# 1NC v Westwood PM

### 1NC – Off

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

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

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

#### It applies to medicines:

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

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

#### Violation: the aff only defends medicines that use indigenous knowledge

#### Vote neg:

#### Semantics outweigh:

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

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

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

#### There are over 20,000 affs

FDA 11/18 [(U.S. Food and Drug Administration, federal agency of the Department of Health and Human Service) “Fact Sheet: FDA at a Glance,” 11/18/2020] JL

There are over 20,000 prescription drug products approved for marketing.

FDA oversees over 6,500 different medical device product categories.

There are over 1,600 FDA-approved animal drug products.

There are about 300 FDA-licensed biologics products.

#### Ground – spec guts core generics like innovation that rely on reducing IP for all medicines because individual medicines don’t affect the pharmaceutical industry broadly – also means there is no universal DA to spec affs

#### TVA solves – read as an advantage to whole rez

#### Paradigm issues:

#### Drop the debater:

#### Their abusive advocacy skewed the debate from the start – 1NC construction was premised on

#### Deters abuse – debaters won’t read args they can’t win on – their interp means reading extra T affs has zero risk

#### Comes before 1AR theory – NC abuse is responsive to them not being topical

#### Competing interps – reasonability invites arbitrary judge intervention and a race to the bottom of questionable argumentation

#### Fairness is a voter ­– necessary to determine the better debater

#### Education is a voter – why schools fund debate

### 1NC - Off

#### Biotech industry strong now.

Cancherini et al. 4/30 [(Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company), “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide] TDI

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues.

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have more than 250 vaccine candidates in their pipelines, along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the top dozen pharma companies having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

#### IP protections for traditional knowledge are key to innovation

Ngatcha 20 [(Beatrice T., lawyer and patent agent in Lavery’s intellectual property group, patent agent registered to practice in Canada and the United States,member of the Quebec Bar, doctoral degree in chemistry from *Université Laval* and post-doctoral fellow at the National Research Council in Ottawa) “Natural Products and Pharmaceutical Innovations: What are the Patent Options?” Lavery, 5/29/2020] JL

Natural products play an important role in pharmaceutical innovation. They are active components in many medicines. For example, nearly half of the small molecules used to treat cancer are natural products or directly derived from natural products.[1](https://www.lavery.ca/en/publications/our-publications/3225-natural-products-and-pharmaceutical-innovations-what-are-the-patent-options-ip-intellectual-property.html#01) They are also components of vaccines.

The pharmaceutical industry is constantly seeking access to natural products and the traditional knowledge associated with them. These include plants (roots, bark, leaves), micro-organisms (terrestrial and marine), toxins, venoms and other natural biological agents.

In the current race to develop a drug and/or vaccine against COVID-19, natural products or derivatives are surely worth considering as a starting point.

The harvesting of natural resources for use by the pharmaceutical industry is usually carried out by partners such as traditional healers, farmers, academics or businesses. Thus, the process usually involves several stakeholders, including providers and users of natural resources and associated traditional knowledge, which are often located in different parts of the world.

Fair and equitable collaboration in such a context requires well-developed collaboration agreements and access and benefit-sharing agreements. Various instruments of international law encourage the signing of such agreements, including:

The Convention on Biological Diversity (CBD), which recognizes the sovereignty of states over their natural resources. The CBD sets out fundamental principles to regulate access and benefit-sharing, including that access to natural resources, their use and the sharing of benefits arising from them should be based on “mutually agreed terms.”[2](https://www.lavery.ca/en/publications/our-publications/3225-natural-products-and-pharmaceutical-innovations-what-are-the-patent-options-ip-intellectual-property.html#02)

The Nagoya Protocol covers the sharing of the results of research and development, the payment of royalties and joint ownership of intellectual property (IP) rights.[3](https://www.lavery.ca/en/publications/our-publications/3225-natural-products-and-pharmaceutical-innovations-what-are-the-patent-options-ip-intellectual-property.html#03)

The World Intellectual Property Organization (WIPO) has developed a guide to assist providers and users of natural resources and associated traditional knowledge in the negotiation and establishment of IP clauses in access and benefit-sharing agreements. The guide describes how IP rights can be exploited and managed to achieve the desired objectives, and how the benefits arising from the use can be created and shared in a fair and equitable manner, thereby promoting the conservation and use of biodiversity.[4](https://www.lavery.ca/en/publications/our-publications/3225-natural-products-and-pharmaceutical-innovations-what-are-the-patent-options-ip-intellectual-property.html#04)

