# 1NC vs Peninsula SM

### 1

#### Interpretation – Debaters must have a 1AC Solvency Advocate that advocates the specific proposal of the 1AC

#### Violation – the plan eliminates IP restrictions completely , but Adler says

WTO issue a “TRIPS waiver.” This action would temporarily suspend WTO intellectual property protections, allowing more companies and countries to produce coronavirus vaccine components

#### Standards –

#### A] Shiftiness – we don’t know what they actually implement until the 1ar which is too late. Stable advocacy is key to reciprocal engagement and is the basis for effective clash.

#### B] Topic lit – it creates an infinite amount of theoretical reductions which aren’t tied to the topic literature which forces debates into stale generics.

Even if this instance wasn’t that abusive the Counterinterp sets the precedent that affs don’t need solvency advocates

a] New affs is Drop the Debater – only way to rectify abuse since there’s nothing else to drop and the abuse already occured.

b] Use Competing Interps – 1] Being fair is a yes/no question, you can’t be reasonably fair and 2] Reasonability invites arbitrary judge intervention and a race to the bottom of questionable argumentation o/ws since you can always just chose the best norm and follow it.

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

Reject 1ar – at least weigh the abuse of reading it vs their arg intervention infinite abuse

Neg abuse outweighs Aff abuse – 1] Infinite prep time before round to frontline 2] 2AR judge psychology and 1st and last speech 3] Infinite perms and uplayering in the 1AR.

### 2

#### Counterplan Text: the member nations of the World Trade Organization ought to

#### temporarily suspend intellectual property restrictions in line with 1AC Adler 21

* **implement a one-and-done approach for patent protection.**

The first plank s**olves the aff – its their own advocate and all their ev is about COVID**

#### It’s not a sunset CP – There’s a defined end date to the TRIPs waiver. At the very least it’s the core of the topic and the 1AC intentionally changing their advocacy from their solvency advocate is the definition of baiting theory and should be rejected. The neg should be able to strategically capitalize on aff mistakes otherwise debate is meaningless.

The second plank solves evergreening while still maintaining innovation.

Feldman 3 Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//SidK + Elmer

I believe that one period of protection **should be enough**. We should make the legal changes necessary to prevent companies **from building patent walls** and piling up mountains of rights. This could be accomplished **by a “one-and-done” approach** for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug. Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. The result, however, is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of data exclusivity (in which no generic is allowed to use the original drug’s safety and effectiveness data), or something else — but **not all of the above** and more. Consider Suboxone, a combination of buprenorphine and naloxone for treating opioid addiction. The drug’s maker has extended its protection cliff eight times, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That makes almost two additional decades in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained. Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals, not for all types of technologies. That way, one-and-done could be implemented through **legislative changes to the FDA’s drug approval system**, and would apply to patents granted going forward. One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing patent obviousness doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented. Either by congressional clarification or judicial interpretation, many pile-on patents could be eliminated with a ruling that the core concept of the additional patent is nothing more than the original formulation. Anything else is merely an obvious adaptation of the core invention, modified with existing technology. As such, the patent would fail for being perfectly obvious. Even without congressional action, a more vigorous and robust application of the existing obviousness doctrine could significantly improve the problem of piled-up patents and patent walls. Pharmaceutical companies have become adept at maneuvering through the system of patent and non-patent rights to create mountains of rights that can be applied, one after another. This behavior lets drug companies keep competitors out of the market and beat them back when they get there. We shouldn’t be surprised at this. Pharmaceutical companies are profit-making entities, after all, that face pressure from their shareholders to produce ever-better results. If we want to change the system, we must change the incentives driving the system. And right now, the incentives for creating patent walls are just too great.

