronomy at Hunter College of the City University of New York and a Fellow of the American Physical Society. He was a Jefferson Science Fellow of the National Academies at the U.S. Department of State; “Leveraging Diplomacy for Managing Scientific Challenges,” American Diplomacy; September 18; <https://americandiplomacy.web.unc.edu/2018/09/leveraging-diplomacy-for-managing-scientific-challenges-an-opportunity-to-navigate-the-future-of-science/>] Justin

At the global level, science diplomacy is defined as cooperation among countries in order to solve complex problems through scientific research and education (1). For example, science diplomacy plays an important role in resolving global issues related to the ecosystem (such as clean water, food safety, energy conservation, and preservation of the environment). It also addresses problems related to the healthcare industry. For example, scientists have served at the international level to forge the Middle Eastern Cancer Consortium a decade ago to facilitate better healthcare and improve cancer research in the region. Whether one considers science for diplomacy or diplomacy for science, international science collaborations benefit from allowing science diplomats (broadly defined as science envoys, science attaches, embassy fellows) to help establish positive international relationships between the U.S., Europe, Latin America, Africa or Asia, particularly when proprietary disputes arise (2, 3). These various types of science diplomats already exist; some, like embassy fellows and science envoys, have one-year appointments so their role may be limited, while attaches usually have two or three year appointments that may allow them to be more successful in long, protracted negotiations. In any event, we believe that scientists can play more of a role in advancing international scientific cooperation. A key point addressed here is how to balance security concerns against the need for free exchange of information needed for innovation and growth.

Both the National Science Foundation and the National Institutes of Health are already engaged in supporting American science and strengthening collaborations abroad. Such efforts take advantage of international expertise, facilities, and equipment. Here, we provide a rationale for the use of diplomacy to address scientific challenges. This approach allows some scientists working as diplomats to help manage complex and potentially conflicting situations that arise between scientific communities and their governments. Such issues include managing disputes such as licensing agreements for intellectual property (IP) and providing protection of IP.

International collaborations can not only support but also accelerate the advancement of science. However, collaborations may carry risk if IP is misappropriated for other purposes. International collaborations should have a basis in strategy and specific goals (for example, drug discovery) in order to justify the use of government and/or corporate funds.

About a decade ago, a group of academics from the University of Manchester in the United Kingdom assembled the “Manchester Manifesto,” subtitled “Who Owns Science” (6). This document addressed the lack of alignment between commercial interests, intellectual rights, and credit to the researcher. In our (and commonly held) view, the groups representing these disparate values could benefit from diplomatic mediation. More recently, it has become increasing apparent that managing China as a science and technology superpower represents another challenge for the U.S. Resolution of issues such as ownership of IP, rights to reagents, or use of skilled laboratory personnel from international collaborations may require the efforts of science diplomats. There are few international offices or “guardians” to protect junior and senior scientists in corporate or academic sectors from misuse of reagents or piracy.

China’s failure to respect IP rights, and the resulting piracy, has drawn much attention. The media have also focused on the failure of watchdog government agencies to detect and manage these unwanted activities. Industrial espionage compromises U.S. interests. Moreover, Chinese and Russian hackers have cyberattacked U.S. technology companies, financial institutions, media groups, and defense contractors. In 2018, industrial spying was even reported in a major medical school in New York City where scientists were alleged to have illegally shared research findings with Chinese companies.

The U.S. has a long history of hiring research personnel from other countries to staff its laboratories and industrial R&D centers. These scientists and engineers have made critical contributions to our nation’s well-being and security. These young Chinese and South Asian graduates of U.S. programs a generation ago now staff our research enterprise. However, recent trends in U.S. graduate school applications in science, technology, engineering and mathematics (STEM) reflect a downturn in foreign applicants, particularly from China. It is becoming increasingly apparent that the number of American-born students seeking STEM degrees is not sufficient to satisfy future demands of our high-tech workforce. While our own educational reforms must be augmented, we cannot ignore the need to continue to recruit overseas talent.