Furthermore, research and development activities in the pharmaceutical industry are known to be associated with high risk and high investment costs. Indeed, it is widely recognized that the process to develop a drug can take up to 15 years, only about 16% of molecules entering the clinical phase will be approved, and only 1 in 5 marketed drugs generates revenues equal to or greater than the research and development costs involved.[5](https://www.lavery.ca/en/publications/our-publications/3225-natural-products-and-pharmaceutical-innovations-what-are-the-patent-options-ip-intellectual-property.html#05)

In the pharmaceutical industry, intellectual property, especially patents and data protection, is thus considered an essential instrument for securing the economic benefits of an innovation.

Efforts in this intense period of development of a drug/vaccine against COVID-19 are of course focused on the technical aspects directly related to research and development. Nevertheless, those involved should not lose sight of the importance of collaboration agreements and access and benefit-sharing agreements.

#### 50% of medicine comes from IK

Eiland 08 [Dr. Eiland received a doctorate in Oriental Archaeology from Oxford University and an LLM from the Munich Intellectual Property Law Center], “Patenting Traditional Medicine”, Nomos Verlagsgesellschaft mbH & Co. KG, pg. 7-10, 2008 //SLC PK

* TM = traditional medicine

In 1982, it was estimated that about 50 % of all filled prescriptions in the US originated from drugs that were derived – one way or another – from natural substances. This generated US sales of about 20 billion.4 Another estimate found that 3/4 of the plants used in prescription drugs originally came to the attention of drug companies because of their use in TM.5 In 1995, the worldwide market value of TM derived pharmaceuticals was estimated to be $43 billon.6 While one could argue about the precise values, TM has significant pharmaceutical applications. Drug companies are interested in acquiring TM, both natural substances, as well as the knowledge about how to use them.

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror.

Marjanovic and Feijao 20 [(Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon.) "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, https://www.rand.org/pubs/perspectives/PEA407-1.html] TDI

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

#### Extinction – defense is wrong

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

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

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

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

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-2

### 1NC – off

#### CP: Member nations of the World Trade Organization should enter into a prior and binding consultation with the World Health Organization over reducing intellectual property protections for medicines based on Indigenous knowledge. Member nations will support the proposal and adopt the results of consultation.

#### WHO says yes –

#### They supports increasing the availability of generics and limiting TRIPS

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

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

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

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

#### they supported the Nagoya Protocol

WHO 17 [“Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications,” World Health Organization, 2/1/2017] JL

The Nagoya Protocol provides a foundation, based on core principles, such as fairness and equity, for a global common approach to accessing pathogens, and sharing benefits arising from their use. As suggested by several respondents to this study, implementation of the Nagoya Protocol in the context of infectious diseases could help to (1) clarify and harmonize the ABS obligations associated with access to pathogens and (2) establish a fairer and more equitable approach for sharing the benefits derived from their use.

Increased clarity, fairness and equity could encourage timely sharing, which would support risk assessment and the development of medical countermeasures. In addition, predictable sharing of benefits could improve access to affordable treatments and help build capacities, such as disease surveillance, and research and development, particularly in developing countries. Through the sharing of benefits such as joint ownership of intellectual property, collaboration and acknowledgment of contributions, the Nagoya Protocol provides an opportunity for Member States to establish pathogensharing systems that support global health equity.

#### Statements on AIDs medicines prove -

WHO 06 [“Access to AIDS medicines stumbles on trade rules,” Bulletin of the World Health Organization, 2006] JL

The holders of traditional knowledge often face a dilemma. How can they benefit from their own traditional knowledge if they don’t patent it? Intellectual property rights are often regarded as incompatible with traditional knowledge because patents are based on innovations or discoveries and held exclusively, while traditional knowledge is collectively owned and based on prior use.

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

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

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

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

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

#### WHO is critical to disease prevention – it is the only international institution that can disperse information, standardize global public health, and facilitate public-private cooperation

Murtugudde 20 [(Raghu, professor of atmospheric and oceanic science at the University of Maryland, PhD in mechanical engineering from Columbia University) “Why We Need the World Health Organization Now More Than Ever,” Science, 4/19/2020] JL

WHO continues to play an indispensable role during the current COVID-19 outbreak itself. In November 2018, the US National Academies of Sciences, Engineering and Medicine organised a workshop to explore lessons from past influenza outbreaks and so develop recommendations for pandemic preparedness for 2030. The salient findings serve well to underscore the critical role of WHO for humankind.

