# 1NC vs Lexington AG preround

## 1

### 1nc – t

#### Interpretation – topical affs must defend a reduction of intellectual property protections for *medicines*.

#### Violation: they reduce IP protections on *vaccines* which is categorically distinct

#### Vaccines are different from medicines in the context of intellectual property

Garrison 04 [Christopher Garrison, Consultant Legal Advisor to WHO. "Intellectual Property Rights and Vaccines in Developing countries," 04-13-2004, accessed 9-2-2021, https://www.who.int/intellectualproperty/events/en/Background\_paper.pdf?ua=1] HWIC

In the last few years, there has been a substantial debate about how intellectual property impacts medicines and in particular how the TRIPS Agreement impacts access to medicines in the developing world. Vaccines are different from medicines in a number of important respects however (at least from the small molecule ‘pill’ medicines if not the newer ‘biotech’ medicines). The issues raised in the access to medicines debate may therefore apply to a greater or lesser extent for vaccines, depending on these differences. This section examines a few of the different forms of intellectual property rights that are relevant in the context of vaccines and outlines the impact of some of the differences between vaccines and medicines.

#### Prefer for limits – allowing non medicines explodes limits to include affs that defend reducing protections for surgeries, therapy, injury prevention, cosmetic procedures, etc. – makes neg prep impossible because the case neg to the Botox and Laser Eye Surgery affs would have no overlap – privileges the aff by stretching pre-tournament neg prep too thin and precluding nuanced rigorous testing of aff

#### Use c/I for norm setting – t is a yes/no question, not a normal theory argument. Being “reasonably topical” doesn’t make sense.

#### No rvis – you have a burden to be topical. Anything else incentivizes chilling debate.

## 2

### 1nc – t

#### Interpretation—topical affs may not specify medicines

#### Bare plurals imply a generic “rules reading” in the context of moral statements

Cohen 1 — (Ariel Cohen, Professor of Linguistics @ Ben-Gurion University of the Negev, PhD Computational Linguistics from Carnegie Mellon University, “On the Generic Use of Indefinite Singulars”. Journal of Semantics 18: 183-209, Oxford University Press, 2001, accessed 12-7-20, HKR-AM) \*\*BP = bare plurals

According to the rules and regulations view, on the other hand, generic sentences do not get their truth or falsity as a consequence of properties of individual instances. Instead, generic sentences are evaluated with regard to rules and regulations, which are basic, irreducible entities in the world. Each generic sentence denotes a rule; if the rule is in effect, in some sense (different theories suggest different characterizations of what it means for a rule to be in effect), the sentence is true, otherwise it is false. The rule may be physical, biological, social, moral, etc. The paradigmatic cases for which this view seems readily applicable are sentences that refer to conventions, i.e. man-made, explicit rules and regulations, such as the following example (Carlson 1995: 225):

(40) Bishops move diagonally.

Carlson describes the two approaches as a dichotomy: one has to choose one or the other, but not both. One way to decide which approach to choose is to consider a case where the behavior of observed instances conflicts with an explicit rule. Indeed, Carlson discusses just such a case. He describes a supermarket where bananas sell for $0.49/lb, so that (41a) is true. One day, the manager decides to raise the price to $1.00/lb. Immediately after the price has changed, claims Carlson, sentence (41a) becomes false and sentence (41b) becomes true, although the overwhelming majority of sold bananas were sold for $0.49/lb.

(41) a. Bananas sell for $0.49/lb.

b. Bananas sell for $1.00/lb.

Consequently, Carlson reaches the conclusion that the rules and regulations approach is the correct one, whereas the inductivist view is wrong.

While I share Carlson’s judgements, I do not accept the conclusion he draws from them. Suppose the price has, indeed, changed, but the supermarket employs incompetent cashiers who consistently use the old price by mistake, so that customers are still charged $0.49/lb. In this case, I think there is a reading of (41a) which is true, and a reading of (41b) which is false. These readings are more salient if the sentence is modified by expressions such as actually or in fact:

(42) a. Bananas actually sell for $0.49/lb.

b. In fact, bananas sell for $1.00/lb.

BP generics, I claim, are ambiguous: on one reading they express a descriptive generalization, stating the way things are. Under the other reading, they carry a normative force, and require that things be a certain way. When they are used in the former sense, they should be analysed by some sort of inductivist account; when they are used in the latter sense, they ought to be analysed as referring to a rule or a regulation. The respective logical forms of the two readings are different; whereas the former reading involves, in some form or another, quantification, the latter has a simple predicate-argument structure: the argument is the rule or regulation, and the predicate holds of it just in case the rule is ‘in effect’.

#### Violation: they specified covid vaccines

#### Vote neg:

**1] Precision – any deviation justifies a jettisoning of the resolution which destroys negative predictability and prep**

**2) c/a Limits impact - there are an infinite number of affs are possible under their interp which is unpredictable and makes it impossible to be neg.**

3**] TVA solves – read the aff as advantage – most authors advocate for a change in WTO policy broadly and no reason why aff spec is key**

## 3

### 1nc – da

#### **Climate innovation is high and solving warming, but continued investment is key -- reducing IP collapses collaboration and investments.**

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/]

“If an IP waiver is purportedly necessary to solve the COVID-19 global health crisis, 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?” the discussions around waiving intellectual property (IP) rights set forth in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are currently (and somewhat amorphously) limited to COVID-19 related drug and medical products, it is probably shortsighted to ignore the implications for other technologies critical to sustaining our environment and advancing a more healthful world. In fact, if we want to ensure continued investment in these technologies, we should be very concerned about the message conveyed by the international political tide: if you overcome a challenging scientific problem and your solution has the potential to save lives, be prepared to be subjected to intense political pressure and to potentially hand over your technology without compensation and regardless of the consequences. The biotech industry is making remarkable advances towards 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), 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 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. International Pressure May Be Influencing Domestic IP Policy 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 compensation and 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 proprietary know-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 international collaborations. 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. 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 invest at the current and required levels. Next on the Chopping Block It is quite reasonable to be worried about the broad implications of a TRIPS IP waiver precedent. International campaigns to weaken IP rights seem to be taking hold in U.S. domestic policy. The TRIPS IP waiver discussions will not conclude in the near term and will not yield more shots in people’s arms. This is not even truly disputed, as our own administration acknowledges that the goal here is technology transfer abroad. Given the signaling that our Administration believes waiving IP rights is an appropriate measure to end global crises, it is proper to worry that facets of the biotech sector addressing climate change may be next on the chopping block.

#### Only a strong private sector can solve climate change

Gulker 19 [Max Gulker, 2-11-2019, "How a Strong Private Sector Will Address Climate Change," AIER, https://www.aier.org/article/how-a-strong-private-sector-will-address-climate-change/]

This is where a society with a free and well-developed private sector ought to shine. The engine of entrepreneurship combined with people responding to facts on the ground with which they alone are intimately aware will yield countless inventions, new construction, and other initiatives great and small. “The private sector” as a whole probably won’t get its due from pundits when the world is adapting to climate change since by its very nature its responses will be decentralized and often hidden in plain sight. We can speculate all we want on entrepreneurial solutions to problems that haven’t yet materialized–but the private sector can shine exactly where our speculation, and that of the public sector, inevitably falls short. Forbes contributor Willy Foote writes, “We need a comprehensive global effort to both mitigate and adapt to the impacts of climate change. But the latter is not a secondary challenge that can be put on hold until the world solves the former. It’s an immediate need.” The private sector is where much of this action will happen: “Social entrepreneurs, investors, and other private actors—unlike most governments—have inherent flexibility. They can experiment, identify the best solutions, and share that knowledge with others.” The environmental left is becoming less shy about wanting to greatly reduce the size and influence of the private sector. Climate change shows why we need a strong private sector–truly unleashing global knowledge and ingenuity to address changes around the world.

#### Warming causes extinction

Klein 14[(Naomi Klein, award-winning journalist, syndicated columnist, former Miliband Fellow at the London School of Economics, member of the board of directors of 350.org), *This Changes Everything: Capitalism vs. the Climate*, pp. 12-14]

