# 1NC vs Summit MR

### 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.

Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A recent report from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

#### IP protections are key to innovation – recouping startup costs and high risk of failure

Grabowski et al 15 [(Henry, Professor of Economics, member of the faculty for the Health Sector Management Program, and Director of the Program in Pharmaceuticals and Health Economics at Duke University) “The Roles of Patents and Research And Development Incentives In Biopharmaceutical Innovation,” Health Affairs, 2/2015] JL

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term.

Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. **5** The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. **6** Only approximately one in eight drug candidates survive clinical testing. **6**

As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). **7**,**8** Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market.

Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents.

New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment.

Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. **11** The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms.

#### 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

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#### 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. Member nations will support the proposal and adopt the results of consultation.

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

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

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

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

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

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

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

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

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

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

#### 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.

#### 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.

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#### Counterplan: Member nations of the World Trade Organization should reduce intellectual property protections for medicines used to treat HIV.

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#### WTO is near consensus on fisheries subsidies – success will require continued focus, flexibility, and cooperation among members

WTO 7/15 [(World Trade Organization) “WTO members edge closer to fisheries subsidies agreement,” News and Events, 7/15/2021] JL

During an all-day meeting with 104 ministers and heads of delegation, WTO members pledged to conclude the negotiations soon and certainly before the WTO's Ministerial Conference in early December, and to empower their Geneva-based delegations to do so. Members also confirmed that the negotiating text currently before them can be used as the basis for the talks to strike the final deal.

“I feel new hope this evening. Because ministers and heads of delegation today demonstrated a strong commitment to moving forward and doing the hard work needed to get these negotiations to the finish line. I applaud you for this. In 20 years of negotiations, this is the closest we have ever come towards reaching an outcome — a high-quality outcome that would contribute to building a sustainable blue economy,” said Director-General Ngozi Okonjo-Iweala.

“One fundamental conclusion that I draw from your interventions today is that members are ready to use the text as the basis for future negotiations. A second takeaway from today was that there is universal agreement about the importance of the food and livelihood security of artisanal fishers in developing and least developed countries. The prospect for a deal in the autumn ahead of our Ministerial Conference has clearly improved.”

The UN Food and Agriculture Organization estimates that one-third of global fish stocks are overfished and most of the rest is fully exploited. This is up from 10% in 1970 and 27% in 2000. Depleted stocks threaten the food security of low-income coastal communities, and the livelihoods of poor and vulnerable fishers who must go further and further from shore only to bring back smaller and smaller hauls.

Each year, governments hand out around $35 billion in fisheries subsidies, two-thirds of which go to commercial fishers. These subsidies keep at sea vessels which would otherwise be economically unviable. World leaders in 2015 made a fisheries subsidies agreement by 2020 part of the Sustainable Development Goals and trade ministers reaffirmed this pledge in 2017.

The negotiations on fisheries subsidies disciplines have been ongoing for nearly 20 years. Although there has been recent progress thanks to the intensive work that led to the development of the negotiating text on which members are working, the lack of political impetus in the talks to close the remaining gaps inspired Director-General Okonjo-Iweala to call this meeting of ministers.

Among the thorniest issues to resolve has been how to extend special and differential treatment to developing and least developed country WTO members while preserving the overall objective of enhanced sustainability of the oceans. Ministers said that the livelihoods and food security of poor and vulnerable artisanal fishers in developing and least developed countries were of great importance, as was preserving the sustainability objective of the negotiations.

Amb. Santiago Wills of Colombia, who chairs the Rules Negotiating Group overseeing the fisheries subsidies negotiations, said he had received some valuable inputs from the discussions. He now has greater clarity on the path forward and the next steps that would be required to harvest an agreement. He will be consulting with the Director-General and WTO members about charting the path forward for the next stage of the talks.

“I am very heartened by the responses and messages that we have heard today. What we sought from ministers today was political guidance to help close these negotiations soon. And we did hear that guidance. We have been given the ingredients to reach a successful conclusion; a commitment to finish well ahead of our Ministerial Conference a text that can be the platform for this final stage of the negotiations and fully empowered heads of delegations in Geneva. This represents a real success,” said Amb. Wills.

The Director-General said that delegations needed to prepare for an intensive period of line by line negotiations.

“As we enter this new phase of text-based discussions, the responsibility to conclude these negotiations is truly in the hands of members. To get from here to an agreement, it will be your job to find the necessary trade-offs and flexibilities. A successful outcome by MC12 is ultimately your responsibility,” she said. “The world is watching. The fisheries subsidies negotiations are a test both of the WTO's credibility as a multilateral negotiating forum and of the trading system's ability to respond to problems of the global commons.  If we wait another 20 years, there may be no marine fisheries left to subsidise — or artisanal fishing communities to support.”

#### IP disputes fragment WTO unity and trade off with subsidies negotiation

Patnaik 3/12 [(Priti, journalist in Geneva, Switzerland, master’s in Development Studies from The Graduate Institute in Geneva and a master’s in Business and Economic Reporting from New York University) “Could Vaccine Nationalism Spur Disputes At The WTO?” Geneva Health Files, 3/12/2021] JL

To protect domestic manufacturers and constituencies, countries may resort to filing disputes, if only to send a signal to other members, experts believe. To be sure, this is not only about vaccines. Going forward, export restrictions on raw materials can have implications for therapeutics as well. So the threat of a dispute may be a tool to deal with competition for scarce medical products during the pandemic, experts say.