The world’s influenza burden has only increased in the last two decades, a period in which there have also been 30 new zoonotic diseases. A warming world with increasing humidity, lost habitats and industrial livestock/poultry farming has many opportunities for pathogens to move from animals and birds to humans. Increasing global connectivity simply catalyses this process, as much as it catalyses economic growth.

WHO coordinates health research, clinical trials, drug safety, vaccine development, surveillance, virus sharing, etc. The importance of WHO’s work on immunisation across the globe, especially with HIV, can hardly be overstated. It has a rich track record of collaborating with private-sector organisations to advance research and development of health solutions and improving their access in the global south.

It discharges its duties while maintaining a dynamic equilibrium between such diverse and powerful forces as national securities, economic interests, human rights and ethics. COVID-19 has highlighted how political calculations can hamper data-sharing and mitigation efforts within and across national borders, and WHO often simply becomes a convenient political scapegoat in such situations.

International Health Regulations, a 2005 agreement between 196 countries to work together for global health security, focuses on detection, assessment and reporting of public health events, and also includes non-pharmaceutical interventions such as travel and trade restrictions. WHO coordinates and helps build capacity to implement IHR.

#### Extinction – defense is wrong

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

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

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

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-2

#### WHO diplomacy solves great power conflict

Murphy 20 [(Chris, U.S. senator from Connecticut serving on the U.S. Senate Foreign Relations Committee) “The Answer is to Empower, Not Attack, the World Health Organization,” War on the Rocks, 4/21/2020] JL

The World Health Organization is critical to stopping disease outbreaks and strengthening public health systems in developing countries, where COVID-19 is starting to appear. Yemen announced its first infection earlier this month, and other countries in Africa, Asia and the Middle East are at severe risk. Millions of refugees rely on the World Health Organization for their health care, and millions of children rely on the WHO and UNICEF to access vaccines.

The World Health Organization is not perfect, but its team of doctors and public health experts have had major successes. Their most impressive claim to fame is the eradication of smallpox – no small feat. More recently, the World Health Organization has led an effort to rid the world of two of the three strains of polio, and they are close to completing the trifecta.

These investments are not just the right thing to do; they benefit the United States. Improving health outcomes abroad provides greater political and economic stability, increasing demand for U.S. exports. And, as we are all learning now, it is in America’s national security interest for countries to effectively detect and respond to potential pandemics before they reach our shores.

As the United States looks to develop a new global system of pandemic prevention, there is absolutely no way to do that job without the World Health Organization. Uniquely, it puts traditional adversaries – like Russia and the United States, India and Pakistan, or Iran and Saudi Arabia – all around the same big table to take on global health challenges. It has relationships with the public health leaders of every nation, decades of experience in tackling viruses and diseases, and the ability to bring countries together to tackle big projects. This ability to bridge divides and work across borders cannot be torn down and recreated – not in today’s environment of major power competition – and so there is simply no way to build an effective international anti-pandemic infrastructure without the World Health Organization at the center.

### 1NC - Off

#### CP: Member nations of the World Trade Organization should establish a sui generis right for holders of traditional knowledge.

#### That solves the aff by preventing biopiracy while ensuring indigenous communities can use IP as an economic bargaining chip

Garcia 07 [(Javier, attorney at Perkins Coie LLP in Seattle, Washington, J.D. from Gonzaga University School of Law and B.A. from the University of Redlands) “Fighting Biopiracy: The Legislative Protection of Traditional Knowledge,” Berkeley La Raza Law Journal,” 3/2007] JL

The establishment of a sui generis right for holders of traditional knowledge would provide compensation for communities that do not otherwise qualify for patent protection. Under Article 8 of the TRIPS agreement, countries can adopt legislation to protect "sectors of vital importance to their socio-economic and technological development."'' 7 s A sui generis right could therefore be adopted in conjunction with domestic legislation as a catch-all provision pursuant to Article 8. The nature of a traditional knowledge sui generis right is detailed below.