We believe that foreign scientists can continue to make critical discoveries in the U. S. provided that their talent is nurtured, developed, and harnessed for the common good. At the same time, American companies cannot hire foreign scientists if they take the ideas they generate in U.S. laboratories back to their home countries without proper credit or permission. If the advancement of science is to succeed, greater diplomatic cooperation is needed to solve and manage proprietary issues for the benefit of all (5, 6).

So, how does one strike the proper balance between security and growth? Science is a universal social enterprise; international conferences lead to friendships and productive collaborations between nations. Given that the U.S. and Chinese governments recognize the need for international communication and collaboration then surely there should be a mechanism for adjudicating anticipated conflicts. One approach would be for government, industrial, and academic stakeholders to form an international panel of scientists and engineers to manage any conflicts of interest between the need to protect proprietary information crucial to a company’s competitive edge, and the need for students and young faculty members to publish their findings. Smaller scale efforts along these lines have recently given rise to unique global partnerships, such as fellowship support by major pharmaceutical companies, which aim to address these conflicts to the benefit of both parties. An added feature of such arrangements is that they often provide corporate financing for research (9). Can this corporate-academic partnership model be adapted to multinational joint R&D efforts while protecting IP? This question falls squarely within the purview of international science diplomacy, whereby science diplomats can establish rules of conduct governing joint global technology development with proper IP protection.

Despite the highly publicized and legitimate piracy allegations against China, at least some data indicates that the Chinese legal system is responding positively to worldwide pressure to honor foreign IP. A 2016 study by Love, Helmers, and Eberhardt, for example, found that between 2006 and 2011, foreign companies brought over 10 percent of patent infringement cases in China, and won over 70 percent of those cases (10). Today, “win rates” average around 80 percent, and “injunction rates,” around 98 percent (10). As Chinese scientists and engineers increasingly enter the top tier of the innovation space, their growing awareness of their own need for IP protection could be a powerful motivating force for the protection of all IP. As stated earlier, science diplomats could catalyze this progress even further by direct negotiations with those parties involved in the conflicts. An obvious flaw in this optimistic outlook is that scientists in the U.S. wield more influence with their government than scientists in China wield with theirs. And to the extent that the Chinese government could be encouraging IP theft, this must be addressed first by those international companies/firms who want to do business with the Chinese. Chinese investments, as well as tech incubators and targeted acquisitions, can enable access to U.S. technologies for commercial development. Although this conveys a level of risk to the developers, it may provide valuable opportunities for U.S. companies as well. In many respects, the extensive engagement and collaboration in innovation between the U.S. and China, often characterized by open exchanges of ideas, talent, and technologies, can be mutually beneficial in enriching and accelerating innovation in both countries.

In summary, we believe that science diplomats could help address the increasingly complex issues that arise between accelerating scientific and engineering advances, and the need to protect national security and corporate IP. We also propose that this might be accomplished by asking the National Academies to **recommend** academic, corporate, and government scientific leaders to serve on an international scientific advisory board, and for the corresponding organizations in other countries to do the same. Access to the free flow of information promotes new knowledge and innovation. A return to a more restrictive intellectual environment is not only harmful to progress, but also nearly impossible to manage in the current internet age. A good place to start would be to engage the newly appointed head of the White House Office of Science and Technology Policy (the Science Advisor to the President of the United States), and working groups within established organizations. These organizations include the American Association for the Advancement of Science (AAAS) or the National Academies of Science, Engineering and Medicine, and corresponding international organizations. What incentive is there for a busy and successful scientist to serve in such capacity? It is the same altruism that motivates us to accept assignments as journal editors, manuscript reviewers, or funding agency panelists for the advancement of science toward the greater good.

#### Solves every existential threat.

Haynes 18—research associate in the Neurobiology Department at Harvard Medical School (Trevor, “Science Diplomacy: Collaboration in a rapidly changing world,” <http://sitn.hms.harvard.edu/flash/2018/science-diplomacy-collaboration-rapidly-changing-world/>, dml) // Re-Cut Justin

Today’s world is extremely interconnected. Most of us take this fact for granted, but its implications cannot be overstated. The rate at which information, resources, and people are able to move from one part of the world to another continues to accelerate at an alarming rate. Undoubtedly, this development has done society immense good. In the last century, global life expectancy has doubled, the percentage of people living in extreme poverty has dropped by about 60%, and world literacy rates have increased by a similar margin. But while these statistics paint a promising picture of human civilization, human progress rests on a fragile foundation of international cooperation; the challenges presented by an interconnected world are immense. War, natural disasters, and economic collapse now exert their effects globally, creating economic and ecological disasters and mass human migrations on an unprecedented scale. And with the US pulling out of major multilateral agreements on trade, climate change mitigation, and denuclearization, you might wonder if our ability to collaborate across borders productively is really up to the task.