In a 2012 report, the World Bank laid out the gamble implied by that target. “As global warming approaches and exceeds 2-degrees Celsius, there is a risk of triggering nonlinear tipping elements. Examples include the disintegration of the West Antarctic ice sheet leading to more rapid sea-level rise, or large-scale Amazon dieback drastically affecting ecosystems, rivers, agriculture, energy production, and livelihoods. This would further add to 21st-century global warming and impact entire continents.” In other words, once we allow temperatures to climb past a certain point, where the mercury stops is not in our control.¶ But the bigger problem—and the reason Copenhagen caused such great despair—is that because governments did not agree to binding targets, they are free to pretty much ignore their commitments. Which is precisely what is happening. Indeed, emissions are rising so rapidly that unless something radical changes within our economic structure, 2 degrees now looks like a utopian dream. And it’s not just environmentalists who are raising the alarm. The World Bank also warned when it released its report that “we’re on track to a 4-C warmer world [by century’s end] marked by extreme heat waves, declining global food stocks, loss of ecosystems and biodiversity, and life-threatening sea level rise.” And the report cautioned that, “there is also no certainty that adaptation to a 4-C world is possible.” Kevin Anderson, former director (now deputy director) of the Tyndall Centre for Climate Change, which has quickly established itself as one of the U.K’s premier climate research institutions, is even blunter; he says 4 degrees Celsius warming—7.2 degrees Fahrenheit—is “incompatible with an organized, equitable, and civilized global community.”¶ We don’t know exactly what a 4 degree Celsius world would look like, but even the best-case scenario is likely to be calamitous. Four degrees of warming could raise global sea levels by 1 or possibly even 2 meters by 2100 (and would lock in at least a few additional meters over future centuries). This would drown some island nations such as the Maldives and Tuvalu, and inundate many coastal areas from Ecuador and Brazil to the Netherlands to much of California and the northeastern United States as well as huge swaths of South and Southeast Asia. Major cities likely in jeopardy include Boston, New York, greater Los Angeles, Vancouver, London, Mumbai, Hong Kong, and Shanghai.¶ Meanwhile, brutal heat waves that can kill tens of thousands of people, even in wealthy countries, would become entirely unremarkable summer events on every continent but Antarctica. The heat would also cause staple crops to suffer dramatic yield losses across the globe (it is possible that Indian wheat and U.S. could plummet by as much as 60 percent), this at a time when demand will be surging due to population growth and a growing demand for meat. And since crops will be facing not just heat stress but also extreme events such as wide-ranging droughts, flooding, or pest outbreaks, the losses could easily turn out to be more severe than the models have predicted. When you add ruinous hurricanes, raging wildfires, fisheries collapses, widespread disruptions to water supplies, extinctions, and globe-trotting diseases to the mix, it indeed becomes difficult to imagine that a peaceful, ordered society could be sustained (that is, where such a thing exists in the first place).¶ And keep in mind that these are the optimistic scenarios in which warming is more or less stabilized at 4 degrees Celsius and does not trigger tipping points beyond which runaway warming would occur. Based on the latest modeling, it is becoming safer to assume that 4 degrees could bring about a number of extremely dangerous feedback loops—an Arctic that is regularly ice-free in September, for instance, or, according to one recent study, global vegetation that is too saturated to act as a reliable “sink”, leading to more carbon being emitted rather than stored. Once this happens, any hope of predicting impacts pretty much goes out the window. And this process may be starting sooner than anyone predicted. In May 2014, NASA and the University of California, Irvine scientists revealed that glacier melt in a section of West Antarctica roughly the size of France now “appears unstoppable.” This likely spells down for the entire West Antarctic ice sheet, which according to lead study author Eric Rignot “comes with a sea level rise between three and five metres. Such an event will displace millions of people worldwide.” The disintegration, however, could unfold over centuries and there is still time for emission reductions to slow down the process and prevent the worst. ¶ Much more frightening than any of this is the fact that plenty of mainstream analysts think that on our current emissions trajectory, we are headed for even more than 4 degrees of warming. In 2011, the usually staid International Energy Agency (IEA) issued a report predicting that we are actually on track for 6 degrees Celsius—10.8 degrees Fahrenheit—of warming. And as the IEA’s chief economist put it: “Everybody, even the school children, knows that this will have catastrophic implications for all of us.” (The evidence indicates that 6 degrees of warming is likely to set in motion several major tipping points—not only slower ones such as the aforementioned breakdown of the West Antarctic ice sheet, but possibly more abrupt ones, like massive releases of methane from Arctic permafrost.) The accounting giant PricewaterhouseCoopers as also published a report warning businesses that we are headed for “4-C , or even 6-C” of warming.¶ These various projections are the equivalent of every alarm in your house going off simultaneously. And then every alarm on your street going off as well, one by one by one. They mean, quite simply, that climate change has become an existential crisis for the human species. The only historical precedent for a crisis of this depth and scale was the Cold War fear that we were headed toward nuclear holocaust, which would have made much of the planet uninhabitable. But that was (and remains) a threat; a slim possibility, should geopolitics spiral out of control. The vast majority of nuclear scientists never told us that we were almost certainly going to put our civilization in peril if we kept going about our daily lives as usual, doing exactly what we were already going, which is what climate scientists have been telling us for years. ¶ As the Ohio State University climatologist Lonnie G. Thompson, a world-renowned specialist on glacier melt, explained in 2010, “Climatologists, like other scientists, tend to be a stolid group. We are not given to theatrical rantings about falling skies. Most of us are far more comfortable in our laboratories or gathering data in the field than we are giving interviews to journalists or speaking before Congressional committees. When then are climatologists speaking out about the dangers of global warming? The answer is that virtually all of us are now convinced that global warming poses a clear and present danger to civilization.”

## 4

### 1nc – da

#### Infrastructure and reconciliation are the priority now. they’ll pass by new deadline

Alemany 10/12 [Jacqueline Alemany and Theodoric Meyer, "The new deadline to pass Biden's agenda is coming up fast", 10/12/21, https://www.washingtonpost.com/politics/2021/10/13/new-deadline-pass-biden-agenda-is-coming-up-fast/]

New deadline, old problems: Less than two weeks after House Democrats missed a deadline to hold a vote on the infrastructure bill, the party is staring down another one.

House Speaker Nancy Pelosi and Senate Majority Leader Chuck Schumer say they’re aiming to pass the $1.2 trillion infrastructure bill and a larger package stuffed full of Democrats’ child care, health care and climate change priorities by Oct. 31, when a short-term extension of highway funding is set to run out.

Coincidentally, Oct. 31 is the day before the much-anticipated United Nations climate summit kicks off in Glasgow, where administration officials are eager to show off legislation that would establish credibility in negotiations with foreign governments. White House press secretary Jen Psaki told reporters last month that Biden expected the reconciliation bill — much of which is focused on fighting climate change — would “move forward in advance of that.”

(Asked about it on Tuesday, Psaki said Biden would tout the administration's commitment to combating climate change in Glasgow “regardless of where the package stands.”)

And two days later, Virginians will head to the polls to elect a new governor in a contest lawmakers and the White House are watching closely. Former Democratic Gov. Terry McAuliffe has implored Democrats in Washington to pass the infrastructure bill by Election Day.

The 18-day sprint

Can Democrats really pass two massive bills in the next 18 days?

“Yes,” Rep. Gerry Connolly (D-Va.) told The Early yesterday evening. “Will it is a different matter. But can it? Yeah. We’re experts at coming right up against the edge and pulling a miracle.”

#### Pushing a WTO takes time, energy, and political capital away from domestic legislation – big pharma and EU allies

**Bhadrakumar 5/9** M K Bhadrakumar is a former Indian diplomat. "Biden’s talk of vaccine IP waiver is political theater." Asia Times, May 9, 2021, asiatimes.com/2021/05/bidens-talk-of-vaccine-ip-waiver-is-political-theater.

On the other hand, Biden, whose political life of half a century was largely spent in the US Congress, is well aware of the **awesome clout** of the pharmaceutical companies in American politics. From that lobby’s perspective, the patent waiver “amounts to the expropriation of the property of the pharmaceutical companies whose innovation and financial investments made the development of Covid-19 vaccines possible in the first place,” as a senior scholar at the Johns Hopkins Center for Health Security puts it. The US pharmaceutical industry and congressional Republicans have already **gone on the offensiv**e blasting Biden’s announcement, saying it undermines incentives for American innovation. Besides, the argument goes, even with the patent waiver, vaccine manufacturing is a complex process and is not like simply flipping a switch. Senator Richard Burr, the top Republican on the US Senate Health Committee, denounced Biden’s decision. “Intellectual property protections are part of the reason we have these life-saving products,” he said. “Stripping these protections only ensures we won’t have the vaccines or treatments we need when the next pandemic occurs.” The Republican senators backed by Republican Study Committee chairman Jim Banks propose to introduce legislation to block the move. Clearly, Biden would rather **spend his political capital on getting the necessary legislation through Congress to advance his domestic reform agenda rather than spend time and energy to take on the pharmaceutical industry** to burnish his image as a good Samaritan on the world stage. Conceivably, Biden could be counting on the “text-based negotiations” at the WTO **dragging on for months, if not years**, without reaching anywhere. The US support for the waiver could even be a tactic to persuade pharmaceutical firms to back less drastic steps like sharing technology and expanding joint ventures to boost global production quickly. So far Covid-19 vaccines have been distributed primarily to the wealthy countries that developed them, while the pandemic sweeps through poorer ones such as India, and the real goal is, after all, expanded vaccine distribution. Biden is well aware that there will be **huge opposition** to the TRIPS waiver from the United States’ **European allies as well**. The British press has reported that the UK has been in closed-door talks at the World Trade Organization in recent months along with the likes of Australia, Canada, Japan, Norway, Singapore, the European Union and the US, who all opposed the idea.

#### The Bill quickly secures the vulnerable grid.

Carney 21 [Chris, August 6; Senior Policy Advisor at Nossaman LLC, former US Representative, Former Professor of Political Science at Penn State University; JD Supra, “The US Senate Infrastructure Bill: Securing Our Electrical Grid Through P3s and Grants,” https://www.jdsupra.com/legalnews/the-us-senate-infrastructure-bill-4989100/]

As we begin to better understand the main components of the Infrastructure Investment and Jobs Act that the US Senate is working to pass this week, it is clear that public-private partnerships ("P3s") are a favored funding mechanism of lawmakers to help offset high costs associated with major infrastructure projects in communities. And while past infrastructure bills have used P3s for more conventional projects, the current bill also calls for P3s to help pay for protecting the US electric grid from cyberattacks. Responding to the increasing number of cyberattacks on our nation’s infrastructure, and given the fragile physical condition of our electrical grid, the Senate included provisions to help state, local and tribal entities harden electrical grids for which they are responsible.

Section 40121, Enhancing Grid Security Through Public-Private Partnerships, calls for not only physical protections of electrical grids, but also for enhancing cyber-resilience. This section seeks to encourage the various federal, state and local regulatory authorities, as well as industry participants to engage in a program that audits and assesses the physical security and cybersecurity of utilities, conducts threat assessments to identify and mitigate vulnerabilities, and provides cybersecurity training to utilities. Further, the section calls for strengthening supply chain security, protecting “defense critical” electrical infrastructure and buttressing against a constant barrage of cyberattacks on the grid. In determining the nature of the partnership arrangement, the size of the utility and the area served will be considered, with priority going to utilities with fewer available resources.

Section 40122 compliments the previous section as it seeks to incentivize testing of cybersecurity products meant to be used in the energy sector, including SCADA systems, and to find ways to mitigate any vulnerabilities identified by the testing. Intended as a voluntary program, utilities would be offered technical assistance and databases of vulnerabilities and best practices would be created. Section 40123 incentivizes investment in advanced cybersecurity technology to strengthen the security and resiliency of grid systems through rate adjustments that would be studied and approved by the Secretary of Energy and other relevant Commissions, Councils and Associations.

Lastly, Section 40124, a long sought-after package of cybersecurity grants for state, local and tribal entities is included in the bill. This section adds language that would enable state, local and tribal bodies to apply for funds to upgrade aging computer equipment and software, particularly related to utilities, as they face growing threats of ransomware, denial of service and other cyberattacks. However, under Section 40126, cybersecurity grants may be tied to meeting various security standards established by the Secretary of Homeland Security, and/or submission of a cybersecurity plan by a grant applicant that shows “maturity” in understanding the cyber threat they face and a sophisticated approach to utilizing the grant.