### 3

#### Strong IP guarantees causes massive Pharma innovation.

Stevens and Ezell 20 Philip Stevens and Stephen Ezell 2-3-2020 "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" <https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work> (Philip founded Geneva Network in 2015. His main research interests are the intersection of intellectual property, trade, and health policy. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division on a range of IP and health issues. Prior to his time with WIPO, Philip worked as director of policy for International Policy Network, a UK-based think tank, as well as holding research positions with the Adam Smith Institute and Reform, both in London. He has also worked as a political risk consultant and a management consultant. He is a regular columnist in a wide range of international newspapers and has published a number of academic studies. He holds degrees from the London School of Economics and Durham University (UK).)//Elmer

The **Current System** Has **Produced a Tremendous Amount of Life-Sciences Innovation** The frontier for biomedical innovation is seemingly limitless, and the challenges remain numerous—whether it comes to diseases that afflict millions, such as cancer or malaria, or the estimated 7,000 rare diseases that afflict fewer than 200,000 patients.24 And while certainly citizens in developed and developing nations confront differing health challenges, those challenges are increasingly converging. For instance, as of this year, analysts expect that **noncommunicable** diseases such as cardiovascular disease and diabetes will account for 70 percent of natural fatalities **in developing countries**.25 Citizens of low- and middle-income countries bear 80 percent of the world’s death burden from cardiovascular disease.26 Forty-six percent of Africans over 25 suffer from hypertension, more than anywhere else in the world. Similarly, 85 percent of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.27 To develop treatments or cures for these conditions, novel biomedical innovation **will be needed from everywhere**. Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over **$1.36 trillion in R&D** in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach $181 billion by 2022.28 In no small part due to that investment, **943 new active substances have been introduced** globally over the prior 25 years.29 The U.S. Food and Drug Administration (FDA) has approved more than **500 new medicines since 2000** alone. And these medicines are getting to more individuals: Global medicine use **in 2020 will reach 4.5 trillion doses**, up 24 percent from 2015.30 Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.31 In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).32 And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the **world’s most intractable diseases**, **including cancer and Alzheimer’s**.33 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved **41 new medicines** (at that point, the most since 1996) many of which were first-in-class medicines.34 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.35 Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through **enhanced clinical efficacy** (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, **or better treatment** for some individuals who don’t respond well to the original drug) and by generating competition that exerts downward price pressures. For example, a patient needing a cholesterol drug has a host of statins from which to choose, which is important because some statins produce harmful side effects for some patients. Similarly, patients with osteoporosis can choose from Actonel, Boniva, or Fosomax. Or take for example Hepatitis C, which until recently was an incurable disease eventually requiring a liver transplant for many patients. In 2013, a revolutionary new treatment called Solvadi was released that boosted cure rates to 90 percent. This was followed in 2014 by an improved treatment called Harvoni, which cures the Hepatitis C variant left untouched by Solvadi. Since then, an astonishing six new treatments for the disease have received FDA approval, opening up a wide range of treatment options that take into account patients’ liver and kidney status, co-infections, potential drug interactions, previous treatment failures, and the genotype of HCV virus.36 “If you have to have Hepatitis C, now is the time to have it,” as Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York, told the Financial Times. “We have these marvellous drugs we can treat you with right now, without side effects,” he added. “And this time next year, we’ll have another round of drugs available.”37 Moreover, the financial potential of this new product category has led to multiple competing products entering the market in quick succession, in turn placing downward pressure on prices.38 As Geoffrey Dusheiko and Charles Gore write in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”39 As noted previously, opponents of the current market- and IP-based system contend patents enable their holders to