Global challenges require global solutions, and global solutions require collaboration between countries both big and small, rich and poor, authoritative and democratic. There are few human enterprises capable of providing continuity across these differences, and as technological solutions are becoming available to some of our most pressing issues, two in particular will be necessary to getting the job done: science and diplomacy. While science has long been utilized as a means to reach political ends—think of British explorer James Cook’s mapping of unexplored continents or the United States’ Manhattan Project—a more formal integration of scientists into the diplomatic process is being undertaken. This effort, which has led to scientists and academics playing a direct role in foreign policy development and international relations, has given birth of a new branch of diplomacy: science diplomacy.

What is science diplomacy?

As both the term and concept of science diplomacy have only recently gained traction in scientific and diplomatic circles, it’s been given a variety of definitions. But common to them all is the focus on applying scientific expertise to an international effort. The focus of these efforts is to solve international problems collaboratively while balancing economic prosperity, environmental protection, and societal wellbeing. The challenge of reaching this balance in the face of a booming global population cannot be understated, but this new branch of diplomacy is already at work and is producing results. International agreements such as the Paris Climate Agreement and the Iran Nuclear Deal are two famous examples, and science diplomacy is also establishing international collaboration in many other important arenas. While these lesser known efforts may not dominate the headlines, they are quietly tackling the global issues of today and preparing us for those of tomorrow.

Natural disasters don’t respect national boundaries (and neither does the aftermath)

In 2013, the number of refugees displaced by natural disasters—hurricanes, droughts, earthquakes—outnumbered those displaced by war. Current projections estimate as many as 1 billion people may be displaced by natural disasters by the year 2050. That would mean 1 in 9 people on the planet displaced and looking for a home. Compare this to the estimated 12 million refugees displaced by the war in Syria, and a frightening picture begins to form. As natural disasters continue to increase in both their frequency and intensity, solutions for mitigating the risk of total catastrophe will be underpinned by science, technology, and the ability of the international community to collaborate. Many organizations are starting to tackle these problems through the use of science diplomacy. The center for Integrated Research on Disaster Risk (IRDR) is composed of ten national committees—a network of government sponsored research institutions across the world in countries ranging the political and economic scale. These working groups have committed to improving disaster-risk-reduction science and technology while providing guidance to policy makers charged with implementing disaster prevention and mitigation strategies.

IRDR is governed by a committee comprising experienced scientists and natural disaster experts. Its members come from all over the world—the US, China, Uganda, Norway, Mexico, Venezuela, and more. The diversity of this organization starts at the top and is crucial to developing comprehensive risk-reduction strategies. Data and insights from countries with varying areas of expertise are being shared and built upon, facilitating more accurate natural disaster forecasting and better strategies for mitigating their destructive power. And by including representatives from countries of varying political and economic power in its leadership, IRDR ensures that its work will consider the needs of the global community at large, rather than just nations with considerable wealth and political standing.

The results of this type of international collaboration speak for themselves. Although humanity is grappling with more natural disasters than ever before, deaths related to these incidents continue to trend downward. Operating outside of the typical political framework that dominates foreign relations, IRDR provides a model for effective collaboration across the geopolitical spectrum in the face of a major global issue.

Explore or Exploit? Managing international spaces

Over the last few decades the polar ice cap that covers much of the Arctic Ocean has been shrinking. So much so, that during the warm season vast areas of previously solid ice have become open waters, creating opportunities for new trade routes and exposing the Arctic’s enormous reserves of oil and natural gas. Depending on your values, this will sound either like an opportunity for huge economic development of the region or the inevitable exploitation of one of the last untouched natural territories on the planet. And if you live there, like the half a million indigenous people who currently do, how this territory is managed will determine where you can live, how (and if) you can make a living, and what the health of the ecosystems that have supported Arctic life for millennia will look like.