Establishing a sui generis right for traditional knowledge holders could resolve problems stemming from patent law's limited term of protection. 7 6 Foremost among them is that certain forms of traditional knowledge may fall under the realm of public domain, and thus, be exempt from any patent protection. 7 Likewise, some traditional knowledge holders may also seek terms of protection that are incompatible with patent law, seek to prevent any sharing of their knowledge, or seek exclusive rights over their knowledge for an unlimited amount of time. 7 1 Such efforts would prove at odds with current patent law, which only rewards patent . . ... . '79 protection for a limited period of time to enable further innovations. Although a sui generis right could address some of these concerns, traditional knowledge holders will likely have to make sacrifices to avoid the misappropriation of their intellectual property rights. For example, the documentation of traditional knowledge will ultimately submit any documented traditional knowledge to the public domain. This may prove contradictory to the values of some traditional knowledge holders who wish to maintain ownership and control of their knowledge forever; nonetheless, it is an adaptation that must be made to avoid the exploitation of traditional knowledge. A traditional knowledge sui generis right could also overcome patent law's relative incompatibility with communal ownership. Confronting this hurdle is necessary since it may be against communal customs for an individual to own knowledge developed and modified over many generations.' Recognition of a sui generis right could also overcome barriers posed by international patent standards that require that an invention be new and subject to industrial applicability. I5 '

Finally, a sui generis right could modify patent law with respect to traditional knowledge holders to allow benefit sharing among communities not considered inventors under current patent law. For example, in 2004, the University of California, Berkeley, signed an agreement with the Samoan government to isolate from an indigenous tree the gene for a promising anti-AIDS drug and to share any royalties from sale of a gene-derived drug with the people of Samoa. 182 The agreement, signed by the prime minister of Samoa and U.C. Berkeley's Vice Chancellor for research, allocates Samoa's fifty percent share to the government, villages, and the families of healers who first shared the knowledge of how to use the plant. 18 Under the agreement, any commercial developer must "first negotiate an equitable benefit-sharing agreement with Samoa."' 184 This landmark agreement could be duplicated in Mexico under domestic legislation. Agreements like these may pose a problem given the amount of government corruption in Mexico and other 185 developing countries. Nevertheless, it may be the lesser of the two evils. Under domestic legislation or a sui generis right, compensation from patent royalties would be guaranteed at least to the State and would hopefully be spent in Mexico, rather than abroad. Furthermore, local government officials may be more entitled to compensation from profitable traditional knowledge than foreign, corporations.

An effective dispute resolution mechanism is necessary to make domestic legislation successful. First, it allows a country to establish jurisdiction over foreign companies that enter the country to extract resources. The mere existence of a dispute resolution process places foreign companies on notice that they are subject to jurisdiction and criminal or civil liability for violative conduct, such as environmental damage resulting from the excavation of resources, misappropriation of intellectual property rights, and civil rights violations. Currently, foreign companies are entering sovereign territories without permission, but governments do not have the legislation in place to regulate them effectively. 186 A dispute resolution mechanism will force entities to abide by the laws and regulations established by the proposed legislation.

The mechanism should provide a dispute resolution process for domestic conflicts and conflicts involving other sovereign states, thus requiring two levels of dispute-resolution. The first level should be for States to resolve disputes. The second level should provide a dispute-resolution mechanism for private parties who claim ownership of traditional knowledge, such as two tribal communities claiming ownership over the same traditional knowledge. 189 This level of dispute resolution will adjudicate intellectual property rights among all domestic entities, including indigenous communities, local inventors, corporations, or any other patent applicants claiming ownership of traditional knowledge.

The protection of traditional knowledge is vital to underdeveloped countries. Traditional knowledge is one of the few resources and bargaining chips these countries still retain. Accordingly, Mexico and other underdeveloped countries should protect themselves from the misappropriation of traditional knowledge that has already begun. Adopting domestic legislation provides the best means to regulate and control foreign entities seeking to extract and exploit traditional knowledge from vulnerable indigenous communities.

#### It competes – the CP is anti-topical action

IPTF 04 [(International Intellectual Property Institute, not-for-profit 501 corporation that provides education and training on intellectual property) “Is a Sui Generis System Necessary?” 1/14/2004] JL

WIPO and the WTO are in the process of establishing international rules for the protection of biodiversity. One of the key questions under consideration is whether or not to create a sui generis system to establish the norms and rules for protection. A “sui generis” system simply means “one that is of its own kind1 ”. In this case it refers to the creation of a new national law or the establishment of international norms that would afford protection to intellectual property dealing with genetic resources -or biodiversity - and the biotechnology that might result. It also refers to a law that might protect creations, inventions, models, drawings, designs, innovations contained in images, figures, symbols, petroglyphs, art, music, history and other traditional artistic expressions.