exploit a (temporary) market monopoly by inflating prices many multiples beyond the marginal cost of production. But rather than a conventional neoclassical analysis, an analysis based on “innovation economics” finds it is exactly this “distortion” that is required for innovation to progress. As William Baumol has pointed out, “Prices above marginal costs and price discrimination become the norm rather than the exception because … without such deviations from behaviour in the perfectly competitive model, innovation outlays and other unavoidable and repeated sunk outlays cannot be recouped.”40 Or, as the U.S. Congressional Office of Technology Assessment found, “Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary **to induce companies to invest** in researching new chemical entities.”41 This is also why, in 2018, the U.S. Congressional Budget Office estimated that because of high failure rates, biopharmaceutical **companies would need to earn a 61.8 percent rate of return on their successful new drug R&D projects in order to match a 4.8 percent after-tax rate of return on their investment**s.42 Indeed, **it’s the ability to recoup fixed costs, not just marginal** costs, through mechanisms such as patent protection that lies at the heart of all innovation-based industries and indeed all innovation and related economic progress. If companies could not find a way to pay for their R&D costs, and could only charge for the costs of producing the compound, **there would be no new drugs developed**, just as there would be no new products developed in any industry. Innovating in the life sciences remains expensive, risky, difficult, and uncertain. Just 1 in 5,000 drug candidates make it all the way from discovery to market.43 A 2018 study by the Deloitte Center for Health Solutions, “Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018,” found that “the average cost to develop an asset [an innovative life-sciences drug] including the cost of failure, has increased in six out of eight years,” and that the average cost to create a new drug has risen to $2.8 billion.44 Related research has found the development of new drugs requires years of painstaking, risky, and expensive research that, for a new pharmaceutical compound, takes an average of 11.5 to 15 years of research, development, and clinical trials, at a cost of $1.7 billion to $**3.2 billion**.45 IP rights—including patents, copyrights, and data exclusivity protections—give innovators, whether in the life sciences or other sectors, the **confidence** to undertake the risky and expensive process of innovation, secure in the knowledge they’ll be able to capture a share of the gains from their efforts. And these gains are often only a small fraction of the true value created. For instance, Yale University economist William Nordhaus estimated inventors capture just 4 percent of the total social gains from their innovations; the rest spill over to other companies and society as a whole.46 Without adequate IP protection, private investors would never find it viable to fund advanced research because lower-cost copiers would be in a position to undercut the legitimate prices (and profits) of innovators, even while still generating substantial profits on their own.47 As the report “Wealth, Health and International Trade in the 21st Century” concludes, “Conferring robust intellectual property rights is, in the pharmaceutical and other technological-development contexts, **in the global public’s long-term interests.** Without adequate mechanisms for directly and indirectly securing the private and public funding of medicines and vaccines, research and development communities across the world will lose future benefits that would far outweigh the development costs involved.”48 Put simply, the current market- and IP-based life-sciences innovation system is producing life-changing biomedical innovation. As Jack Scannell, a senior fellow at Oxford University’s Center for the Advancement of Sustainable Medical Innovation has explained, “I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995.” He continued, “Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good.”49 For example, on September 14, 2017, the FDA approved Mvasi, the first biosimilar for Roche’s Avastin, a breakthrough anticancer drug when it came out in the mid-1990s for lung, cervical, and colorectal cancer.50 In other words, a medicine to treat forms of cancer that barely existed 20 years ago is now available as a generic drug today. It’s this dynamic that enables us to imagine a situation wherein drugs to treat diseases that aren’t available anywhere at any price today (for instance, treatments for Alzheimer’s or Parkinson’s) might be available as generics in 20 years. But that will only be the case if we preserve (and improve where possible) a life-sciences innovation system that is generally working. The current system does not require wholesale replacement by a prize-based system that—notwithstanding a meaningful success here or there—has produced nowhere near a similar level of novel biomedical innovation.