While the final outcome of the Infrastructure Investment and Jobs Act may still be weeks or months away, inclusion of these provisions not only demonstrates a positive step forward for the application of federal P3s and grants generally, they also show that Congress recognizes the seriousness of the cyber threats our electrical grids face. Hopefully, through judicious application of both public-private partnerships and grants, the nation can quickly secure its infrastructure from cyberattacks.

#### Grid vulnerabilities spark nuclear war – extinction.

Klare 19 [Michael; November; Professor Emeritus of Peace and World Security Studies at Hampshire College; Arms Control Association, “Cyber Battles, Nuclear Outcomes? Dangerous New Pathways to Escalation,” https://www.armscontrol.org/act/2019-11/features/cyber-battles-nuclear-outcomes-dangerous-new-pathways-escalation]

Yet another pathway to escalation could arise from a cascading series of cyberstrikes and counterstrikes against vital national infrastructure rather than on military targets. All major powers, along with Iran and North Korea, have developed and deployed cyberweapons designed to disrupt and destroy major elements of an adversary’s key economic systems, such as power grids, financial systems, and transportation networks. As noted, Russia has infiltrated the U.S. electrical grid, and it is widely believed that the United States has done the same in Russia.12 The Pentagon has also devised a plan known as “Nitro Zeus,” intended to immobilize the entire Iranian economy and so force it to capitulate to U.S. demands or, if that approach failed, to pave the way for a crippling air and missile attack.13

The danger here is that economic attacks of this sort, if undertaken during a period of tension and crisis, could lead to an escalating series of tit-for-tat attacks against ever more vital elements of an adversary’s critical infrastructure, producing widespread chaos and harm and eventually leading one side to initiate kinetic attacks on critical military targets, risking the slippery slope to nuclear conflict. For example, a Russian cyberattack on the U.S. power grid could trigger U.S. attacks on Russian energy and financial systems, causing widespread disorder in both countries and generating an impulse for even more devastating attacks. At some point, such attacks “could lead to major conflict and possibly nuclear war.”14

## 5

### 1nc – cp

#### CP: The EU should:

* substantially increase COVID vaccine production to meet the global demand
* sign bilateral intellectual property licensing contracts with low and middle-income countries to share vaccines
* donate all necessary vaccines at no cost to low and middle-income nations unable to license intellectual property rights

#### EU funding can ramp up vaccine manufacturing globally

Philippe Aghion 20, Professor, College de France and London School of Economics; CEPR Research Fellow, “How to strengthen European industries’ leadership in vaccine research and innovation,” No Publication, 9-1-2020, https://voxeu.org/article/how-strengthen-european-industries-leadership-vaccine-research-and-innovation

A renewed EU support strategy to the development and commercialisation of innovative technologies could be extended to other areas, for example, defence-related technologies, on the model of the Defense Advanced Research Projects Agency (DARPA) in the US. Interestingly, the latter has been instrumental in a number of non-defence innovations as well. Note that we are not talking here about a renewed industrial policy amounting to ‘picking one winner’ but funding several competing vaccines. The DARPA model is one that mixes top-down and bottom-up: government funds are devoted to financing competing teams that work on making new ‘tough technologies’ become operational. Once selected by the government, team leaders have full autonomy in deciding on how to organise the research process and whom to involve in that process. The various teams will typically compete not only within Europe, but also on a more global scale, with the US, but also China and possibly Russia. So, this is about competition-friendly industrial policy, as advocated in Aghion et al. (2015). How would a European BARDA work? While there are a number of institutional specifications to address, let us just make two remarks. First, this is an area where joining forces with Britain makes sense, given its (academic and industrial) expertise (the same is true for defence). Second, one wants of course to identify the optimal trade-off between scale and adaptiveness/flexibility, since speed is often key. This would plead for an open ‘coalition of the willing’, which can possibly build on insights from EU success stories (like the European Research Council, which includes non-EU partners) but should clearly avoid rigidities (e.g. juste retour, seven-year budgets) enforced by (near) unanimity voting rules. Competition between Europe and the US would accelerate vaccine development and supply, which can be good for the world as a whole. Naturally, ‘pressure’ on pharmaceutical companies to avoid excessive profits, as well as sufficient international (public and private) aid to ensure global access, will be very important. To sum up, in order to strengthen European industries leadership in vaccine research and innovation, we recommend the creation of a European BARDA to which EU member-states plus the UK would be welcome to participate on a voluntary basis. Although the BARDA model should be adapted to ensure a decision process that is science-based and transparent, we suggest that the launch of a BARDA-type initiative should be considered in the forthcoming Horizon Europe framework programme for Research and Innovation. The strategy we suggest would be complementary to Europe’s other assets when facing epidemiological shocks, namely an evidence-based sanitary policy and a social model that can mitigate such shocks.

#### Eliminating IPR for vaccines gives China a massive competitive edge on innovation broadly – tanks pharma, undermines pandemic response, and tech leadership – BUT domestic production and distribution solves

Okutsu & Sharma 21 [Akane, staff writer for Nikkei International, and Kiran, LPC, The College of Law, Guildford, 1997 BA (Hons), Law, Gonville & Caius College, Cambridge University, 1996. “Vaccine Patent Waiver: COVID Stopper or Innovation Killer?” https://asia.nikkei.com/Spotlight/Coronavirus/COVID-vaccines/Vaccine-patent-waiver-COVID-stopper-or-innovation-killer]

Western pharmaceutical companies are telling U.S. officials that they fear exposing their technologies to China, the Financial Times reported. The still-under-wraps expertise could be used not only for COVID-19 shots but other vaccines and therapeutics, stripping the companies of their competitive edge.

Pfizer and Moderna have produced what are called messenger RNA vaccines, a new technology that does not contain live virus and instead instructs cells to produce a protein found in the coronavirus, creating immunity. China's vaccine producers, meanwhile, have relied on conventional methods using weakened virus.

The Pharmaceutical Research and Manufacturers of America released a statement that the U.S. stance on the waiver means "handing over American innovations to countries looking to undermine our leadership in biomedical discovery."

But some say the waiver would not be an automatic win for China.

One reason is that its pharmaceutical companies would not be immune if prices fall. "There would be competitive pressure and a negative impact on pharmaceutical companies in and outside of the U.S." including China, said Banri Ito, professor at Japan's Aoyama Gakuin University.

The stock market seems to agree. Chinese vaccine makers including CanSino Biologics and Shanghai Fosun Pharmaceutical Group fell after the U.S. announcement, just like the shares of Pfizer and Moderna.

China's state media has been lukewarm toward the U.S. move, calling it a "political tactic."

How would it affect the pharmaceutical industry over the long term?

One major concern is a loss of incentives for costly research and development.

Pharmaceutical research has a low success rate and requires enormous sums of money. Without the profits generated from intellectual property rights, "there would be no new drugs," as companies would have no hope of recouping their investments, a JPMA spokesperson said.

Ito said this raises "concerns about how to respond to future pandemics." Speedy vaccine development, he said, is driven in part by the chance to corner the market.

If the patents are to be waived, Ito suggested other steps to spur innovation will be needed, such as establishing a fund to buy such knowledge. But setting prices and deciding how to deal with the technical secrets would be no easy task.

Ito said a quicker solution might be for Group of Seven countries to "consider policies to expand production capacity and strengthen the [World Health Organization's] COVAX initiative to purchase and distribute vaccines to developing countries."

#### Biopharma innovation is key to overall competitiveness – US still has a razor thin lead but IP is uniquely key

Ezell 20 [Stephen Ezell, Director of Global Innovation Policy at the Information Technology and Innovation Foundation (ITIF). "Ensuring U.S. Biopharmaceutical Competitiveness." 7/16/20. https://itif.org/publications/2020/07/16/ensuring-us-biopharmaceutical-competitiveness]

Nations are competing for increased market share in a wide array of advanced-innovation industries, understanding that these industries are the key to competitiveness, national security, and good jobs. China’s “Made in China 2025” strategy is perhaps the most visible of these efforts, but by no means the only one.

Many nations, including China, have targeted the biopharmaceuticals industry—an industry which the United States has long led—especially in drug innovation. One result has been that over the last decade U.S. biopharmaceutical manufacturing value-added output has fallen by almost one-third, as the U.S. trade deficit in drugs and inputs has increased. Fortunately, America still leads in innovation and drug development, in large part due to effective life-science policies, including significant federal investment in life-sciences basic research, robust intellectual property (IP) protections, effective technology transfer policies, investment incentives, and, importantly, drug pricing policies that enable companies to invest in high-risk drug development.

But if the story of the past decline, and even loss, of other critical U.S. industries provides any guide, loss of U.S. production will ultimately lead to the loss of innovation capabilities as well. It is not enough for the United States to lead in drug development, it must also at least hold its own in drug production. This is especially true given the coming challenge from China, which intends to dominate the global drug industry, at all phases, from innovation to production to marketing.

Now is not the time for free-market complacency, hoping that America’s entrepreneurial spirit and rule of law will somehow suffice (the United States didn’t gain its biopharma lead from a laissez faire approach, and it certainly won’t keep its lead with it alone). Nor is it the time for drug populism, a political movement that both sides of the aisle, but especially progressives, have unfortunately embraced. Drug populism and its accompanying policies of weaker IP protections and draconian drug price controls would likely result in cheaper drugs. But there should be no confusion that it will lead to a hollowing out of U.S. capabilities, not just in production but also in innovation (and, not to mention, fewer new lifesaving drugs). If the United States is serious about competitiveness overall, and competitiveness in the biopharma sector specifically, an industry that the United States still has strong capabilities in—unlike the telecom equipment or flat-panel display industries, to name just two—then it’s time for Washington to articulate and embrace a robust national biopharmaceutical competitiveness strategy.

#### Chinese tech leadership causes nuke war

Kroenig & Gopalaswamy 18, \*Associate Professor of Government and Foreign Service at Georgetown University and Deputy Director for Strategy in the Scowcroft Center for Strategy and Security at the Atlantic Council. \*\*Director of the South Asia Center at the Atlantic Council. He holds a PhD in mechanical engineering with a specialization in numerical acoustics from Trinity College, Dublin. (Matthew & Bharath, 11-12-2018, "Will disruptive technology cause nuclear war?", *Bulletin of the Atomic Scientists*, https://thebulletin.org/2018/11/will-disruptive-technology-cause-nuclear-war/)

Rather, we should think more broadly about how new technology might affect global politics, and, for this, it is helpful to turn to scholarly international relations theory. The dominant theory of the causes of war in the academy is the “bargaining model of war.” This theory identifies rapid shifts in the balance of power as a primary cause of conflict.