Luckily, such a scenario was predicted decades ago. In 1987, Mikhail Gorbachev, then leader of the then Soviet Union, delivered a speech outlining his aspirations for the arctic to be explored rather than exploited—to radically reduce military presence, create a collaborative multinational research effort, cooperate on matters of environmental security, and open up the Northern Sea Route for trade. This speech laid the foundation for the Arctic Council (Figure 1), which is one of the most successful examples of science diplomacy at work. Composed of the eight Arctic nations, including geopolitical rivals US and Russia, and numerous groups of indigenous peoples, the Arctic Council was established to maintain Gorbachev’s vision for the region while giving the indigenous peoples a seat at the negotiating table. The council’s activities are conducted by six scientific and technology-based working groups who conduct research in the area and provide knowledge and recommendations to the council members. As a result of this research, and allowing scientists to take part in the negotiations, the Arctic council has enacted several legally binding agreements regarding the sustainable development and environmental protection of the Arctic Ocean. These agreements have facilitated cooperation on a number of important issues including search and rescue operations, prevention and containment of maritime oil pollution, and, most recently, enhanced data sharing and scientific research collaborations. Against a backdrop of rapidly deteriorating diplomatic relations, the US and Russia have co-chaired task forces that laid the foundation for these agreements, proving to the world that meaningful results can be achieved through the avenue of science diplomacy, regardless of geopolitics.

Science diplomacy going forward

The technical expertise that characterizes science diplomacy will continue to be in demand across many realms of foreign policy. For example, synthetic biology and gene-editing technology continue to factor into matters regarding agriculture and trade. Also, digital currencies, such as bitcoin, have changed the way economists and businesses are approaching markets. Finally, machine learning and artificial intelligence are being used by governments as a means for population control, giving rise to a new type of governance—digital authoritarianism.

While this expertise will be necessary for managing such issues, building international coalitions can’t be done through a purely scientific and technical lens. Convincing others to cooperate means providing them with a convincing argument to do so, and in terms they understand and find compelling. To achieve this, scientists must be trained to communicate their expertise in a way that moves stakeholders in policy discussions to act. This means appealing to motivations they have been largely taught to put to the side—whether they be political, economic, or emotional in nature—without obscuring the data and insights they have to offer.

For our leaders, policy makers, and diplomats to effectively understand issues underpinned by science and technology, experts in these fields must continue to be integrated into the mechanisms of governance. With scientists in the US running for elections in numbers like never before, we can expect this trend to continue. And in the face of a rising wave of nationalism across the world, it is crucial that we do everything we can to foster collaboration. The future of human civilization depends on it.

### 1NC – OFF

#### The Council for TRIPs should vote to [reduce intellectual property protections by implementing a one and done approach to patent protections] amending TRIPs to mandate the plan.

#### The United States should:

#### --Publicly rescind support for the reduction

#### -- Veto this motion and refuse to comply

#### The remaining member nations should initiate proceedings against the United States through the World Trade Organization, Dispute Settlement Body, which ought to find against the United States. The United States ought to comply with this ruling.

#### The counterplan has the United States oppose the plan but get overruled by the other nations. After the WTO DSB finds against them, they will comply---that solves the case but avoids the perception link on the climate da because the US initially opposed the reduction and was forced into it.

#### Counterplan competes ---

#### 1] The plan has the “member nations” act individually, while the counterplan is the WTO through the Council and eventually the DSB. That’s distinct, since member nations are not international bodies.

**Collins Dictionary n.d.** “member nations” RJP, DebateDrills https://www.collinsdictionary.com/us/dictionary/english/member-nations

member nations

The [United](https://www.collinsdictionary.com/us/dictionary/english/unite) [Nations](https://www.collinsdictionary.com/us/dictionary/english/nation) is an [international](https://www.collinsdictionary.com/us/dictionary/english/international) organization [comprised](https://www.collinsdictionary.com/us/dictionary/english/comprise) of about 180 member nations.