## Case

### Framing

1. **Util isn’t violent – you don’t disprove the goodness of pleasure and badness of pain, or provide an alternative, which means we need to prevent extinction.**
2. **First, pleasure and pain are intrinsically valuable. People consistently regard pleasure and pain as good reasons for action, despite the fact that pleasure doesn’t seem to be instrumentally valuable for anything.**

**Moen 16** [Ole Martin Moen, Research Fellow in Philosophy at University of Oslo “An Argument for Hedonism” Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281] SJDI

Let us start by observing, empirically, that a widely shared judgment about intrinsic value and disvalue is that pleasure is intrinsically valuable and pain is intrinsically disvaluable. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues**.** This inclusion makes intuitive sense, moreover, for there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative.2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values**.** If you tell me that you are heading for the convenience store, I might ask: “What for?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable**.** You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good.3 As Aristotle observes**:** “We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that if something is painful, we have a sufficient explanation of why it is bad. If we are onto something in our everyday reasoning about values, it seems that pleasure and pain are both places where we reach the end of the line in matters of value.

1. **Moreover, *only* pleasure and pain are intrinsically valuable. All other values can be explained with reference to pleasure; Occam’s razor requires us to treat these as instrumentally valuable.**

**Moen 16** [Ole Martin Moen, Research Fellow in Philosophy at University of Oslo “An Argument for Hedonism” Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281] SJDI

I think several things should be said in response to Moore’s challenge to hedonists. First, **I do not think the burden of proof lies on hedonists to explain why the additional values are not intrinsic values. If someone claims that X is intrinsically valuable, this is a substantive, positive claim, and it lies on him or her to explain why we should believe that X is in fact intrinsically valuable.** Possibly, this could be done through thought experiments analogous to those employed in the previous section. Second, **there is something peculiar about the list of additional intrinsic values** that counts in hedonism’s favor**: the listed values have a strong tendency to be well explained as things that help promote pleasure and avert pain.** To go through Frankena’s list, life and consciousness are necessary presuppositions for pleasure; activity, health, and strength bring about pleasure; and happiness, beatitude, and contentment are regarded by Frankena himself as “pleasures and satisfactions.” The same is arguably true of beauty, harmony, and “proportion in objects contemplated,” and also of affection, friendship, harmony, and proportion in life, experiences of achievement, adventure and novelty, self-expression, good reputation, honor and esteem. Other things on Frankena’s list, such as understanding, **wisdom, freedom, peace, and security, although they are perhaps not themselves pleasurable, are important means to achieve a happy life, and as such, they are things that hedonists would value highly.** **Morally good dispositions and virtues, cooperation, and just distribution of goods and evils, moreover, are things that, on a collective level, contribute a happy society, and thus the traits that would be promoted and cultivated if this were something sought after.** To a very large extent, the intrinsic values suggested by pluralists tend to be hedonic instrumental values. Indeed, pluralists’ suggested intrinsic values all point toward pleasure, for while the other values are reasonably explainable as a means toward pleasure, pleasure itself is not reasonably explainable as a means toward the other values. Some have noticed this. Moore himself, for example, writes that though his pluralistic theory of intrinsic value is opposed to hedonism, its application would, in practice, look very much like hedonism’s: “Hedonists,” he writes “do, in general, recommend a course of conduct which is very similar to that which I should recommend.”24 Ross writes that “[i]t is quite certain that by promoting virtue and knowledge we shall inevitably produce much more pleasant consciousness. These are, by general agreement, among the surest sources of happiness for their possessors.”25 Roger Crisp observes that “those goods cited by non-hedonists are goods we often, indeed usually, enjoy.”26 What Moore and Ross do not seem to notice is that their observations give rise to two reasons to reject pluralism and endorse hedonism. The first reason is that if **the suggested non-hedonic intrinsic values are potentially explainable by appeal to just pleasure and pain** (which, following my argument in the previous chapter, we should accept as intrinsically valuable and disvaluable), **then—by appeal to Occam’s razor—we have at least a pro tanto reason to resist the introduction of any further intrinsic values and disvalues. It is ontologically more costly to posit a plurality of intrinsic values and disvalues, so in case all values admit of explanation by reference to a single intrinsic value and a single intrinsic disvalue, we have reason to reject more complicated accounts.** **The fact that suggested non-hedonic intrinsic values tend to be hedonistic instrumental values does not, however, count in favor of hedonism solely in virtue of being most elegantly explained by hedonism; it also does so in virtue of creating an explanatory challenge for pluralists.** The challenge can be phrased as the following question: **If the non-hedonic values suggested by pluralists are truly intrinsic values in their own right, then why do they tend to point toward pleasure and away from pain?**27