Although trade restrictive measures are short-sighted and not a preferred policy option, governments see them as powerful instruments to meet political goals, to send a message to domestic stakeholders, sources said.

“My hunch is that all countries are sort of sitting on both sides of the fence. On the one hand, governments would like to maintain the discretion and the ability to impose export restrictions if they need to or if they think they need to. Whether that is medical products or personal protective equipment. On the other hand, everybody dislikes it when other countries impose export restrictions. So I think there is enough of an incentive for countries to sit down and negotiate,” one legal expert noted.

Sources also pointed to political declarations last year where WTO members came together and said that they would not impose restrictive trade measures. “In order to be constructive, countries decided that they were going to signal to members that will not introduce exports restrictive measures even though it may be expedient to do so,” one trade expert said. The way out, some feel, is to find solution to placing limits on export restrictions.

It is not just trade restrictive measures that could result in trade disputes. The heated political discussions on the TRIPS waiver at WTO is also aggravating the potential for disputes, according to experts involved in litigations in international trade in Geneva. Therefore these ostensibly independent processes, can catalyse disputes.

“The waiver discussion is very heated and it is aggravating the discussion on the EU's export restrictions. If the waiver succeeds, then the opposing members cannot do anything about it. So they will be looking at other ways to beat up on behavior they do not like on the COVID-19 front,” one trade law expert said.  Do not rule out disputes against supporters of the TRIPS waiver proposal, in case the waiver is adopted, the source added.

In their statement at the WTO General Council meeting last week, the EU said, “In order to ensure that vaccines and their ingredients are not directed to export destinations in unjustified volumes, the European Union had no choice but to introduce a transparency mechanism on Covid-19 vaccine export transactions.” The EU has said that the measures are WTO-consistent.

It added “Since the entry into force of the scheme on the 1 February, we have received 150 requests for export authorisation. All of them have been accepted. I repeat, all of them.” This week, the European Commission extended transparency and authorisation mechanism for exports of COVID-19 vaccines.

The EU is also a part of the Ottawa Group proposal on Trade and Health that also spells out commitments towards export restrictions. (See also *E.U. Exports Millions of Covid Vaccine Doses Despite Supply Crunch at Home*)

“Members bring disputes all the time, even when they know that it's going to take a long time to get a result and often they bring a dispute as leverage for negotiations. Filing a dispute does not mean they are looking for a solution. It does not mean the dispute will be litigated all the way to the end,” a trade lawyer said.

It could also result in a negotiated arrangement, like it was in 2001 in the U.S.-Brazil case. “Why did the U.S. bring a case against Brazil? It gave them leverage in negotiations, and to satisfy domestic stakeholders,” the lawyer added.

The impasse at the Appellate Body may not be a deterrent for countries to dissuade countries from bringing a dispute, some believe.

“The Appellate Body not being functional is not a problem. Countries have recourse to Article 25 under the Dispute Settlement Understanding (DSU) that provides for ‘expeditious arbitration as a alternate means to dispute settlement’,” a source involved in the WTO litigation process said. (The EU, for example, is a signatory to the Multi-party interim appeal arbitration arrangement, MPIA.)

While disputes may take up precious energy and resources of members already stretched in fighting to address the pandemic, it may likely be a strategy to address trade protectionism. Not all agree.

“I think the law is not really an answer here, I hate to say that because I'm a lawyer. But I really don't think the law is an answer because the law is so generically drafted right that and it's politically so sensitive. Which WTO panel will tell a member that restricting vaccines is not legitimate? It will ultimately harm the legitimacy of the trading system,” the person added.

#### Overfishing collapses biodiversity

DUJS 12 [(Dartmouth Undergraduate Journal of Science, official open access science journal of Dartmouth College, publishing original scientific research, multidisciplinary review articles, and science news) “The Threats of Overfishing: Consequences at the Commercial Level,” 3/11/2012] JL

According to marine ecologists, overfishing is the greatest threat to ocean ecosystems today (1). Overfishing occurs because fish are captured at a faster rate than they can reproduce (2). Advanced fishing technology and an increased demand for fish have led to overfishing, causing several marine species to become extinct or endangered as a result (3, 4). In the long-term, overfishing can have a devastating impact on ocean communities as it destabilizes the food chain and destroys the natural habitats of many aquatic species (2).