Sociology (1995)

At the Nato [summit](https://www.collinsdictionary.com/us/dictionary/english/summit), he called on all the member nations to [pledge](https://www.collinsdictionary.com/us/dictionary/english/pledge) to [spend](https://www.collinsdictionary.com/us/dictionary/english/spend) at least 2% of their [national](https://www.collinsdictionary.com/us/dictionary/english/national) [income](https://www.collinsdictionary.com/us/dictionary/english/income) on [defence](https://www.collinsdictionary.com/us/dictionary/english/defence" \o "Definition of defence).

Times, Sunday Times (2015)

The [beneficiaries](https://www.collinsdictionary.com/us/dictionary/english/beneficiary) will not be [limited](https://www.collinsdictionary.com/us/dictionary/english/limit) to EU member nations, but [worldwide](https://www.collinsdictionary.com/us/dictionary/english/worldwide).

Times, Sunday Times (2012)

Definition of 'nation'

nation

(neɪʃən)[Explore 'nation' in the dictionary](https://www.collinsdictionary.com/us/dictionary/english/nation)

COUNTABLE NOUN

A nation is an individual country considered together with its social and political structures.

#### 2] Counterplan is neither certain nor immediate---the US reduction hinges on the outcome of DSB. That makes the counterplan competitive.

#### “Resolved” is definite and immediate

Collins 3 Collins English Dictionary – Complete and Unabridged © HarperCollins Publishers 1991, 1994, 1998, 2000, 2003

http://www.thefreedictionary.com/resolved

resolved [rɪˈzɒlvd] adj

fixed in purpose or intention; determined

#### Ought and should are used interchangeably.

Anastasia **Koltai 18**. CEO of MyEnglishTeacher, “Difference Between Ought to and Should,” MyEnglishTeacher, September 25, 2018, <https://www.myenglishteacher.eu/blog/difference-between-ought-to-and-should/>, RJP, DebateDrills.

In most cases, SHOULD and OUGHT TO are used interchangeably today. Both SHOULD and OUGHT TO are used to express advice, obligation, or duty.

#### “Should” is immediate

Summers 94 (Justice – Oklahoma Supreme Court, “Kelsey v. Dollarsaver Food Warehouse of Durant”, 1994 OK 123, 11-8, http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13)

¶4 The legal question to be resolved by the court is whether the word "should"[13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13) in the May 18 order connotes futurity or may be deemed a ruling *in praesenti*.[14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn14) The answer to this query is not to be divined from rules of grammar;[15](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn15) it must be governed by the age-old practice culture of legal professionals and its immemorial language usage. To determine if the omission (from the critical May 18 entry) of the turgid phrase, "and the same hereby is", (1) makes it an in futuro ruling - i.e., an expression of what the judge will or would do at a later stage - or (2) constitutes an in in praesenti resolution of a disputed law issue, the trial judge's intent must be garnered from the four corners of the entire record.[16](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn16)

[CONTINUES – TO FOOTNOTE]

[13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn13) "*Should*" not only is used as a "present indicative" synonymous with *ought* but also is the past tense of "shall" with various shades of meaning not always easy to analyze. See 57 C.J. Shall § 9, Judgments § 121 (1932). O. JESPERSEN, GROWTH AND STRUCTURE OF THE ENGLISH LANGUAGE (1984); St. Louis & S.F.R. Co. v. Brown, 45 Okl. 143, 144 P. 1075, 1080-81 (1914). For a more detailed explanation, see the Partridge quotation infra note 15. Certain contexts mandate a construction of the term "should" as more than merely indicating preference or desirability. Brown, supra at 1080-81 (jury instructions stating that jurors "should" reduce the amount of damages in proportion to the amount of contributory negligence of the plaintiff was held to imply an *obligation* *and to be more than advisory*); Carrigan v. California Horse Racing Board, 60 Wash. App. 79, [802 P.2d 813](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=802&box2=P.2D&box3=813) (1990) (one of the Rules of Appellate Procedure requiring that a party "should devote a section of the brief to the request for the fee or expenses" was interpreted to mean that a party is under an *obligation* to include the requested segment); State v. Rack, 318 S.W.2d 211, 215 (Mo. 1958) ("should" would mean the same as "shall" or "must" when used in an instruction to the jury which tells the triers they "should disregard false testimony"). [14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn14) *In praesenti* means literally "at the present time." BLACK'S LAW DICTIONARY 792 (6th Ed. 1990). In legal parlance the phrase denotes that which in law is *presently* or *immediately effective*, as opposed to something that *will* or *would* become effective *in the future [in futurol*]. See Van Wyck v. Knevals, [106 U.S. 360](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=106&box2=U.S.&box3=360), 365, 1 S.Ct. 336, 337, 27 L.Ed. 201 (1882).