1. **Moral uncertainty means preventing extinction should be our highest priority.  
   Bostrom 12** [Nick Bostrom. Faculty of Philosophy & Oxford Martin School University of Oxford. “Existential Risk Prevention as Global Priority.” Global Policy (2012)]  
   These reflections on **moral uncertainty suggest** an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate.¶ **Our present understanding of axiology might** well **be confused. We may not** nowknow — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet **be able to imagine the best ends** of our journey. **If we are** indeedprofoundly **uncertain** about our ultimate aims,then we should recognize that **there is a great** option **value in preserving** — and ideally improving — **our ability to recognize value and** to **steer the future accordingly. Ensuring** that **there will be a future** version of **humanity** with great powers and a propensity to use them wisely **is** plausibly **the best way** available to us **to increase the probability that the future will contain** a lot of **value.** To do this, we must prevent any existential catastrophe.
2. **Reducing the risk of extinction is always priority number one.   
   Bostrom 12** [Faculty of Philosophy and Oxford Martin School, University of Oxford.], Existential Risk Prevention as Global Priority.  Forthcoming book (Global Policy). MP. [http://www.existenti...org/concept.pdf](http://www.existential-risk.org/concept.pdf)Even if we use the most conservative of these estimates, which entirely ignores the   possibility of space colonization and software minds, **we find that the expected loss of an existential   catastrophe is greater than the value of 10^16 human lives**.  **This implies that the expected value of   reducing existential risk by a mere one millionth of one percentage point is at least a hundred times the   value of a million human lives.**  The more technologically comprehensive estimate of 10  54 humanbrain-emulation subjective life-years (or 10  52  lives of ordinary length) makes the same point even   more starkly.  Even if we give this allegedly lower bound on the cumulative output potential of a   technologically mature civilization a mere 1% chance of being correct, we find that the expected   value of reducing existential risk by a mere one billionth of one billionth of one percentage point is worth   a hundred billion times as much as a billion human lives. **One might consequently argue that even the tiniest reduction of existential risk has an   expected value greater than that of the definite provision of any ordinary good, such as the direct   benefit of saving 1 billion lives.**  And, further, that the absolute value of the indirect effect of saving 1  billion lives on the total cumulative amount of existential riskâ€”positive or negativeâ€”is almost   certainly larger than the positive value of the direct benefit of such an action.

### Advantage

#### ROB is to vote for the better debater – anything else is arbitrary, self–serving, and impact justified – they haven’t justified how debate shapes subject formation – it doesn’t – the role of individual debate rounds is white noise – *can you remember what happened round () of () your senior year?*

#### They can only leverage the amount of settler colonialism solved by the aff – alt causes – Chinese oppression of Uighurs, Turkey’s involvement in Syria, and Native Americans making $.60 to the dollar

#### Patents prevent biopiracy

Erstling 09 [(Jay, Emeritus Professor of Law at Mitchell Hamline School of Law, J.D., Cornell University Law School, 1974) “Using Patents to Protect Traditional Knowledge,” Texas Wesleyan Law Review, 2009] JL

Finally, while the patent system has been accused of facilitating biopiracy by tolerating third-party patenting of TK, using the patent system appropriately to protect TK can serve more to prevent biopiracy than to permit it. Biopiracy generally refers to the exploitation of traditional knowledge or genetic resources-typically by multinational companies-without the authorization of the holders of that knowledge, and/or the patenting of inventions based on traditional knowledge without the consent of the knowledge holders or payment of compensation.24 Several cases of alleged biopiracy, including patents granted for neem, turmeric, the enola bean, and quinoa, have aroused controversy and focused attention on how patenting can lead to unjust results.25 Although it is extremely difficult to estimate the extent to which biopiracy actually takes place in any particular country, protecting TK could provide some assurance against misappropriation by clarifying the duty that third parties owe to the holders of the knowledge when the knowledge has contributed to an invention that is the subject of a patent application.