International politics often presents states with conflicts that they can settle through peaceful bargaining, but when bargaining breaks down, war results. Shifts in the balance of power are problematic because they undermine effective bargaining. After all, why agree to a deal today if your bargaining position will be stronger tomorrow? And, a clear understanding of the military balance of power can contribute to peace. (Why start a war you are likely to lose?) But shifts in the balance of power muddy understandings of which states have the advantage.

You may see where this is going. New technologies threaten to create potentially destabilizing shifts in the balance of power.

For decades, stability in Europe and Asia has been supported by US military power. In recent years, however, the balance of power in Asia has begun to shift, as China has increased its military capabilities. Already, Beijing has become more assertive in the region, claiming contested territory in the South China Sea. And the results of Russia’s military modernization have been on full display in its ongoing intervention in Ukraine.

Moreover, China may have the lead over the United States in emerging technologies that could be decisive for the future of military acquisitions and warfare, including 3D printing, hypersonic missiles, quantum computing, 5G wireless connectivity, and artificial intelligence (AI). And Russian President Vladimir Putin is building new unmanned vehicles while ominously declaring, “Whoever leads in AI will rule the world.”

If China or Russia are able to incorporate new technologies into their militaries before the United States, then this could lead to the kind of rapid shift in the balance of power that often causes war.

If Beijing believes emerging technologies provide it with a newfound, local military advantage over the United States, for example, it may be more willing than previously to initiate conflict over Taiwan. And if Putin thinks new tech has strengthened his hand, he may be more tempted to launch a Ukraine-style invasion of a NATO member.

Either scenario could bring these nuclear powers into direct conflict with the United States, and once nuclear armed states are at war, there is an inherent risk of nuclear conflict through limited nuclear war strategies, nuclear brinkmanship, or simple accident or inadvertent escalation.

This framing of the problem leads to a different set of policy implications. The concern is not simply technologies that threaten to undermine nuclear second-strike capabilities directly, but, rather, any technologies that can result in a meaningful shift in the broader balance of power. And the solution is not to preserve second-strike capabilities, but to preserve prevailing power balances more broadly.

#### Erfani is wrong – aff just says companies can recouple r and d, not the cp is specifically bad

#### Lindsey – no reason why it flips innovation

## case

### solvency

#### we’ll straight turn the entire aff – the turns destroys all of their advantages since they rely on COVID rates

#### Here’s the laundry list of reasons IPR counters counterfeit meds – 10 warrants

FIFARMA 21 (FIFARMA - Latin American Federation of the Pharmaceutical Industry that represents 6 research-based biopharmaceutical companies and 11 local associations dedicated to discovering and developing safe health products and services that improve the lives of patients in Latin America and the Caribbean, “This is how we fight counterfeit medicines with Intellectual Property”, https://fifarma.org/en/this-is-how-we-fight-counterfeit-medicines-with-intellectual-property/, 22 April 2021, EmmieeM)

This is how we fight counterfeit medicines with Intellectual Property

There is a threat to health security that is present in every country in the world: counterfeit medicines. These may appear as a promise to cure any disease, but they contain excessive, insufficient or no doses of the active ingredient that treats the disease. Counterfeit medicines also include stolen drugs, drugs that have been stored in poor conditions or are expired, so they may be ineffective or may be contaminated.

In the end, the only goal of counterfeit medicines is to make money, regardless of the consequences they may have on people’s health. In fact, according to the World Health Organization (WHO), this business represents more than $30 billion dollars in low- and middle-income countries.

Recently, EFPIA did a podcast where it deepens the relationship between the decrease in the distribution of counterfeit medicine and Intellectual Property. You can find it in the following link: Fighting the fakes – what’s industry’s role?

Why does this relationship occur? Counterfeit medicines are more present where there is less strict regulatory control, where there is a lack of basic medicines, where there are unregulated supply chains, where medicines are priced very differently in the market, where intellectual property is not protected, and where no attention is paid to quality assurance.

Therefore, this is a transversal issue to different sectors outside the health industry. It is necessary for different actors to be part of the solution. Decision-makers can create campaigns to inform people about the existence of these medicines. They must go hand in hand with regulatory agencies, as they are the ones that control the entry of medicines into countries.

Likewise, the pharmaceutical industry must take action, since they are the ones who research and manufacture products. Thus, the international Fight The Fakes campaign, supported by FIFARMA, aims at raising awareness regarding the dangers of counterfeit medicines.

Each actor must play a role, however, without partnerships and collaboration between different parties, it is difficult to fight the problem. Moreover, there are other tools that contribute to the elimination of these threats to public health, such as Intellectual Property (IP).

The role of IP

In addition to functioning as a tool to maintain constant innovation in the industry, IP helps reducing counterfeit medicines because medicines have better technologies and ingredients are more difficult to copy. This means that, through market incentives, the industry manages to have high quality infrastructure, new technology and trained personnel, to create specialized and specific medicines and therapies, which is why they are difficult to replicate.

On the other hand, political will functions as another important axis, as it must prosecute those who are making counterfeit medicines. This is achieved through a constant conversation between industry and governments. Therefore, it will be absolutely clear how to identify the authenticity of medicines.

In short, IP allows quality standards to be clearer and stricter, and regulators to have greater knowledge and traceability of each product that enters the market. Through IP, you can establish a record of all products globally, which makes it easier to find possible counterfeit medicines.

Consequently, the best way to fight counterfeit medicines is through accessing the best quality medicines and for this to happen, an ecosystem between countries, regulators and industry is needed. This ecosystem shall take into account the structural deficiencies of each country and addresses them in a holistic manner, to provide the best quality medicines.

In the end, with the Intellectual Property associated with the creation of the product, there are also associated standards of transparency and detailed information that every regulatory agency can access. Moreover, the value chains will receive all this information in order to be aware of the appearance of products that are not registered with the standards of a product protected by IP.

Also,IP helps to combat counterfeit medicines internationally, since there are laws that cover all member countries of the United Nations and punish more severely those who commit this crime. Likewise, these laws provide countries with the necessary mechanisms to take concrete action once a counterfeit medicine is discovered. This, of course, must go hand in hand with the political will of each country, because only with collaboration between different actors will it be possible to prosecute the entire chain of counterfeit medicines.

Plus, IP owners can receive electronic notifications worldwide more quickly and can take direct communication actions. In a nutshell, IP allows the industry to show the public almost immediately that there is a counterfeit medicine in a country or that a website is selling counterfeit medicines. This is because legally infringing a product protected by IP allows action to be taken to prosecute the counterfeit products.

This is especially important for those consumers or small organizations that do not have access to information like a hospital or public health center has. However, it is necessary to involve other actors of the health system so that information about counterfeit medicines reaches remote regions or places, which do not have an internet connection.

On the other hand, thanks to IP, the industry is creating specialized safety technology in order for each country to easily identify a drug that comes with a brand but does not belong to that brand. The industry has also used mobile laboratories to test samples of suspected medicines and report them quickly to the value chain. Thus, technology is becoming an important element in fighting this problem.

Counterfeit medicines have a wide range of negative effects for different actors and especially for the people who fall victim of them. However, more and more governments and industries are creating concrete actions to pursue the entire chain of counterfeiters, as this is the only way to eradicate the problem all together. The tools to combat counterfeiting exist, the important thing is that actors know how to use them for the benefit of the greatest number of people in the world.

#### Damage from counterfeits outweighs and forms a large part of the issue with access to medications – IPR drastically lowers this – we cite the WHO, OECD, and Senate hearings

Acri 16 (Kristina M.L. Acri – Associate Professor of Economics @ the Department of Economics & Business at Colorado College w/a PhD in Economics @ UC Berkeley/she focuses on IPRs and has testified in more than a dozed states on the economics of pharmaceutical counterfeiting/received Thomas Edison Innovation Fellowship by the Center for the Protection of Intellectual Property @ the George Mason University School of Law/worked w/the US FDA/Reconnaissance International/PhRMA/the National Peace Foundation/OEDC/Fraster Institute/World Bank/etc, “Counterfeit Medicines and the Role of IP in Patient Safety”, https://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/, 27 June 2016, EmmieeM)

The threat of counterfeit goods took center stage on June 15th in a hearing convened by Senate Finance Committee Chairman Orrin Hatch (R-Utah). Focusing on trade opportunities and challenges for American businesses in the digital age, Senator Hatch stated:

“The Organization for Economic Co-Operation and Development (OECD) recently released a study that shows that counterfeit products accounted for up to 2.5 percent of world trade, or $461 billion, in 2013.  This is a dramatic increase from a 2008 estimate that showed that fake products accounted for less than half that amount.  Counterfeits are a worldwide problem, but the OECD estimates that the United States is the hardest hit, followed by Italy and France.  Of the estimated $461 billion in counterfeit trade in 2013, goods with registered intellectual property rights in the U.S. represented 20 percent, or $92 billion, of the OECD estimate.”[1]

As the author of the chapter on illicit trade in counterfeit medicines within the OECD report, I worry that global policymakers may be working against each other when it comes to battling counterfeit drugs, especially in the context of intellectual property rights. While the Senate Hearing and the OECD report highlight the importance of strong IP protection in combating the growing threat of counterfeit goods, their efforts coincide with an initiative by the UN Secretary-General that has the potential to greatly worsen the problems of counterfeit pharmaceuticals.   UN Secretary General Ban Ki Moon’s High Level Panel on Access to Medicines proposes “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”[2] The High Level Panel is a thinly veiled attempt to undermine the intellectual property rights architecture that incentivizes pharmaceutical innovation and protects patients from counterfeit medicines.

While patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation, they also serve to inhibit counterfeiting. The World Health Organization has determined that counterfeiting is facilitated where “there is weak drug regulatory control and enforcement; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels; there is lack of effective intellectual property protection; due regard is not paid to quality assurance”.[3]

[Kristina]

According to INTERPOL estimates, approximately 30 percent of drugs sold worldwide are counterfeit.[4] However, as is the case with many other counterfeit trade statistics, the origins of this figure are somewhat uncertain, as is the methodology used to make the calculation. Perhaps the most widely-cited statistic originates from the World Health Organization, which estimates that 10 percent of the global market for pharmaceuticals is comprised of counterfeits and reports place the share in some developing countries as high as 50-70%.[5]

While difficult to measure, estimates do exist on the extent of the market for counterfeit drugs and the harm done to human health. As noted in my chapter in the OECD report,

“INTERPOL estimates that more than one million people die each year from counterfeit drugs.[6] While counterfeit drugs seem to primarily originate in Asia, Asian patients are also significantly victimized by the problem. A 2005 study published in PLoS Medicine estimate that 192,000 people are killed in China each year by counterfeit medicines.[7] According to work done by the International Policy Network, an estimated 700,000 deaths from malaria and tuberculosis are attributable to fake drugs.[8] The World Health Organization presents a much more modest number noting that malaria claims one million lives annually and as many as 200,000 may be attributed to counterfeit medicines which would be avoidable if the medicines available were effective, of good quality and used correctly.[9] Even this number is double that presented by academic researchers Amir Attaran and Roger Bate who claim that each year more than of 100,000 people around the world may die from substandard and counterfeit medications.[10]” [11]

Given the devastating impact of counterfeit medicines on patients and the importance of intellectual property protection in combating pharmaceutical counterfeiting, it is troubling that the UN High Level Panel seems poised to prevent a series of recommendations that will undermine public health under the guise of enhancing access. Without the assurance of quality medicines, access is meaningless. Moreover, while falsely presenting intellectual property rights as the primary obstacle to global health care, the High Level Panel downplays a host of other factors that prevent developing country patients from getting the drugs they need:  inadequate medical infrastructure, insufficient political will, a shortage of clinical trials in nations where neglected diseases are endemic, poverty, and insufficient market incentives.

If the United Nations is serious about addressing the critical need for access to medicines, the Secretary General must come to terms with the reality surrounding the challenges of access to medicine. Although the international patent system may be in need of improvement, it is overly simplistic to blame drug patents, international trade agreements and the global pharmaceutical industry for the access problem. The problem is far more nuanced and complicated than portrayed by the High Level Panel. As the WHO, OECD and Senator Hatch recognize, intellectual property rights are part of the solution. To truly address the access problem, we must move beyond blaming IPRs and begin the difficult work of grappling with structural deficiencies and poverty.

#### Decks COVID vaxx solvency and independently a huge threat to public health, the employment sector, and pharmaceutical innovation

Dechert 21 (Dechert LLP is a global specialist law firm – this was published in JD Supra, which is a daily source of legal intelligence on all topics business and personal, distributing news, commentary & analysis from leading lawyers & law firms, “UK Life Sciences and Healthcare Newsletter: Counterfeit Medicines: A Growing Threat to Consumers and Pharmaceutical Companies”, https://www.jdsupra.com/legalnews/counterfeit-medicines-a-growing-threat-5751564/, 28 January 2021, EmmieeM)

Counterfeit pharmaceuticals pose a particular risk, both in economic and social terms. Poorly formulated drugs are an axiomatic danger to public health as the counterfeit drugs often fail to contain the necessary active ingredients to treat the targeted condition and also often contain other undeclared and potentially dangerous substances increasing the likelihood of dangerous side effects on individuals already otherwise unwell. The Report estimates that 72,000 to 169,000 children may die from pneumonia every year after receiving counterfeit drugs. Similarly, fake anti-malaria medication may have been responsible for an additional 116,000 annual deaths.

There are also costs to the employment sector, with the Report stating that more than 80,000 jobs are thought to have been lost in the EU pharmaceuticals sector as a result of the trade in counterfeit pharmaceuticals. Pharmaceutical companies in the USA and throughout Europe (France, Germany and Switzerland in particular), have also seen their IPR infringed with ostensible impunity leading to lost sales, loss of reputation and increased expenditure on brand protection and enforcement. Although such commercial concerns may initially seem superficial in comparison to the public health impact, when considering the raison d’être of trade marks to serve as a guarantee of the origin of the products, there is a clear and material nexus between the infringement of those IPR and the detriment of public health.

Intellectual Property and the Pharmaceutical Sector

The Report states that the global pharmaceutical sector saw estimated sales of US$1.2 trillion in 2018, with a growth of 6.3 percent during the period of 2014 to 2018. The Report attributed this growth, and an expected increase of 3 percent to 6 percent by 2023, to demand driven by the USA and emerging markets in countries such as China. As such, the potential value of transformative pharmaceutical products and the substantial investment that is required in terms of research, development and clinical trials means that the IPR of pharmaceutical products are fiercely protected. In this light, the Report notes that the number of registered trade mark applications covering pharmaceutical products continues to rise, with 390,888 registered in 2016 compared to 282,311 registrations in 2013. In 2016, this accounted for 4.3 percent of the world registered trade mark applications making pharmaceuticals the 4th most intense industry in terms of trade mark applications (the highest number of applications in 2016 were in China followed by India, the USA and the EU). The number of patent applications for products related to the pharmaceutical industry also continues to grow year on year, with the industry now ranking 7th out of the 35 fields of technology found by the World Intellectual Property Office.

Given the value of trade mark and patent rights to the pharmaceutical industry these statistics are not surprising. Equally unsurprising is the fact that intellectual property infringement in the pharmaceutical sector directly correlates with the locations of the world’s largest pharmaceutical firms, with companies in the USA, Switzerland, the United Kingdom, France, Austria and Germany heavily impacted by the trade in counterfeit pharmaceuticals. As alluded to above, not only does this have a direct impact on consumers by eroding trust in trade marks as badges of origin, the detrimental financial consequences of the counterfeit trade on a company’s balance sheet have a material impact on budgets for R&D, which in turn indirectly impacts us all through the slowing of innovation.

The Significance of the Challenge

A myriad of counterfeit pharmaceutical products are discovered at borders, including many which are purported to treat serious life threatening conditions such as, HIV/AIDS, cancer, epilepsy, heart disease and blood pressure issues. Consequently, the hope remains that the severity of the issue will lead to improved solutions.

However, the problem appears set to worsen for customs authorities given the significant challenges in detecting counterfeit pharmaceuticals at international borders. Primarily, this is because counterfeit medicines mimic the packaging of the authentic products and the counterfeiters are becoming ever more adept at copying the packaging perfectly to cloak their illegitimacy. Depending on the nature of the product, identifying counterfeit medicines can require an expert examination of the product itself to verify its authenticity, or further scientific testing which is both time-consuming and costly2. In addition, the modernisation of transport, such as small postal shipments, the rise of e-commerce and the growth of free trade zones have compounded the global pharmaceutical supply chain’s vulnerabilities in favour of unscrupulous traders. Time constraints mean that smaller packages in particular are more difficult to detect at international borders and have the added cost-benefit to the counterfeiter namely that, if detected, only a small volume of counterfeit drug is impounded.

The lifecycle of counterfeit medicinal products also makes them difficult to track. The packaging is often made in a different location to the product, with assembly taking place in a further jurisdiction. In 2016, India was the main provenance economy of counterfeit pharmaceuticals, (accounting for 53 percent) followed by China (accounting for 30 percent between 2014 and 2016), the UAE (4 percent) and Hong Kong (4 percent). During the same period, the main transitional hubs for counterfeit medicines were the UAE, Hong Kong, Egypt, Cameroon, Turkey, Singapore and Iran (with Switzerland and the USA serving as specific transitional jurisdictions for counterfeit medication destined for Europe).

Counterfeiters also readily exploit the nature of the medicinal supply chain. Doctors that prescribe medication do not administer it directly to patients and the intermediary pharmacists obtain the drugs from wholesalers creating a complex network. Clearly, when multiple suppliers are used, it becomes easier to mask the origin of goods and facilitates a less onerous route into the supply chain. This problem is exacerbated in developing countries where secure, regulated distribution is less common.

The scale of the problem has also risen in all territories especially with the proliferation of rogue on-line pharmacies which provide counterfeit products at a discounted price. Consumers have shown a propensity to purchase such products online despite the potential risks of doing so and, critically, this problem has also spread significantly to social media (according to Pfizer, between 2015 and 2018, more than 10,000 Facebook and 1,000 Instagram accounts were identified and reported for selling counterfeit Pfizer products).

Preventative Measures

The trade in counterfeit pharmaceuticals is attractive as it combines high profitability with a low risk of prosecution and weak penalties. As explained above, it is also an incredible challenge to combat. Nevertheless, governments and industry have been working in unison to try to fight the problem through actions including legislation, enforcement and awareness raising campaigns. International initiatives have also been launched including programmes run by Interpol and the World Health Organisation. For example, in 2008 INTERPOL initiated ‘Operation Pangea’ targeting the online sale of counterfeit and illicit medicines and medical devices. Each year participating agencies (the number of countries participating in the operation increased from 8 to 123 between 2008 and 2017) undertake co-ordinated activities in the same week against illegal websites to identify the criminal networks behind the trafficking. In the 2018 operation, authorities from 116 countries made 859 arrests worldwide and seized US$14 million worth of potentially dangerous pharmaceuticals and 500 tonnes of illicit pharmaceuticals.

From a legislative perspective, the Falsified Medicines Directive (the “Directive”) implemented a number of new steps to tackle the growing counterfeit pharmaceuticals market in the EU, including the requirement of printing a unique identifier encoded in a two-dimensional barcode on each unit of product, together with an anti-tampering device on the outer packaging and obligating those who are authorised to dispense medicines to the public to authenticate the products (requiring them to visually check the anti-tamper device and perform a verification scan of the barcode at the point of supplying the product to the public). To seek to address the panoply of problems posed by online sales, the Directive requires online retailers to display an encrypted logo which enables visitors to check the validity of the website under the Directive (an equivalent encrypted logo operating on similar lines has also been introduced in the UK by the Royal Pharmaceutical Society of Great Britain).

Pharmaceutical companies have also sought to address some of the problems themselves. For example, to seek to combat the social media problems referred to above, Pfizer introduced steps such as blocking and filtering terms associated with their business and developing new technology to identify when a person is trying to sell drugs online.