In the past, fishing was more sustainable because fishermen could not access every location and because they had a limited capacity for fish aboard their vessels. Today, however, small trawlers and fishing boats have been replaced by giant factory ships that can capture and process extremely large amounts of prey at a given time (2). These ships use sonar instruments and global positioning systems (GPS) to rapidly locate large schools of fish (1). Fishing lines are deployed with thousands of large hooks that can reach areas up to 120 kilometers deep. The trawling vessels and machines can even reach depths of 170 kilometers and can store an extraordinarily large volume of fish. Each year, these huge trawling ships comb an area twice the size of the United States. They use massive nets 50 meters wide with the capacity to pull the weight of a medium-sized plane (2). They also have several plants for processing and packing fish, large freezing systems, fishmeal processing plants, and powerful engines that can carry this enormous fishing gear around the ocean. Because these ships have all the equipment necessary to freeze and tin fish, they only need to return to their base once they are full. Even when the ships are filled, however, the fish are often transferred to refrigerated vessels in the middle of the ocean and are processed for consumption later (4). As such, industrial fishing has expanded considerably and fishermen can now explore new shores and deeper waters to keep up with the increased demand for seafood. In fact, it has been reported by the United Nations Food and Agricultural Organization (FAO) that over 70 percent of the world’s fisheries are either ‘fully exploited’, ‘over exploited’ or ‘significantly depleted’ (5). The annual total global catch of fish is 124 million metric tons, which is equivalent in weight to 378 Empire State Buildings (2).

Fishing gear is often non-selective in the fish it targets. For example, any fish that are too big to get through the mesh of a net are captured. Therefore, overfishing does not only threaten the species of fish that is targeted for food, but also many non-target species. As a result, these other species, including marine mammals and seabirds, are accidentally caught in the fishing gear and killed (6). For example, for every ton of prawn caught, three tons of other fish are killed and thrown away. Those in the trade refer to this practice of inadvertent catching of other species as bycatch (4). The FAO has pointed out that about 25 percent of the world’s captured fish end up thrown overboard because they are caught unintentionally, are illegal market species, or are of inferior quality and size. Many of the fish caught this way include endangered and over exploited species, 95 percent of which are eventually thrown away (2). Bycatch is not just limited to just unwanted fish, but rather affects all types of marine life, including whales, dolphins, porpoises, fur seals, albatrosses, and turtles. For example, tuna fisheries are indirectly responsible for the deaths of an estimated one million sharks annually due to bycatch. Small cetaceans, such as dolphins and porpoises, are also targets of bycatch as they are often caught in fishing nets. In fact, hundreds of dolphin corpses are washed up on the beaches of Europe every year, bringing attention to the growing scale of this problem (6).

Many modern fishing methods are also irreversibly destructive. For example, bottom trawling, a technique that uses extremely wide nets armed with heavy metal rollers, can crush everything in the path of the gear, destroying fragile corals, smashing rock formations, and killing several tons of fish and animals as bycatch (7). As such, these practices can wreak havoc on delicate marine ecosystems.

Not surprisingly, it has been reported that industrial fishing takes between only 10 and 15 years to wipe out a tenth of whichever species it targets (2). In fact, several marine species have already been fished to commercial extinction, and this number is rapidly increasing (1). One of the reasons for this is that the regulation of fishing vessels and the fishing industry is universally inadequate. Roughly two-thirds of the ocean is free of laws and fishing vessels only follow the laws ratified by their country of origin. However, most fishing countries have not ratified any international convention to protect the sea or marine life (2). Moreover, fishing factory ships and companies are given access to fisheries before the long–term impact of their fishing practices is understood (1).

Today, the number of fish caught worldwide is actually shrinking as the fishing industry is in decline from many years of overfishing (2). The year 1988 was the first time in human history that global wild fish catches dropped and they have continued to fall ever since. In European waters, four out of every five known fish stocks are already beyond safe biological limits (7). Illegal and unreported fishing have also contributed a great deal to the depletion of the oceans and continues to be a serious problem.

A new study conducted by the International Union for Conservation of Nature (IUCN) found that 5 out of the 8 tuna species are at risk of extinction (8). All three species of bluefin tuna, for example, are threatened with extinction and are at a population that makes their recovery practically irreversible (2). The IUCN has also reported that freshwater fish are among the most endangered species, with more than a third facing extinction. Not surprisingly, among those at the greatest risk are species like the Mekong giant catfish, the freshwater stingray, and the European eel, which are used to make some of the most expensive caviars. The Mekong giant catfish is the closest to extinction, with as few as 250 left. Overfishing has reduced the numbers of Mekong freshwater stingray by over 50 percent in Southeast Asia and has reduced the giant Mekong salmon carp population by over 90 percent (9).

As previously mentioned, shark populations have also been greatly affected by overfishing. There are already more than 135 species of shark on the IUCN’s list of endangered animals and more are being added each year. For example, the number of scalloped hammerhead shark has decreased by 99% over the past 30 years. Other species recently added to the endangered list include the smooth hammerhead, shortfin mako, common thresher, big-eye thresher, silky, tiger, bull, and dusky (10). Besides being caught as bycatch, sharks are now also being targeted by commercial fishermen for their fins which can fetch a substantial price on the Asian food market. Sharks are particularly vulnerable to exploitation because they have long life spans, are exceptionally slow to mature (taking as long as 16 years in some cases), and are relatively unprolific breeders (11). Recent reports suggest that over fishing has caused a 90% decline in shark populations across the world’s oceans and up to 99% along the US east coast, which are some of the best managed waters in the world. Because sharks are at the top of the food chain, a decline in their numbers has devastating consequences on marine ecosystems (10).