#### **Eliminating IP protections chills future investment – even the perception of wavering commitment scares off companies.**

Grabowski et al. ’15 (Harry; Professor Emeritus of Economics at Duke, and a specialist in the intersection of the pharmaceutical industry and government regulation of business; February 2015; “The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation”; Health Affairs; <https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047>; Accessed: 8-31-2021; AU)

Patents and other forms of **intellectual property** **protection** play **essential roles** in encouraging innovation in biopharmaceuticals. As part of the “21st Century Cures” initiative, Congress is reviewing the policy mechanisms designed to accelerate the discovery, development, and delivery of new treatments. Debate continues about how best to balance patent and intellectual property incentives to encourage innovation, on the one hand, and generic utilization and price competition, on the other hand. We review the current framework for accomplishing these dual objectives and the important role of patents and regulatory exclusivity (together, the patent-based system), given the lengthy, costly, and risky biopharmaceutical research and development process. We summarize existing targeted incentives, such as for orphan drugs and neglected diseases, and we consider the pros and cons of proposed voluntary or mandatory alternatives to the patent-based system, such as prizes and government research and development contracting. We conclude that patents and regulatory exclusivity provisions are likely to remain the core approach to providing incentives for biopharmaceutical research and development. However, prizes and other voluntary supplements could play a useful role in addressing unmet needs and gaps in specific circumstances. Technological innovation is widely recognized as a key determinant of economic and public health progress. 1,2 Patents and other forms of intellectual property protection are generally thought to play essential roles in encouraging innovation in biopharmaceuticals. This is because the process of developing a new drug and bringing it to market is **long, costly, and risky**, and the costs of imitation are low. After a new drug has been approved and is being marketed, its **patents protect it** from competition from chemically identical entrants (or entrants infringing on other patents) for a period of time. **For firms** to have an **incentive** to **continue to invest** in innovative development efforts, they must have an **expectation** that they can **charge enough** during this period to **recoup** costs and make a profit. After a drug’s patent or patents expire, **generic rivals** can enter the market at **greatly reduced development cost** and prices, providing added consumer benefit but **eroding** the **innovator drug** company’s revenues. The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) was designed to balance innovation incentives and generic price competition for new drugs (generally small-molecule chemical drugs, with some large-molecule biologic exceptions) by extending the period of a drug’s marketing exclusivity while providing a regulatory framework for generic drug approval. This framework was later changed to encompass so-called biosimilars for large-molecule (biologic) drugs through the separate Biologics Price Competition and Innovation Act of 2009. Other measures have been enacted to provide research and development (R&D) incentives for antibiotics and drugs to treat orphan diseases and neglected tropical diseases. Discussion continues about whether current innovation incentives are optimal or even adequate, given evolving public health needs and scientific knowledge. For instance, the House Energy and Commerce Committee recently embarked on the “21st Century Cures” initiative, 3 following earlier recommendations by the President’s Council of Advisors on Science and Technology on responding to challenges in “propelling innovation in drug discovery, development, and evaluation.” 4 In this context, we discuss the importance of patents and other forms of intellectual property protection to biopharmaceutical innovation, given the unique economic characteristics of drug research and development. We also review the R&D incentives that complement patents in certain circumstances. Finally, we consider the pros and cons of selected voluntary (“opt-in”) or mandatory alternatives to the current patent- and regulatory exclusivity–based system (such as prizes or government-contracted drug development) and whether they could better achieve the dual goals of innovation incentives and price competition. 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. Universities also play a key role in the R&D ecosystem because they conduct basic biomedical research supported by sponsored research grants from the National Institutes of Health (NIH) and the National Science Foundation (NSF). The Patent and Trademark Law Amendments Act of 1980 (commonly known as the Bayh-Dole Act) gave universities the right to retain title to patents and discoveries made through federally funded research. This change was designed to encourage technology transfer through industry licensing and the creation of start-up companies. Universities received only 390 patents for their discoveries in 1980, 12 compared to 4,296 in 2011, with biotechnology and pharmaceuticals being the top two technology areas (accounting for 36 percent of all university patent awards in 2012). 13

#### **R&D’s key to innovation – otherwise, future pandemics.**

Marjanovic et al. ’20 (Sonja; Ph.D. at the University of Cambridge; May 2020; “How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis”; RAND; <https://www.rand.org/pubs/perspectives/PEA407-1.html>; Accessed: 8-31-2021; AU)

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.**

#### Evolving superbugs trigger extinction.

Srivatsa ’17 (Kadiyali; specialist in pediatric intensive and critical care medicine in the UK. Invented the bacterial identification tool ‘MAYA’; 1-12-2017; "Superbug Pandemics and How to Prevent Them", American Interest; https://www.the-american-interest.com/2017/01/12/superbug-pandemics-and-how-to-prevent-them/, Accessed: 8-31-2021; AU)