Conclusion and moving forward

Despite the various measures adopted to date, the continuing threat posed by counterfeit pharmaceuticals to public and social health is staggering. Criminals are continually exploiting weaknesses found both at international borders and in the pharmaceutical supply chain. The accessibility of online pharmacies and the willingness of consumers to purchase pharmaceutical goods from those online outlets without knowing their provenance (or having to attend a pharmacy or obtain a Doctor’s prescription) means that the market for counterfeit pharmaceuticals continues to proliferate. A growing consumer base and unregulated market place online mean that illegal medicinal products will continue to penetrate even the most well-regulated jurisdictions.

Advances in technology are ostensibly the obvious way to combat the problem, but a lack of financial resources at government level (or a willingness to deploy those resources to confront this issue) may continue to limit their success (and on the flip side, the counterfeiters can also use advances in technology to their own benefit). To this author, educational campaigns at a national and international level targeting users of online pharmacies and highlighting the inherent risks of doing seem worthy of further significant investment (especially in view of their relative simplicity and cost effectiveness, compared to international operations targeting criminal networks) and such schemes can involve joint efforts between governments and pharmaceutical companies. At a time where various vaccinations are being launched globally to fight COVID-19, never before has the need for such a campaign been more pressing. Indeed, given the decimation of the health and economy of almost every nation on the planet from the impact of COVID-19, the risk of counterfeit COVID-19 vaccines entering the market is a very clear and present danger. This might provide the global community with a renewed impetus to reinforce their efforts to combat the scourge of counterfeit pharmaceuticals.

### adv 1

#### Specifically, counterfeits link turn their South Africa scenario – they are the most pressing problem, massively destabilizes the entire continent, which outweighs

Aminu et al 17 (Nafiu Aminu – School of Pharmaceutical Sciences @ Universiti Sains Malaysia; Abubakar Sha’aban – Faculty of Pharmaceutical Sciences @ Usmanu Danfodiyo University; Abdulhakim Abubakar – Faculty of Pharmaceutical Sciences @ Ahmadu Bello University; Mahmud S. Gwarzo – Faculty of Pharmaceurical Sciences @ Bayero University Kano, “Unveiling the peril of substandard and falsified medicines to public health and safety in Africa: Need for all-out war to end the menace”, https://journals.sagepub.com/doi/pdf/10.5301/maapoc.0000023, Med Access @ Point Care, e145-e152, 23 December 2017, EmmieeM)

There are many problems bedeviling most of the African countries that require holistic and urgent attention, and one of them is the proliferation and circulation of substandard and falsified medicines (SFM). This has grossly affected the healthcare systems and treatment outcomes in the African continent. The menace of SFM is not receiving adequate attention in the region with regards to decisively abating and tackling it. The United Nations Sustainable Development Goals’ Article No. 3.8. is targeted access to safe, effective, quality, and affordable essential medicines (1, 2). However, this goal seems to be unachievable in the near future in low income African nations because of the menace of SFM. SFM are still taking a devastating toll on human lives silently and regularly, especially in poor African, Asian, and Latin American countries (3).

Substandard or sometimes poisonous medicines can harm patients directly by compromising the treatment of many life-threatening diseases in these countries. An estimated 627,000-1,238,000 deaths occur each year as a result of malaria – the majority of which are in Africa (4). A study conducted in the sub-Saharan African countries on the cause of mortalities associated with poor quality medicines, which were referred to as “falsified, substandard, or degraded” antimalarial medicines, revealed that 122,350 children under 5 years old died in 2013 alone due to reliance on poor-quality antimalarial medicines for the treatment of malaria (4).

Although adulteration, falsification, and fraudulent manufacture of medicines is not a new problem, the recent expansions in industrialization and trade have aggravated the scale of the problem (5). The global sales of falsified medicines are rising significantly, which is evident by the increasing number of countries that report breaches of their supply chain, as well as product falsifications (6). The reported scale of this crime and its potential hazardous effects on the health of the public is quite alarming. In January 2017, it was reported that 113 million potentially dangerous and illicit medicines (estimated to be worth €52 million) were seized during an operation called Action Against Counterfeit and Illicit Medicines (ACIM) which was conducted in the African continent in September 2016 (7). The operation, which lasted 10 days, was jointly organized by the World Customs Organization (WCO) and the International Institute for Research Against Counterfeit Medicines (IRACM), and it involved 16 African customs administrations, with the largest interceptions in Nigeria, Benin Republic, Kenya, and Togo (7). According to the World Health Organization (WHO), between 2005 and 2010, the sales of SFM increased up to 90%, and the market size surpassed US$75 billion (8) – or between US$70 billion and US$200 billion, according to another source (9). It is estimated that about 15% of total medicines sold worldwide are SFM (10). This percentage can be as high as 70% in some parts of Africa and Asia (9). Asia accounts for the largest volume of the trade of SFM (8), with China and India being the major sources (3, 11, 12), and recently Russia became involved (9). Internet marketing of pharmaceuticals through online chemists has further contributed to the pervasion of SFM (10). WHO estimates that up to 50% of the medicines being sold on the internet are fake (9).

Despite the report that a lot of people suffer unnecessarily prolonged illness or become disabled or even die due to lack of adequate access to effective healthcare rather than because of medicine falsification (13), curbing medicine falsification is still pertinent to effective healthcare delivery. A safe, reliable, effective, qualitative and affordable medicine is essential for quality healthcare delivery, but unfortunately, this is largely missing in nations with weak regulatory bodies (14), many of them in Africa. This prompted the call for strengthening the drug regulatory systems, especially in the African continent. Poor-quality medicines lead to a compromise in the therapy of chronic and infectious diseases, which, in turn, could result in drug resistance, worsening of the disease, and ultimately death (5). A strong drug regulatory system is required to overcome the menace of SFM and its consequences (15).

The problem of SFM is not limited to African continent alone; it is a global phenomenon that has spread to even highly regulated countries in Europe and America (16). This emphasizes the need for sound collaborative efforts between the national drug regulatory authorities in Africa and the rest of the world, along with the WHO, nation states’ governments, pharmacies, pharmaceutical manufacturers, enforcement agencies (e.g. Police, Customs, Immigration), legitimate drug supply organizations and nongovernmental organizations (NGOs), in order to effectively fight the menace of SFM by disrupting its supply chains and bringing the culprits to justice, as well as preventing the medicines from reaching the innocent patients (13, 17, 18).

However, it is worth mentioning that there have been commendable increased efforts in Africa to counter the menace of SFM in recent years by both national and international regulatory agencies. The inter-governmental operations that led to the seizures of counterfeit and illicit medicines in the continent over the last few years, which amounted to around 900 million packets of SFM, is a good step in the right direction (7). In another development, a recent study conducted to determine substandard and falsified antimicrobial medicines’ prevalence in faith-based and public healthcare centers of part of Malawi revealed some encouraging findings, because out of the 155 samples investigated, only 1 sample was found to be falsified and 6 were found to be substandard medicines (1). The drug regulatory agencies in Nigeria, Ghana, Kenya, Rwanda, and a few other countries have intensified their efforts in curbing the menace by employing state of the art detection instruments and increasing public awareness (3, 15, 18). The recent amendment and passage of falsified related medicines bill in Nigeria into law, which provided tough penalties, such as life imprisonment and expensive fines for SFM offenders, is also a remarkable development (19). Ziemer (20), in his correspondence, argued that although there is a need for regulatory authorities of medicines in Africa to be strengthened, important progress is being made (20). Although these recent developments are highly commendable but the prevailing SFM pandemic signifies that they are grossly inadequate for the attainment of the desired quality of healthcare delivery and for safeguarding the public health in the region.

This review was aimed to update its readers on the latest dangers posed by SFM to the African healthcare sector and to public safety. The magnitude and the actions being taken to address the problem have been extensively discussed.

Definitions

There is lack of consensus on a common definition of what constitutes falsified/counterfeit medicine, as the current definitions vary from one country to another (21). This disagreement had a negative impact on the efforts to stop the SFM peril in developing countries. According to the WHO, counterfeit medicine is defined as “the one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with an insufficient active ingredient or with fake packaging” (22). The term “counterfeit” is increasingly being replaced with “falsified” because of the argument for emphasis on intellectual property rights and commercial interests rather than public health and safety (23, 24). Therefore, we avoid using “counterfeit” in this article because of these concerns.

In a typical expression, falsified medicines were referred to as those medicines that have been fraudulently fabricated and distributed and which failed to meet the quality criterion for that particular medicine (18). The meaning of other related terms has been defined elsewhere, such as substandard (out of specification), unregistered/unlicensed (25), degraded, poor quality (18), and fake medicines (5). Among these terms, counterfeit, falsified, fake and substandard medicines are used interchangeably (11, 26), so we grouped them under the umbrella of “substandard and falsified medicines (SFM),” except in some areas where the original source of information specifically referred to a particular term

The WHO, in its 70th World Health Assembly, adopted the term “Substandard and Falsified (SF) medical products” to replace the erstwhile term “substandard/spurious/falselylabelled/falsified/counterfeit (SSFFC)” (25). This is part of its effort to promote a universal understanding of SF, global data comparison and analysis, and to redirect stakeholders to the public health implications of SF rather than debating over intellectual property rights.

Extent of the problem

The clinical effect of substandard and falsified medicines in Africa

Falsification of medicines may have a number of clinical consequences ranging from poisoning, drug resistance, treatment failure, the masking of clinical symptoms of ailments, and ultimately death in the worst cases. There are some reported poisoning incidences in Africa, which occurred as a result of the contamination of medicines. In 2008, a tragic incident occurred in Nigeria where many children developed acute kidney injury and later died due to the consumption of a supposed teething problem remedy called “My Pikin,” which was contaminated by the inadvertent or deliberate addition of diethylene glycol (DEG) as a solvent in place of propylene glycol (27-29). DEG is cheap but lethal, and it looks, smells, and tastes like glycols and glycerine, which are harmless but more expensive (27). Similar incidences happened earlier where the same DEG was used instead of propylene glycol in South Africa in 1969 and in Nigeria in 1990, which resulted in 7 and 47 deaths, respectively (27). In another tragic story, a Ghanaian woman developed a serious skin cancer when she consumed SFM that contained a carcinogenic substance (3).