Overfishing impacts not just the particular species that is exploited, but also damages other species of fish and disrupts local ecosystems. The stability of ecological communities depends largely on the interactions between predators and prey (12). Thereby, the balance of the food chain is disturbed when certain species are removed. As a result, many ocean species are disappearing and losing their habitats. The evolutionary process of marine species is also being altered, causing cycles of premature reproduction and relative decreases in the size of fish across generations. As predators diminish, the populations of smaller fish escalate because they were previously the food source of the bigger fish. In addition, the disappearance of these species affects many other species, like seabirds and sea mammals, which are vulnerable to the lack of food (2).

A recent study found that overfishing is also decreasing the genetic diversity of fish worldwide. Diversity is projected to be reduced further if overfishing continues at the same rate (13). This has serious effects on nutrient recycling in marine ecosystems because fish species vary widely in their rates of nitrogen and phosphorus excretion. As such, altering fish communities creates divergent nutrient recycling patterns and disrupts the functioning of the ecosystem. Recently conducted studies in lakes affected by overfishing show that loss of species contributes to a decline in nutrient recycling and destabilizes the ecosystem (14).

While it is often overlooked for other environmental issues, overfishing has historically caused more ecological extinction than any other human influence on coastal ecosystems, including water pollution (5). Unfortunately, due to a lack of data, the extent of this damage has only recently been recognized (15).

#### Continued biodiversity loss causes extinction

Carrington 18 [(Damian, the Guardian's Environment editor) "Humanity has wiped out 60% of a animal populations since 1970, report finds," The Guardian, 10/29/18] TDI

Humanity has wiped out 60% of mammals, birds, fish and reptiles since 1970, leading the world’s foremost experts to warn that the annihilation of wildlife is now an emergency that threatens civilisation.

The new estimate of the massacre of wildlife is made in a major report produced by WWF and involving 59 scientists from across the globe. It finds that the vast and growing consumption of food and resources by the global population is destroying the web of life, billions of years in the making, upon which human society ultimately depends for clean air, water and everything else.

“We are sleepwalking towards the edge of a cliff” said Mike Barrett, executive director of science and conservation at WWF. “If there was a 60% decline in the human population, that would be equivalent to emptying North America, South America, Africa, Europe, China and Oceania. That is the scale of what we have done.”

“This is far more than just being about losing the wonders of nature, desperately sad though that is,” he said. “T**his is** actually now jeopardising the future of people. Nature is not a ‘nice to have’ – it is our life-support system.”

“We are rapidly running out of time,” said Prof Johan Rockström, a global sustainability expert at the Potsdam Institute for Climate Impact Research in Germany. “Only by addressing both ecosystems and climate do we stand a chance of safeguarding a stable planet for humanity’s future on Earth.”

Many scientists believe the world has begun a sixth mass extinction, the first to be caused by a species – Homo sapiens. Other recent analyses have revealed that humankind has destroyed 83% of all mammals and half of plants since the dawn of civilisation and that, even if the destruction were to end now, it would take 5-7 million years for the natural world to recover.

The Living Planet Index, produced for WWF by the Zoological Society of London, uses data on 16,704 populations of mammals, birds, fish, reptiles and amphibians, representing more than 4,000 species, to track the decline of wildlife. Between 1970 and 2014, the latest data available, populations fell by an average of 60%. Four years ago, the decline was 52%. The “shocking truth”, said Barrett, is that the wildlife crash is continuing unabated.

Wildlife and the ecosystems are vital to human life, said Prof Bob Watson, one of the world’s most eminent environmental scientists and currently chair of an intergovernmental panel on biodiversity that said in March that the destruction of nature is as dangerous as climate change.

“Nature contributes to human wellbeing culturally and spiritually, as well as through the critical production of food, clean water, and energy, and through regulating the Earth’s climate, pollution, pollination and floods,” he said. “The Living Planet report clearly demonstrates that human activities are destroying nature at an unacceptable rate, threatening the wellbeing of current and future generations.”

The biggest cause of wildlife losses is the destruction of natural habitats, much of it to create farmland. Three-quarters of all land on Earth is now significantly affected by human activities. Killing for food is the next biggest cause – 300 mammal species are being eaten into extinction – while the oceans are massively overfished, with more than half now being industrially fished.

Chemical pollution is also significant: half the world’s killer whale populations are now doomed to die from PCB contamination. Global trade introduces invasive species and disease, with amphibians decimated by a fungal disease thought to be spread by the pet trade.

The worst affected region is South and Central America, which has seen an 89% drop in vertebrate populations, largely driven by the felling of vast areas of wildlife-rich forest. In the tropical savannah called cerrado, an area the size of Greater London is cleared every two months, said Barrett.

“It is a classic example of where the disappearance is the result of our own consumption, because the deforestation is being driven by ever expanding agriculture producing soy, which is being exported to countries including the UK to feed pigs and chickens,” he said. The UK itself has lost much of its wildlife, ranking 189th for biodiversity loss out of 218 nations in 2016.

The habitats suffering the greatest damage are rivers and lakes, where wildlife populations have fallen 83%, due to the enormous thirst of agriculture and the large number of dams. “Again there is this direct link between the food system and the depletion of wildlife,” said Barrett. Eating less meat is an essential part of reversing losses, he said.