## Case

### 1NC – Underview

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

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

#### Reasonability on 1AR shells – 1AR theory is very aff-biased because the 2AR gets to line-by-line every 2NR standard with new answers that never get responded to– reasonability checks 2AR sandbagging by preventing really abusive 1NCs while still giving the 2N a chance.

#### DTA on 1AR shells - They can blow up a blippy 20 second shell to 3 min of the 2AR while I have to split my time and can’t preempt 2AR spin which necessitates judge intervention and means 1AR theory is irresolvable so you shouldn’t stake the round on it.

Doesn’t come first – theres always a theory violation the 1ar can find plus they have a poisitive time trade off to the 2nr so it isn’t a good check on abuse

Nc theory isn’t dta – speaking in the dark means shouldn’t justify abuse since there are community norms like topicality you should be prepared for

No reasonability we cant dump for 6 minutes on a shell without losing substance

No rvis – it doesn’t allow for topic ed since you force the round to a theory debate

Not key to reciprocity you get things like condo bad we cant access – plus t is a de facto expectation of the aff

### 1NC – AT: Disclosure

A screenshot of a computer

Description automatically generated with medium confidence

Lol you didn’t disclose your r4

Graphical user interface

Description automatically generated

Graphical user interface, application

Description automatically generated

I meet but they don’t – they didn’t include a ss of the time stamp which means the violation is NOT verifiable – read their interp text it says an hour after the round

Yes rvis on 1ac theory – otherwise the 1ac can spam a ton of underdeveloped shells that the 1nc has to sift through skewing strategy – their warrant is incoherent this is a specific reason for rvis on 1ac theory