Consumption of SFM – especially antibiotics, antimalarials, and other antimicrobials – by patients may result in the subtherapeutic blood concentration of such medicines, and that may lead to drug resistance (15, 30) and/or treatment failure (31). A study of uterotonic medicines in Ghana found that 89% of the analyzed samples were less than the requirements of British Pharmacopoeia for an active pharmaceutical ingredient (API) (32). Postpartum hemorrhage was the primary cause of 16.8% (33) and 22.5% (34) of maternal deaths in Ghanaian hospitals during the study period (33, 34). Although the deaths were not directly linked to SFM, but considering the high level of substandard injectable uterotonic medicines (ergometrine and oxytocin) found in a region of Ghana (32), it may be reasonable to speculate that SFM has contributed to the problem, since it is these medicines that are mainly used for both inducing labor and controlling postpartum hemorrhage in the country.

A team of researchers investigated the quality of metformin tablets in Nigeria and found that half of the popular tablet’s products that were sampled failed at least 1 pharmacopoeia test of bioequivalence (5). A similar study, which was conducted to assess the stability of medicines in Rwanda revealed that up to 20% of the medicines sampled was substandard at the time of purchasing them in public and private pharmacies (5). These are the kinds of medicine hazards that could lead to the deterioration of a patient’s condition and to treatment failure. For example, the incidence of recrudescence of seizures and death due to falsified antiepileptic medicines were reported in Guinea-Bissau and Nigeria (35). In Uganda, an appalling incidence of lethal bacterial meningitis, which is likely due to substandard ceftriaxone, was reported (36). A patient (an adolescent boy) failed to respond to the treatment and eventually died after being treated according to the Standard Treatment Guideline. As part of the investigation of what possibly caused the treatment failure and eventual death of the patient, an untampered vial of a similar ceftriaxone product that was used to treat the patient was sent for analysis by mass spectrometry at the University of Ottawa, Canada. The result revealed that the product contained only 0.455 g of the API, which was contrary to the claimed 1 g by its manufacturer (36). This means that a subtherapeutic dose of ceftriaxone had been administered to the patient, if similarly compromised vials of the product were used on him, and this may have contributed to the failure of the treatment (36). The fact that the report highlighted limitations – some of which arose from resource-poor settings, such as deficiency of reliable diagnostic tools, delayed or inadequate interventions, and an uncertainty as to whether the analyzed vial belonged to the same lot as those used to treat the patient – precluded a 100% causal link to the substandard ceftriaxone. However, the finding that the analyzed ceftriaxone contained less than 50% of the stated API cannot be ignored, because therapy of bacterial meningitis with such a product has a high propensity of causing drug resistance, treatment failure, and/or death. Therefore, substandard or falsified ceftriaxone medicine may be a contributing factor to the problem of treatment failure in bacterial meningitis therapy in Africa (36).

Findings from a review article, which included 21 surveys of antimalarial medicines from 21 countries in subSaharan Africa, revealed that from the analyzed samples, 35% (796/2297) failed chemical analysis and 20% (79/389) were identified as falsified medicines (37). Similarly, a survey that was conducted in parts of Africa and Asia to evaluate the level of SFM in 10 faith-based drug supply organizations using a low-cost Global Pharma Health Fund (GPHF) Minilab, revealed that 2.4% (i.e., 21 out of 869) of the tested samples were confirmed to be substandard or falsified medicines (17). GPHF is a charitable organization assisted by a pharmaceutical company from Germany (Merck KGaA), while its Minilab is a detection technology that is capable of analyzing up to 85 different essential medicines by using thin-layer chromatography (TLC). The GPHF Minilab is a simple detection tool that can be used as a field test kit to identify and estimate the amount of API (17). The results of the SFM surveillance shows that Cameroon possessed the highest proportion of SFM, followed by the Democratic Republic (D.R.) of Congo, and Nigeria, and that antimalarial medicines have the highest frequency of falsification among the medicines studied (17). In Malawi, a falsified antimalarial tablet product, which contained a mixture of paracetamol and co-trimoxazole tablets instead of the claimed sulfadoxine/pyrimethamine tablets, was detected by the GPHF Minilab and confirmed by high performance liquid chromatography (HPLC) (33). The absence of the declared antimalarial agent and the presence of another API (paracetamol and co-trimoxazole), which can mask the feverish symptoms of malaria, represented a potential threat to public health (38).

The economic effects of substandard and falsified medicines in Africa

Besides the discussed clinical and public health consequence associated with SFM in Africa, SFM also constitutes a substantial economic problem for the patients, the pharmaceutical companies, and the governments in the continent. This economic effect is like a chain reaction, whereby one factor may lead to the other. The SFM may inflict economic burden on: (i) individual patients and their families, by wasting their funds in the purchase of useless, if not harmful, medicines, which, unknown to them, are SFM; (ii) legitimate pharmaceutical companies, by losing huge revenues due to competition for the market with SFM; and (iii) the governments, through the loss of revenue from unpaid taxes and spending money in fighting the SFM menace (3, 5, 21, 39).

The global market size of falsified medicines has been estimated to reach about US$75 billion annually (6, 39, 40), which is far less than the estimated 2016 global pharmaceutical market value of US$1,105 billion (41). This could be a potential opportunity cost attributable to global SFM business. In Africa, the estimates of the United Nations Office on Drugs and Crime (UNODC) for the sales of falsified antimalarial medicines in West Africa alone is US$438 million (12), which indicated a huge market loss for pharmaceutical companies that manufacture and trade legitimate antimalarial medicines in this region. This amount, which is being lost for antimalarial medicines alone, has exceeded the Gross Domestic Product (GDP) of Guinea-Bissau (42).

Falsified medicines have caused governments in African countries to lose tax revenues estimated to be worth hundreds of millions of U.S. dollars. The East African countries, which include Tanzania, Burundi, Kenya, Uganda, and Rwanda, have reported unremitted taxes related to falsified medicines and other goods to be more than US$500 million, and the worst scenario is in Tanzania, which is annually losing up to US$617 million as a result of tax evasion associated with falsified products (42). The overall detrimental effects of SFM in Africa could lead to: (i) loss of revenues by pharmaceutical firms and governments; (ii) poor or no investment from industrialized countries due to fear of losing revenue to counterfeiters; and (iii) job losses.

Inadequate health financing in Africa is another obstacle that has further compounded the healthcare problem in the region. The weaker economy of some African countries, increasing healthcare costs, and the recent economic downturn arising as a result of a crash in the price of crude oil (which was heavily relied upon by some of the African countries such as Nigeria, Angola, D.R. Congo, Sudan, etc.) may have contributed to the acute shortage of funds that prevent adequate financing of healthcare sectors in some African countries. However, lack of commitment by the government of these countries is another key setback, which has further exacerbated poor health financing, as the majority of the countries failed to fulfil the year 2001 adopted Abuja Declaration, which set a target of allocating a minimum of 15% of the annual budget for each member state to its health sector (43). As of 2011, only Rwanda and South Africa were able to achieve the “at least 15%” target of the Abuja Declaration (43). Similarly, a report from the WHO revealed that the average total health expenditure for the year 2010 in African countries to be US$135 per capita, which is more than 20 times less than the one spent (i.e., US$3,150) by affluent countries (44). The majority of African citizens are not covered by a reliable and affordable health insurance scheme. It is reported that household out-of-pocket payments account for 40% or more of the total health expenditure in about half of the African nations, and this may create financial barriers that may block people from accessing health services, and may put them at the risk of impoverishment (44). To address this problem, there is an urgent need for the African countries to significantly improve the funding of their health systems. Affordable insurance schemes should be provided to enhance access to quality health services by the populace. This may reduce demands for cheaper medicines, which in many cases are SFM.

The social effects of substandard and falsified medicines in Africa

The healthcare systems in the majority of African countries are underdeveloped. SFM further undermine the already weak confidence in all public health institutions as well as the entire healthcare system in many African countries. Victims of SFM are usually unaware they are victims (5); what they often think is that they are not responding well to the treatment. This sometimes creates mistrust in pharmacies, and in the physicians because the patients question the accuracy of their diagnosis. A systematic review suggests that patients in approximately 39 Sub-Saharan African countries and some parts of Asia have a negative impression on their healthcare systems. They are especially doubtful of the staffs’ clinical skills and professional competence, and the availability of medicines (45).

The proliferation and trade of SFM can cause other social troubles such as: (i) encouraging corruption, as many counterfeiters use bribery to persuade corrupt officials responsible for regulating the import and circulation of medicines; (ii) increasing criminal activities, as the business is often conducted by criminal cartels that usually generate huge amounts of money from the sale of falsified medicines and use it to purchase ammunition, cause public disorder, and influence corrupt officials (12, 46); and (iii) deteriorating the already weak political infrastructure that permits their continuous circulation (5).

#### Haven’t read ev about south african war, just african, so doesn’t matter

**No African war – empirics, too expensive, not effective.**

**Hendrix & Salehyan ‘11** (Dr. Cullen Hendrix is Assistant Professor at the University of North Texas, Research Associate at the Centre for the Study of Civil War at the International Peace Research Institute, Oslo, and Associate at the Robert S. Strauss Center for International Security and Law. Dr. Idean Salehyan is Assistant Professor at the University of North Texas and Associate at the John Goodwin Tower Center for Political Studies at Southern Methodist University, the International Peace Research Institute, Oslo, and the Robert S. Strauss Center for International Security and Law. “The Brewing Storm? Climate Change, Rainfall, and Social Conflict in Africa,” February 2011, CCAPS - Climate Change and African Political Stability, http://ccaps.strausscenter.org/system/research\_items/pdfs/43/original.pdf?1299598361)

Traditionally, the study of conflict has been dominated by a focus on international and civil war, where at least one of the combatants is a government. Yet, interstate war has been **extremely rare** in Africa. (One notable exception is the Ethiopia-Eritrea conflict in the late 1990s.) And while civil wars and insurgencies have occurred more often than warfare between states, they are still relatively uncommon given the high cost of mobilizing, financing, and equipping rebel armies. Moreover, civil wars are predicated on people’s belief that the central government is the most appropriate target of action. If conflict is about competition over scarce water and land, then attacking the government is only useful if the government effectively controls those resources or has the power to redistribute them within society— preconditions that are not met in many African states. Often, it is easier to take resources from a neighboring community than to challenge the state and its armed forces. And if a constituency is politically important, then peaceful opposition activities are often sufficient to secure the group’s goals. Given the above, it seems far from clear that competition over dwindling resources and scarce arable land will lead directly to interstate war or rebellion in Africa. More likely, one would expect that environmental stress will provoke economic downturns and food insecurity, which in turn will spark episodic demonstrations, riots, labor unrest, and communal conflicts—and such conflicts may target not only governments but non-state actors too, such as tribal groups, private citizens, and corporations. If not addressed, these conflicts can contribute to long-term state fragility.