The Living Planet Index has been criticised as being too broad a measure of wildlife losses and smoothing over crucial details. But all indicators, from extinction rates to intactness of ecosystems, show colossal losses. “They all tell you the same story,” said Barrett.

Conservation efforts can work, with tiger numbers having risen 20% in India in six years as habitat is protected. Giant pandas in China and otters in the UK have also been doing well.

But Marco Lambertini, director general of WWF International, said the fundamental issue was consumption: “We can no longer ignore the impact of current unsustainable production models and wasteful lifestyles.”

## Case

### Framing

**The standard is maximizing expected wellbeing**

**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.

**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

#### No ! to structural violence being k2 freedom – death ow bc it is the ultimate prevention of freedom

#### Extinction should come first –

**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.

**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.pdfEven 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.

#### I’ll answer their reasons to prefer:

#### Extinction is the ultimate example of slow violence – not only does it prevent all future pleasure but is hugely painful and targets those impacted by structural systems of oppression the most – i.e. disease and nw center around urban areas where historically low ses or minorities live

#### The warrant for why effects being exponential mattering is why our framing is correct – sustained conflicts are bad bc produce pain or extinction

#### We don’t make debate unsafe – this assumes we are saying oppression good or doesn’t exist – we aren’t – we just are proving that if pleasure and pain are good and bad then preventing extinction prevents larger amounts of pain

#### Nothing triggers presumption and permissibility – there is always risk of offense or a coherent moral theory A] statements are more often false than true – why we don’t believe conspiracy theorists on face and any part can be false B] if everything is permissible so is not affirming

**Negating negates – hold the line on 1AC spikes – they are underwarrented and not complete arguments -- doesn’t assume aff is worthy of contestation it is just structure of debate – didn’t justify truth testing which means isn’t offense**

**Negate if we win the plan is a bad idea - no position is objectively true – if we are winning the 1nc that doesn’t mean it is a truism, just that the aff is a bad idea so no ethical ob to affirm**

### HIV

#### HIV medicine isn’t patented – there is a reason their patents bad ev is from 2000

WTO 01 [(World Trade Organization) “Declaration on the TRIPS agreement and public health” World Trade Organization, 11/14/2001. https://www.wto.org/english/thewto\_e/minist\_e/min01\_e/mindecl\_trips\_e.htm] BC

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

#### Squo HIV prevention and treatment works – medicines are still being created and distributed with IPPFE

Feldscher 12/1 [(Karen, Associate Director, News, at the Harvard T.H. Chan School of Public Health) an interview with Shapiro (Roger, associate professor of immunology and infectious diseases, has worked for over two decades to improve health outcomes for HIV-infected pregnant women and their children. Here, he assesses progress in the decades-long fight against HIV/AIDS.) “In fight against HIV/AIDS, there are bright spots, areas for improvement” Harvard T.H. Chan School of Public Health, 12/1/2020. https://www.hsph.harvard.edu/news/features/in-fight-against-hiv-aids-there-are-bright-spots-areas-for-improvement/] BC

On the other hand, COVID may present some real opportunities for HIV prevention efforts. When people stay home because of COVID lockdowns or the closure of bars, less HIV transmission will occur. COVID has shown the world, or at least most of the world, that preventive measures such as mask use and distancing can be used to fight a deadly virus. The challenges for HIV prevention are very different, but we may be able to harness some of the messaging about the use of personal protection measures from the COVID epidemic and apply it to the HIV epidemic. We are also gaining a massive amount of experience regarding COVID vaccine development, some of which has been built on the HIV research infrastructure, and soon we will learn lessons in worldwide distribution

. These lessons can be applied to HIV down the road, whether for treatment, a future vaccine, or the rollout of PrEP (pre-exposure prophylaxis)—medication for preventing HIV—in hard-to-reach places.

Q: What are some highlights of the progress that’s been made this year?

A: We are always moving forward on treatment and prevention, and 2020 was no exception. I think the best news this year has been the successful trial of a long-acting injectable antiretroviral, called cabotegravir, for HIV prevention in women in Africa. In the past, poor adherence to PrEP has been a limitation, and this recent study found that a long-acting injection every eight weeks was highly effective at blocking HIV transmission, and over eight times as protective as standard oral PrEP. There has also been progress this year in treatment options available for pregnant women, with encouraging outcomes with newer regimens. A more cautionary tale this year has been further evidence for substantial weight gain with newer treatment combinations, and this remains an active area of research.

In terms of drug development, there has been progress toward new medicines that might last for up to six months, which will open up new possibilities for long-term treatment and prevention. And finally, we are learning more all the time about how to use broadly neutralizing monoclonal antibodies to treat HIV and to drive the amount of virus in the body to lower and lower levels. These new products are getting better all the time, and might lead to future treatment options that can be dosed every few months, perhaps in combination with the long-acting antivirals that are being developed.