It is by now no secret that the human species is locked in a race of its own making with “superbugs.” Indeed, if popular science fiction is a measure of awareness, the theme has pervaded English-language literature from Michael Crichton’s 1969 Andromeda Strain all the way to Emily St. John Mandel’s 2014 Station Eleven and beyond. By a combination of massive inadvertence and what can only be called stupidity, we must now invent new and effective antibiotics faster than deadly bacteria evolve—and regrettably, they are rapidly doing so with our help. I do not exclude the possibility that bad actors might deliberately engineer deadly superbugs.1 But even if that does not happen, humanity faces an existential threat largely of its own making in the absence of malign intentions. As threats go, this one is entirely predictable. The concept of a “black swan,” Nassim Nicholas Taleb’s term for low-probability but high-impact events, has become widely known in recent years. Taleb did not invent the concept; he only gave it a catchy name to help mainly business executives who know little of statistics or probability. Many have embraced the “black swan” label the way children embrace holiday gifts, which are often bobbles of little value, except to them. But the threat of inadvertent pandemics is not a “black swan” because its probability is not low. If one likes catchy labels, it better fits the term “gray rhino,” which, explains Michele Wucker, is a high-probability, high-impact event that people manage to ignore anyway for a raft of social-psychological reasons.2 A pandemic is a quintessential gray rhino, for it is no longer a matter of if but of when it will challenge us—and of how prepared we are to deal with it when it happens. We have certainly been warned. The curse we have created was understood as a possibility from the very outset, when seventy years ago Sir Alexander Fleming, the discoverer of penicillin, predicted antibiotic resistance. When interviewed for a 2015 article, “The Most Predictable Disaster in the History of the Human Race,” Bill Gates pointed out that one of the costliest disasters of the 20th century, worse even than World War I, was the Spanish Flu pandemic of 1918-19. As the author of the article, Ezra Klein, put it: “No one can say we weren’t warned. And warned. And warned. A pandemic disease is the most predictable catastrophe in the history of the human race, if only because it has happened to the human race so many, many times before.”3 Even with effective new medicines, if we can devise them, we must contain outbreaks of bacterial disease fast, lest they get out of control. In other words, we have a social-organizational challenge before us as well as a strictly medical one. That means getting sufficient amounts of medicine into the right hands and in the right places, but it also means educating people and enabling them to communicate with each other to prevent any outbreak from spreading widely. Responsible governments and cooperative organizations have options in that regard, but even individuals can contribute something. To that end, as a medical doctor I have created a computer app that promises to be useful in that regard—of which more in a moment. But first let us review the situation, for while it has become well known to many people, there is a general resistance to acknowledging the severity and imminence of the danger. What Are the Problems? Bacteria are among the oldest living things on the planet. They are masters of survival and can be found everywhere. Billions of them live on and in every one of us, many of them helping our bodies to run smoothly and stay healthy. Most bacteria that are not helpful to us are at least harmless, but some are not. They invade our cells, spread quickly, and cause havoc that we refer to generically as disease. Millions of people used to die every year as a result of bacterial infections, until we developed antibiotics. These wonder drugs revolutionized medicine, but one can have too much of a good thing. Doctors have used antibiotics recklessly, prescribing them for just about everything, and in the process helped to create strains of bacteria that are resistant to the medicines we have. We even give antibiotics to cattle that are not sick and use them to fatten chickens. Companies large and small still mindlessly market antimicrobial products for hands and home, claiming that they kill bacteria and viruses. They do more harm than good because the low concentrations of antimicrobials that these products contain tend to kill friendly bacteria (not viruses at all), and so clear the way for the mass multiplication of surviving unfriendly bacteria. Perhaps even worse, hospitals have deployed antimicrobial products on an industrial scale for a long time now, the result being a sharp rise in iatrogenic bacterial illnesses. Overuse of antibiotics and commercial products containing them has helped superbugs to evolve. We now increasingly face microorganisms that cannot be killed by antibiotics, antifungals, antivirals, or any other chemical weapon we throw at them. Pandemics are the major risk we run as a result, but it is not the only one. Overuse of antibiotics by doctors, homemakers, and hospital managers could mean that, in the not-too-distant future, something as simple as a minor cut could again become life-threatening if it becomes infected. Few non-medical professionals are aware that antibiotics are the foundation on which nearly all of modern medicine rests. Cancer therapy, organ transplants, surgeries minor and major, and even childbirth all rely on antibiotics to prevent infections. If infections become untreatable we stand to lose most of the medical advances we have made over the past fifty years.