#### Impact turn

### adv 2

#### somos is wrong – just says that there could be an increase in conflict, not that the countries would escalate with each other

#### No Indo-Pak war – history proves de-escalation

* History proves:
* Kargil war ended without escalation
* Terror attacks in ’01 and ’02 didn’t cause war
* Pakistan military doesn’t want war, neither does Modi
* Both leaders understand MAD – speeches prove
* Current moves are theatrics and unlikely to escalate

Ganguly 3/5**/19** [Sumit Ganguly is Distinguished Professor of Political Science and Rabindranath Tagore Chair in Indian Cultures and Civilizations at Indiana University, Bloomington. Why the India-Pakistan Crisis Isn’t Likely to Turn Nuclear. March 5, 2019. https://www.foreignaffairs.com/articles/india/2019-03-05/why-india-pakistan-crisis-isnt-likely-turn-nuclear]

Worried analysts now fear that, since India and Pakistan have breached the informal norm against using air power across the border, they will be unable to prevent further escalation. Hawkish publics in both countries are calling for retaliation. Can the politicians exercise restraint?

THE LESSONS OF HISTORY

No one can say for sure, but history suggests that there is cause for optimism. During the Kargil War, India worked to contain the fighting to the regions around Pakistan’s original incursions and the war concluded with no real threat of nuclear escalation.

Less than two years later, the two countries plunged into crisis once again. In December 2001, five terrorists from the Pakistan-based groups Lashkar-e-Tabia and Jaish-e-Mohammed attacked the parliament building in New Delhi with AK-47s, grenades, and homemade bombs, killing eight security guards and a gardener. In response, India launched a mass military mobilization designed to induce Pakistan to crack down on terrorist groups. As Indian troops deployed to the border, terrorists from Pakistan struck again. In May 2002, three men killed 34 people in the residential area of an Indian army camp in Kaluchak, in Jammu and Kashmir. Tensions spiked. India seemed poised to unleash a military assault on Pakistan. Several embassies in New Delhi and Islamabad withdrew their nonessential personnel and issued travel advisories. The standoff lasted for several months, but dissipated when it became apparent that India lacked viable military options and that the long mobilization was taking a toll on the Indian military’s men and materiel. The United States also helped ease tensions by urging both sides to start talking. India claimed victory, but it was a Pyrrhic one, as Pakistan failed to sever its ties with a range of terrorist organizations.

Other nuclear states have also clashed without resorting to nuclear weapons. In 1969, China, then an incipient nuclear weapons state, and the Soviet Union, a full-fledged nuclear power, came to blows over islands in the Ussuri River, which runs along the border between the two countries. Several hundred Chinese and Soviet soldiers died in the confrontation. Making matters worse, Chinese leader Mao Zedong had a tendency to run risks and dismissed the significance of nuclear weapons, reportedly telling Indian Prime Minister Jawaharlal Nehru that even if half of mankind died in a nuclear war, the other half would survive and imperialism would have been razed to the ground. Yet despite Mao’s views, the crisis ended without going nuclear, thanks in part to the efforts of Soviet Prime Minister Alexei Kosygin, who took the first step by travelling to Beijing for talks.

There’s reason to believe that the current situation is similar. Pakistan’s overweening military establishment undoubtedly harbors an extreme view of India and determines Pakistan’s policy toward its neighbor. The military, however, is not irrational. In India, although Prime Minister Narendra Modi has a jingoistic disposition, he, too, understands the risks of escalation, and he has a firm grip on the Indian military.

Another source of optimism comes from what political scientists call the “nuclear revolution,” the idea that the invention of nuclear weapons fundamentally changed the nature of war. Many strategists argue that nuclear weapons’ destructive power is so great that states understand the awful consequences that would result from using them—and avoid doing so at all costs. Indian and Pakistani strategists are no different from their counterparts elsewhere. Even Pakistani Prime Minister Imran Khan, a political neophyte, underscored the dangers of nuclear weapons in his speech addressing the crisis last week. And Modi, for all his chauvinism, has scrupulously avoided referring to India’s nuclear capabilities.

The decision by India and Pakistan to allow their jets to cross the border represents a major break with the past. Yet so far both countries have taken only limited action. Their principal aim, it appears, is what the political scientist Murray Edelman once referred to as “dramaturgy”—theatrical gestures designed to please domestic audiences. Now that both sides have gone through the motions, neither is likely to escalate any further. Peering into the nuclear abyss concentrates the mind remarkably.

### adv 3

#### not reading jecker and aruire will be their downfall – means they have no reverse causal ev that the aff solves anything so the turn ow/s

#### pro patent arg makes 0 sense against our turn – we don’t need to say

#### Pandemics doesn’t cause extinction.

Halstead 19 John Halstead, doctorate in political philosophy. [Cause Area Report: Existential Risk, Founders Pledge, https://founderspledge.com/research/Cause%20Area%20Report%20-%20Existential%20Risk.pdf]//BPS

However, there are some reasons to think that naturally occurring pathogens are unlikely to cause human extinction. Firstly, Homo sapiens have been around for 200,000 years and the Homo genus for around six million years without being exterminated by an infectious disease, which is evidence that the base rate of extinction-risk natural pathogens is low.82 Indeed, past disease outbreaks have not come close to rendering humans extinct. Although bodies were piled high in the streets across Europe during the Black Death,83 human extinction was never a serious possibility, and some economists even argue that it was a boon for the European economy.84 Secondly, infectious disease has only contributed to the extinction of a small minority of animal species.85 The only confirmed case of a mammalian species extinction being caused by an infectious disease is a type of rat native only to Christmas Island. Having said that, the context may be importantly different for modern day humans, so it is unclear whether the risk is increasing or decreasing. On the one hand, due to globalisation, the world is more interconnected making it easier for pathogens to spread. On the other hand, interconnectedness could also increase immunity by increasing exposure to lower virulence strains between subpopulations.87 Moreover, advancements in medicine and sanitation limit the potential damage an outbreak might do.

**variations and adaption solve any future pandemics**

Amesh **Adalja 16**, infectious-disease physician at the University of Pittsburgh, 6/17/16, “Why Hasn't Disease Wiped out the Human Race?,” <https://www.theatlantic.com/health/archive/2016/06/infectious-diseases-extinction/487514/>

But when people ask me if I’m worried about infectious diseases, they’re often not asking about the threat to human lives; they’re asking about the threat to **human life**. With each outbreak of a headline-grabbing emerging infectious disease comes a fear of **extinction itself**. The fear envisions a large proportion of humans succumbing to infection, leaving no survivors or so few that the species can’t be sustained. I’m not afraid of this apocalyptic scenario, but I do understand the impulse. Worry about the end is a quintessentially human trait. Thankfully, **so is our resilience**. For most of mankind’s history, infectious diseases were the existential threat to humanity—and for good reason. They were quite successful at killing people: The 6th century’s Plague of Justinian knocked out an estimated 17 percent of the world’s population; the 14th century Black Death decimated a third of Europe; the 1918 influenza pandemic killed 5 percent of the world; malaria is estimated to have killed half of all humans who have ever lived. Any yet, of course, humanity continued to flourish. Our species’ recent explosion in lifespan is almost exclusively the result of the control of infectious diseases through sanitation, vaccination, and antimicrobial therapies. Only in the modern era, in which many infectious diseases have been tamed in the industrial world, do people have the luxury of death from cancer, heart disease, or stroke in the 8th decade of life. Childhoods are free from watching siblings and friends die from outbreaks of typhoid, scarlet fever, smallpox, measles, and the like. So what would it take for a disease to wipe out humanity now? In Michael Crichton’s The Andromeda Strain, the canonical book in the disease-outbreak genre, an alien microbe threatens the human race with extinction, and humanity’s best minds are marshaled to combat the enemy organism. Fortunately, outside of fiction, there’s no reason to expect alien pathogens to wage war on the human race any time soon, and my analysis suggests that any real-life domestic microbe reaching an extinction level of threat probably is just as unlikely. Any apocalyptic pathogen would need to possess a very special combination of two attributes. First, it would have to be so unfamiliar that no existing therapy or vaccine could be applied to it. Second, it would need to have a high and surreptitious transmissibility before symptoms occur. The first is essential because any microbe from a known class of pathogens would, by definition, have family members that could serve as models for **containment and countermeasures**. The second would allow the hypothetical disease to spread without being detected by even the most astute clinicians. The three infectious diseases most likely to be considered extinction-level threats in the world today—influenza, HIV, and Ebola—don’t meet these two requirements. Influenza, for instance, despite its well-established ability to kill on a large scale, its contagiousness, and its unrivaled ability to shift and drift away from our vaccines, is still what I would call a “known unknown.” While there are many mysteries about how new flu strains emerge, from at least the time of Hippocrates, **humans have been attuned to its risk**. And in the modern era, a full-fledged industry of influenza preparedness exists, with effective vaccine strategies and antiviral therapies. HIV, which has killed 39 million people over several decades, is similarly limited due to several factors. Most importantly, HIV’s dependency on blood and body fluid for transmission (similar to Ebola) requires intimate human-to-human contact, which limits contagion. Highly potent antiviral therapy allows most people to live normally with the disease, and a substantial group of the population has genetic mutations that render them impervious to infection in the first place. Lastly, simple prevention strategies such as needle exchange for injection drug users and barrier contraceptives—when available—can curtail transmission risk. Ebola, for many of the same reasons as HIV as well as several others, also falls short of the mark. This is especially due to the fact that it spreads almost exclusively through people with easily recognizable symptoms, plus the taming of its once unfathomable 90 percent mortality rate by simple supportive care. Beyond those three, **every other known disease** falls short of what seems required to wipe out humans—which is, of course, why we’re still here. And it’s not that diseases are ineffective. On the contrary, diseases’ failure to knock us out is a testament to just how resilient humans are. Part of our evolutionary heritage is our immune system, one of the most complex on the planet, even without the benefit of vaccines or the helping hand of antimicrobial drugs