#### No warrant for why patents are bad – just assirts that they are the problems

### Developing economies

#### Developing economies are exempt from TRIPS

WTO ND [(World Trade Organization) “Intellectual property: protection and enforcement” WTO, no date. https://www.wto.org/english/thewto\_e/whatis\_e/tif\_e/agrm7\_e.htm] BC

While the WTO agreements entered into force on 1 January 1995, the TRIPS Agreement allowed WTO members certain transition periods before they were obliged to apply all of its provisions. Developed country members were given one year to ensure that their laws and practices conform to the TRIPS Agreement. Developing country members and (under certain conditions) transition economies were given five years, until 2000. Least-developed countries initially had 11 years, until 2006 — now extended to 1 July 2034

in general.

In November 2015, the TRIPS Council agreed to further extend exemptions on pharmaceutical patent and undisclosed information protection for least-developed countries until 1 January 2033 or until such date when they cease to be a least-developed country member, whichever date is earlier. They are also exempted from the otherwise applicable obligations to accept the filing of patent applications and to grant exclusive marketing rights during the transition period.

#### No ! to developing countries innovation – not key to global medicine production

#### High drug prices are necessary for long-term innovation that outweighs short-term costs – most comprehensive meta-analysis

Kennedy 19 [(Joseph, senior fellow at the Information Technology and Innovation Foundation, professor of Law, Economics and International Policy at Georgetown’s School of Foreign Service, Senior Principal Economist at MITRE, Inc., former Chief Economist for the Department of Commerce and Senior Counsel for the Senate Permanent Subcommittee on Investigations, PhD in economics from George Washington University) “The Link Between Drug Prices and Research on the Next Generation of Cures,” Information Technology and Innovation Foundation, 9/9/2019] JL

The justification for high prices on any particular drug therefore depends on the assumption that they are needed to fund the subsequent round of innovation. This link has been established by numerous empirical studies over the last several decades. A recent survey summarized the scholarly literature this way: “The preponderance of evidence suggests that raising reimbursements for pharmaceuticals stimulates innovation, primarily because the expected rewards for innovation go up and secondarily because the cost of financing falls for cash-constrained pharmaceutical firms.”63

Previous government reports have summarized the link between biopharmaceutical profits and innovation within the drug industry. CBO pointed to two underlying reasons why this link might be so strong.64 First, as in most industries, the introduction of successful new drugs often leads to higher profits as companies are able to capture some of the social value created by their products. The profitability of current drugs also serves as a proxy for the profitability of future drugs. If biopharmaceutical firms are allowed to make reasonably large profits from their current products, they are likely to conclude that the same will be true in the future. This may cause them to increase both the speed and amount of their research activities. Conversely, they may view current attempts to hold down prices as likely to continue into the future, in which case they may decrease research funding.

The second reason CBO identified is adequate profits generate significant cash flow, which allows companies to finance the next round of innovation.65 The availability of cash flow is important because raising significant amounts of money in the stock or bond markets is more costly. Biopharma companies have a much more detailed knowledge of disease models, the status of their current research, and the probabilities of success. Because investors cannot adequately assess these risks for themselves, they demand higher returns for investing. Assuming firms invest in R&D until their cost of capital exceeds the rate of return, financing through cash flow should allow them to justify more projects than if they have to raise the money from outside investors.

The Organization for Economic Cooperation and Development (OECD) conducted a detailed study of this issue in the pharmaceutical industry. It found that “[p]harmaceutical pricing and reimbursement policies stand to affect innovation through multiple channels, influencing both the incentives to invest in private R&D and the costs of investment. The main channel of prospective influence is the impact of pricing and reimbursement policies on the *expected return on investment* in R&D.”66 In fact the generation of large revenues is closely related to the amount of research an individual company does. Figure 9 shows R&D expenditures and sales of the 151 largest pharmaceutical firms in the world in 2006. There was clearly a very strong correlation (0.97).

Pricing policies affect not only the amount of research conducted (leading-edge or marginal improvements) but also the type and the decision of whether and when to introduce a new product to the market.

The Government Accountability Office recently completed its own review of trends in pharmaceutical profits and R&D.68 It found that both experts and academic research has concluded that high revenue potential associated with a large number of patients, or the ability to charge a high price, is an important incentive for R&D investment.69 Exclusivity periods and patent protection, tax incentives, and expedited review programs were also cited as influencing R&D. Of course, while biopharmaceutical companies, like other firms, would like to charge as high a price as possible, their ability to do so is limited by both buyers not being willing to pay more for a drug than the benefits it delivers in terms of longer, healthier lives, and the presence of at least some competition in the marketplace.

Academic studies that explore the causal link between drug revenues and research face a common difficulty in finding good data. They also take different approaches to choosing the inputs, outputs, and econometric model to measure the relationship between prices and profits, and research and innovation. So it is somewhat remarkable that, collectively, they arrive at the common answer that high prices for today’s treatments are closely associated with more research and a larger number of future drugs. There appear to be no scholarly studies that show no relationship between current prices and future innovation. Given their common conclusion that short-term price declines will endanger future drug innovation, it is worthwhile to discuss some of the major studies individually.

Two studies by Duke University’s Henry Grabowski and John A. Vernon from the University of North Carolina at Chapel Hill looked at the relationship between expected returns and cash flows on the one hand, and company research on the other. The first study covered the period from 1962 to 1975.70 This followed passage of the Kefauver-Harris Amendment to the Food, Drug, and Cosmetic Act, which required a showing of efficacy as well as safety in order to get FDA approval. This increased development times by several years and R&D costs per new drug by several-fold. The authors found that research productivity, defined as sales of recent new drug introductions divided by lagged R&D spending, declined rapidly during the period. This eventually influenced cash flows, the decline of which along with the fall in research productivity together had the effect of reducing R&D.