#### Unpatented medicine cause counterfeits—

Lynbecker 16 [(Kristina M. L. Acri née, an Associate Professor of Economics at Colorado College in Colorado Springs, where she is also the Associate Chair of the Department of Economics and Business and the Gerald L. Schlessman Professor of Economics. Dr. Lybecker’s research analyzes the difficulties of strengthening intellectual property rights protection in developing countries, specifically special problems facing the pharmaceutical industry.) “Counterfeit Medicines and the Role of IP in Patient Safety,” IPWatchDog, 7/27/16. <https://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/>] RR

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.

#### Generic medicine is dangerous—contamination and unsanitary manufacturing conditions.

White 19 [(C. Micheal, Professor and Head of the Department of Pharmacy Practice, University of Connecticut) “Why your generic drugs may not be safe and the FDA may be too lax” The Conversation, 12/4/19. <https://theconversation.com/why-your-generic-drugs-may-not-be-safe-and-the-fda-may-be-too-lax-125529>] RR

This leads to a vital question: Are generics safe? If drug manufacturers followed the FDA’s strict regulations, the answer would be a resounding yes. Unfortunately for those who turn to generics to save money, the FDA relies heavily on the honor system with foreign manufacturers, and U.S. consumers get burned. Eighty percent of the active ingredients and 40% of the finished generic drugs used in the U.S. are manufactured overseas.

As a pharmacist, I know that the safety of prescription medications is vital. My research, recently published in the “Annals of Pharmacotherapy,” raises alarming concerns about our vulnerabilities.

Do experts have something to add to public debate?

Where are your drugs being made?

A pharmacist at a drug plant outside Mumbai in 2012, shortly after a change in patent law allowed production of a generic cancer drug. Rafiq Mugbool/AP Photo

Generic drug manufacturers either make bulk powders with the active ingredient in them or buy those active ingredients from other companies and turn them into pills, ointments or injectable products.

In 2010, 64% of foreign manufacturing plants, predominantly in India and China, had never been inspected by the FDA. By 2015, 33% remained uninspected.

In addition, companies in other countries are informed before an inspection, giving them time to clean up a mess. Domestic inspections are unannounced.

Faking results

The FDA informs manufacturing plants in other countries when it plans to inspect their plants. Andrew Harnik/AP Photo

As I detail in my paper, when announced foreign FDA inspections began to occur in earnest between 2010 and 2015, numerous manufacturing plants were subsequently barred from shipping drugs to the U.S. after the inspections uncovered shady activities or serious quality defects.

Unscrupulous foreign producers shredded documents shortly before FDA visits, hid documents offsite, altered or manipulated safety or quality data or utilized unsanitary manufacturing conditions. Ranbaxy Corporation pleaded guilty in 2013 to shipping substandard drugs to the U.S. and making intentionally false statements. The company had to withdraw 73 million pills from circulation, and the company paid a $500 million fine.

These quality and safety issues can be deadly. In 2008, 100 patients in the U.S. died after receiving generic heparin products from foreign manufacturers. Heparin is an anticoagulant used to prevent or treat blood clots in about 10 million hospitalized patients a year and is extracted from pig intestines.

Some of the heparin was fraudulently replaced with chondroitin, a dietary supplement for joint aches, that had sulphur groups added to the molecule to make it look like heparin.

One of the heparin manufacturers inspected by the FDA received a warning letter after it was found to have used raw material from uncertified farms, used storage equipment with unidentified material adhering to it and had insufficient testing for impurities.

These issues continue to this day. Dozens of blood-pressure and anti-ulcer drugs were recalled in 2018 and 2019 due to contamination with the potentially carcinogenic compounds N-nitrosodimethylamine or N-nitrosodiethylamine.

One of the major producers of these active ingredient powders used by multiple generic manufacturers was inspected in 2017. The FDA found that the company fraudulently omitted failing test results and replaced them with passing scores.

This raises a critical question: How many more violations would occur with inspections occurring as frequently as they do in the U.S., and more importantly, if they were unannounced? Relatively speaking, the number of drugs proved to be tainted or substandard has been small, and the FDA has made some progress since 2010. But the potential for harm is still great.