Ci we don’t have to –

Key to portable skills and education

### 1NC – AT: Framework

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

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

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

#### AT: Predictions false

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

#### 2---Predictions of high-magnitude impacts are accurate and valuable.

Gleditsch 12 (Kristian S. Gleditsch, Department of Government, University of Essex & Peace Research Institute Oslo, and Michael D. Ward, Department of Political Science, Duke, 2012, “Forecasting is difficult, especially about the future: Using contentious issues to forecast interstate disputes,” Journal of Peace Research, 50(1) 17–31, Sage Journals)  
There have been remarkably few efforts to generate global forecasts or risk profiles for interstate conflict. Moreover, the most prominent efforts to consider the predictive ability of models of interstate conflicts have based their research on models that were not actually proposed with forecasting in mind. A notable example here is Beck, King & Zeng (2000), who essentially adopt the so-called liberal peace model of Russett & Oneal (2001). Certainly, nothing akin to the Political Instability Task Force’s now annual projections (beginning with Gurr, Marshall & Khosla, 2000) exists for international conflicts. Perhaps not surprisingly, many observers are very skeptical of the ability of academic researchers to anticipate conflict between states, at least beyond very short time horizons. Research in recent decades has seen a large number of hypotheses generated to explain under what conditions militarized interstate conflict is more or less likely. This avenue of research has been primarily inspired by research on the so-called democratic peace, or the absence of conflict between democracies. Indeed, there are thousands of scholarly works mentioning the term militarized interstate dispute (MID), most of which use these data for some kind of empirical examination of a proposition about disputes. Yet, the evidence suggests that the ability of this body of work to forecast conflict out-of-sample is decidedly disappointing. Ward, Siverson & Cao (2007) found that most of the recent statistical studies of militarized interstate disputes in prominent political science and international relations journals were unable to predict the outbreak of a single dispute out-of-sample (see also Beck, King & Zeng, 2000). Many researchers have sought to improve on the ability to forecast militarized interstate conflict by turning to alternative statistical methods. Beck, King & Zeng (2000), for example, find that neural networks perform marginally better than generalized linear regression models in forecasting conflict from the same input factors.1 Changes in estimation methods or statistical techniques per se, however, have at best led only to limited improvements in out-of-sample predictive ability. Our argument is that simply identifying inappropriate methods as the key source of the problem in forecasting conflict may give us the wrong diagnosis and lead us down less productive avenues. A more fundamental problem is models that provide a poor basis for forecasting by disregarding the motives for conflict to arise, or by only considering motives in a relatively superficial manner. Models that have been proposed for research on the democratic peace, notably the work of Russett & Oneal (2001), are primarily intended to examine whether certain characteristics of liberal institutions, such as democracy and trade, make conflict on average less likely relative to baseline risks of conflict. Although these approaches may be appropriate for testing the original propositions of interest, they essentially ignore the contentious issues that might cause states to resort to violence and instead treat these contentious issues as exogenous features, typically hidden inside a so-called ‘black box’ of the baseline risk of conflict. Our own initial foray into out-of-sample prediction for a state-level model indicates that spatial information about other conflict events can help to improve forecasts (see Ward & Gleditsch, 2002). Although this allows predictions of conflict to be conditional on other observed events rather than treating each conflict as an independent observation, the approach still ignores the issues over which such conflicts may have arisen initially. We believe that greater attention to the specific reasons for the occurrence of conflicts and the incompatibilities that may generate the use of violence can help improve our ability to forecast conflict. Although we recognize that different models may be appropriate to evaluate particular propositions and to forecast events, in our view the enterprise of prediction has great potential for winnowing bad ideas out of theories on the causes of conflict and avoiding the problem of retrospective biases in conventional hypothesis testing on the data used to develop the hypotheses in the first place (see Ward, Greenhill & Bakke, 2010). In fairness, much of the existing work on the statistical modeling of conflict has bypassed motivation since it is genuinely difficult to establish what states fight over and what their possible motivation for fighting might be. Nevertheless, the fact that something is difficult to evaluate does not mean that simply ignoring it is the best course of action. Another tradition in research on conflict has sought to identify incompatibilities in terms of contentious issues, such as territorial or maritime claims (Diehl, 1992; Mansbach & Vasquez, 1981). Recent efforts to examine these propositions empirically have found considerable evidence that cases where such claims exist are more likely to see militarized activities (Hensel, 2001; Hensel et al., 2008; Hensel & Mitchell, 2010). Even so, at present this line of research has primarily engaged in testing hypotheses about whether coefficient estimates are significantly different from 0 or the in-sample post-diction of conflicts, and has not yet examined if information on contentious issues may be helpful for forecasting dyadic conflict out-of-sample. Here we explicitly consider whether taking into account information on contentious issues and conflict management can help improve on forecasting interstate conflict and our understanding of conflict dynamics. Although we focus on statistical approaches to interstate conflict in this article, many of our arguments also apply to problems in traditional theories of conflict and qualitative approaches to prediction or anticipating political events (see Tetlock, 2005). Traditional theories of interstate conflict tend to focus on structural features presumed to influence the opportunities for conflict such as the distribution of power in the international system or relative balance of power (see e.g. Waltz, 1979). These theories display little interest in the specific incompatibilities that may motivate the use of violence. However, structural factors rarely change rapidly, but violent conflict tends to be episodic, and hence cannot be adequately explained merely by reference to permissive conditions (see Fearon, 1995). Likewise, our core argument applies to studies of civil war, which tend to emphasize opportunities for conflict rather than motivations for conflict (see Cederman, Weidmann & Gleditsch, 2011), and where evidence for the predictive ability of existing statistical efforts seems similarly disappointing (see Ward, Greenhill & Bakke, 2010). Many political and area study experts, typically using informal methods for deriving predictions, often have strong confidence in their ability to forecast events. However, the comprehensive series of studies by Tetlock (2005), who asked experts to rate a series of outcomes which could then be compared against the historical record, provide little support for the forecasting ability of political experts.

#### AT: Nixon

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

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

### 1NC – AT: Adv 1

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

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

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

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

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

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

#### Authorized Generics decimate competition.

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

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

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

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

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