A later study looked at research spending between 1974 and 1994 in 11 firms specializing in prescription drugs.71 Together, these firms represented just over 40 percent of the U.S. market and half of the innovative output (defined as the first 3 years’ sales of all new chemical entities introduced in a period of time). Unlike the previous period, research productivity rose over 50 percent. Grabowski and Vernon found that both expected productivity of R&D and available cash flow positively affect R&D spending. Again, the link between cash flow and research is due to the fact that internally generated funds, which are often the result of higher profits, cost less than either borrowed funds or new equity, and therefore lower the required rate of return for new research at the margin.72

In 2004, Congress asked the U.S. Department of Commerce to study the effect of pharmaceutical price controls in OECD countries.73 The department concluded that most OECD countries use a variety of controls to limit the price of patent-protected drugs in their countries. These restrictions reduced the revenue of drug companies by $18 billion to $27 billion per year. The department estimated that lower revenues reduced global R&D by $5 billion to $8 billion, or 3 to 4 new drug entities annually. This latter effect was based on outside estimates regarding the cost of developing a new drug. Note that using a lower cost of development would imply that the reduction in research spending resulted in a higher number of new drugs not being discovered. Access to these new drugs would benefit U.S. consumers by $5 billion to $7 billion a year. In contrast, OECD countries also used price floors on generic drugs in order to protect their domestic manufacturers. Eliminating these floors would save Europeans $5 billion to $30 billion annually, potentially paying for restoring a competitive market to patent drugs. The study also found that significantly more new active substances were available in the United States than in other countries, which it attributed to companies’ increased ability to capture more of the social benefit from current drugs.74

One problem with modeling the relationship between prices and research is the causation may go both ways. It is possible that better research increases profits rather than the other way around. To get at this problem, economists Daron Acemoglu and Joshua Linn examined the pharmaceutical industry using the theory of induced innovation, which says that changes in the real prices of different goods or inputs should cause companies to change the direction of innovation.75 Their 2004 study looked at changes in demographic trends between 1970 and 1990. Demographic changes affect the potential market size for a drug but they do not depend on the amount of research being done. If research spending and the size of the market move together, causation should run from prices to research.

Acemoglu and Linn divided specific drugs into categories depending on the age of the population that primarily used them. The results showed a strong relationship between market size and the entry of new drugs. As baby boomers aged over a 30-year period, the market for drugs mostly consumed by the young declined, while those used by older individuals increased. This produced a matching change in the number of new drugs in each category. A 1-percent increase in the potential market size led to a 6-percent increase in the number of new drugs entering that market. Although much of this increase came from generics, both the number of nongeneric drugs (those not identical or bioequivalent to an existing drug) and the number of new molecular compounds (drugs containing an active component that has never been approved by the FDA or marketed in the United States) increased by at least 4 percent. They also found that drug firms anticipated these demographic changes with a lead of 10 to 20 years.

Another study, by Giaccotto, Santerre, and Vernon, found a strong link between real drug prices and firm R&D.76 Their 2005 study focused on R&D intensity (the ratio of R&D spending to product sales) rather than the level of research, and found that real drug prices, real GDP per capita, and the amount of foreign sales as a percentage of total sales all had a strong impact on R&D intensity the following year. Specifically, a 10-percent increase in real prices caused firms to increase their R&D intensity by nearly 6 percent the following year. Applying this result to the past, they estimated that if drug prices had not increased in real terms between 1980 and 2001, R&D spending would have been 30 percent below its actual level. The number of new drugs entering the market during this time would have fallen by between 330 and 365, or about one-third of the actual number.

Some studies have tried to estimate the impact of future price controls on research. In 2005, economists Thomas Abbott of Thomson-Medstat and John A. Vernon

found a strong impact on future innovation.77 They used the history of specific firms to look at the impact of prices on the initial decision whether to start Phase I trials on a perspective drug. With data on actual development costs, drug revenues, and a measure of the uncertainty facing firms, they found that minor price changes would have relatively little effect. A price decline of 5 to 10 percent would reduce product development by about 5 percent. But larger price declines would have a more serious impact. For example, a price cut of 40 to 45 percent in real terms would reduce the number of new development projects by 50 to 60 percent.

A 2006 study by Frank Lichtenberg looks at relationships between expected market revenues on the one hand and both the number of chemotherapy regimens for treating a cancer site (i.e., skin, lungs) and the number of articles published in scientific journals pertaining to drug therapy for that cancer site.78 As the importation of drugs would decrease the U.S. price and therefore the expected revenues, Lichtenberg hypothesized that importation would cause both the number of regimens and the number of publications to fall. He started by assuming that the responsiveness of innovation to a change in revenues is at least as great as its responsiveness to the number of patients. To estimate the latter, he looked at both changes in the number of patents with particular types of cancer in Canada and the United States, and the number of regimens and research papers devoted to that type of cancer. The results showed the elasticity of the number of cancer patients to the number of chemotherapy regimens available to treat a specific type of cancer is 0.53. The elasticity of journal citations is 0.60. Therefore, a 10-percent fall in drug prices is likely to cause a 5- to 6-percent decline in both cancer regimens and research articles.

The study also looked at the relationship between the number of innovations within a company (defined as FDA-approved active ingredients contained in products sold by the company that are not contained in any other company’s products) and the number of its employees. It finds an elasticity of 0.71 across 14 pharmaceutical companies; a 10-percent reduction in new approved active ingredients would cut the number of employees by 7 percent.

In 2009, economists Abdulkadir Civan and Michael Maloney looked at both the existing drugs available to treat specific diseases and the number of new drugs in development for those same diseases.79 After correcting for the number of existing treatments available for a specific condition, they found a positive relationship between the average price of available drugs and the number of new drugs being developed. A 30-percent increase in drug prices for a given condition would increase the number of drugs in development for that condition by 25 percent. Of course, as generics enter the market in response to favorable market conditions, prices usually fall.

Economists Joseph Golec of the University of Connecticut and John A. Vernon looked at the relationship between an index of drug prices in both the United States and Europe and the profitability, research spending, and stock price of U.S. and EU pharmaceutical firms, respectively.80 Between 1993 and 2004, European price controls prevented pharmaceutical prices from rising in inflation-adjusted terms, whereas real prices in the United States rose by 50 percent. However, the authors found a statistically significant positive correlation (0.64) between changes in the price increases and R&D spending.81

Market conditions not only affected the size of research spending, it also affected its location. Looking at other sets of data, they found biopharmaceutical research in the EU countries exceeded research conducted in the United States by 24 percent in 1986. But by 2004, U.S. levels were 15 percent greater than EU levels.82 This is mostly due to EU spending stalling between 1997 and 2001, roughly the same time the two price indexes diverged. Total U.S. biopharma research by foreign firms has been growing at a faster rate than foreign research by U.S. firms, largely because U.S. prices for on-patent drugs are higher than those in Europe. Higher prices have therefore caused foreign companies to divert their attention to the U.S. market, thereby strengthening the U.S. domestic industry.

#### IP enables critical information sharing

Simon 6/25 [(Brenda, professor at California Western School of Law, research interests focus on how technological developments affect intellectual property and information law, former teaching fellow for the Law, Science and Technology LL.M. Program at Stanford Law School, and a research fellow in the Stanford Center for Law and the Biosciences, JD from UC Berkeley School of Law) “Patents, Information, and Innovation,” Brooklyn Law Review, 6/25/2020] JL

Patents play numerous roles in encouraging the exchange of information during the investment-seeking process in the medical device industry. One role is reducing the likelihood that the medical device will be expropriated. The risks of expropriation at this stage vary depending on the circumstances, which were set forth from a theoretical perspective in Part I and will be contextualized with examples from the medical device industry in this Part. Some of the variables in assessing expropriation risks, and consequently the function of patents in enabling information exchange, include whether the medical device is self-disclosing and easily reverse engineered, the importance of reputational and industry norms, and whether staging disclosure over time is an option.222 Time and resource constraints may limit the efficacy of some of these alternative mechanisms to patents in mitigating the risks of expropriation.223

Apart from their ability to ensure exclusivity, patents have an independent function of providing a useful signal to investors about information distinct from the medical device invention, such as resource allocation and the experience of the executive team, similar to their role in the biotechnology industry.224 An issued patent can also provide an indication about the viability of the invention, such as the ability to limit competition, extend the first mover advantage, and provide an independent source of value to the company through licensing or sale.225

One survey of twenty venture capital fund managers looked at the importance of intellectual property protection in assessing the risk-return ratio of portfolio companies .226 For medical device companies, respondents ranked intellectual property protection third, after reimbursement and regulatory concerns at the FDA.227 The authors of the survey reasoned that intellectual property protection was a concern of venture fund managers, given the high patenting rates among venture-backed companies and that the size of medical device companies necessitated "their reliance on patent protection to maintain barriers to market entry by competitors ."228 Additionally, court decisions that cast doubt on whether patent protection would be available for some medical devices have also raised concerns.229

#### 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.

#### IP protection is critical to innovation – it incentivizes risk-taking by boosting investments

Ezell and Cory 19 [(Stephen, vice president, global innovation policy, at the Information Technology and Innovation Foundation, B.S. from the School of Foreign Service at Georgetown University, and Nigel, associate director covering trade policy at the Information Technology and Innovation Foundation, former researcher in the Southeast Asia Program at the Center for Strategic and International Studies, MA in public policy from Georgetown University) “The Way Forward for Intellectual Property Internationally,” Information Technology and Innovation Foundation, 4/25/2019] JL

IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47 In contrast, IPR reform has been associated with increased innovative activity, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts.

The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that R&D to GDP ratios are positively related to the strength of patent rights, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56

#### Reducing IP protections stifles innovation by undermining incentives

Bacchus 12/16 [(James, member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida) “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines,” Cato Institute, 12/16/2020] JL

The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”18 The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐​based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation.

In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19