### 1NC – Framing

#### The standard is maximizing expected well-being. ROTB better debater

#### Prefer –

#### 1] Pleasure is an intrinsic good—solves regress.

Moen ’16 – (Ole Martin, PhD, Research Fellow in Philosophy @ University of Oslo, "An Argument for Hedonism." Journal of Value Inquiry 50.2 (2016): 267). Modified for glang

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 what her~~is~~ 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. Although pleasure and pain thus seem to be good candidates for intrinsic value and disvalue, several objections have been raised against this suggestion: (1) that pleasure and pain have instrumental but not intrinsic value/disvalue; (2) that pleasure and pain gain their value/disvalue derivatively, in virtue of satisfying/frustrating our desires; (3) that there is a subset of pleasures that are not intrinsically valuable (so-called “evil pleasures”) and a subset of pains that are not intrinsically disvaluable (so-called “noble pains”), and (4) that pain asymbolia, masochism, and practices such as wiggling a loose tooth render it implausible that pain is intrinsically disvaluable. I shall argue that these objections fail.

#### Outweighs –

A] Other FWs rely on long questionable claims that make them less likely. Only util is epistemically accessible.

B] History – Thousands of years of debating haven’t settled ethical questions, so presume util since there’s good in making the world a better place

#### 2] States must use util – they seek practical benefits for constituents and aren’t unified agents so they don’t have intentions. No calc indicts since states use util successfully all the time and they just prove util’s hard to use not impossible.

#### 3] Death outweighs – agents can’t act ethically if they fear bodily harm. Means extinction first – future value, magnitude, risk parity

Pummer 15 Theron, Junior Research Fellow in Philosophy at St. Anne's College, University of Oxford. “Moral Agreement on Saving the World” Practical Ethics, University of Oxford. May 18, 2015 AT, recut BWSEK

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists tendency only. There is a to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But that is a huge mistake. Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; it is not the view that the latter don’t matter. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. We should also take into account moral uncertainty. What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable.

Kessler is silly – its not infinite, just really really large. If our scenario is actually absurd then probability\*magnitude would prove why.

Winter and Leighton assumes there is no structural impact to ABR – it will disproportionately hurt disadvantaged communities. This card also has no warrant or implication cuz its 1 sentence.

The Medina card assumes you know exactly what minorities in the global south want. Neither of us do, but probability\*magnitude and pain and pleasure are our best bet since it’s what we’ve evolved to.

Memmi is just a rhetorical claim that racism is always bad. IMO it’s a lot more racist to sacrifice the global south to ABR.

Matheson is about nukes.

### 1NC – COVID Defense

#### The Plan can’t solve COVID -

#### 1] Lack of key supplies

Tepper 21 James Tepper, 4/10 [James Tepper, (James M. Tepper is an American neuroscientist currently a Board of Governors Professor of Molecular and Behavioral Neuroscience and Distinguished Professor at Rutgers University and an Elected Fellow of the American Association for the Advancement of Science.)]. "Global Covid vaccine rollout threatened by shortage of vital components." Guardian, 4-1-2021, Accessed 8-8-2021. https://www.theguardian.com/world/2021/apr/10/global-covid-vaccine-rollout-threatened-by-shortage-of-vital-components // duongie

Vaccine-makers around the world face shortages of vital components including large plastic growbags, according to the head of the firm that is manufacturing a quarter of the UK’s jab supply. Stan Erck, the chief executive of Novavax – which makes the second vaccine to be grown and bottled entirely in Britain – told the Observer that the shortage of 2,000-litre bags in which the vaccine cells were grown was a significant hurdle for global supply. His warning came as bag manufacturers revealed that some pharmaceutical firms were waiting up to 12 months for the sterile single-use disposable plastic containers, which are used to make medicines of all kinds, including the Pfizer, Moderna and Novavax Covid-19 vaccines. But Erck and his British partners said they were confident they had enough suppliers to avoid disruption to the supply of Novavax. The vaccine is waiting for approval from the Medicines and Healthcare products Regulatory Agency (MHRA) but the first of 60 million doses ordered by the government are already in production in Teesside. The Fujifilm Diosynth Biotechnologies factory began growing the first cells for the Novavax vaccine in Billingham, County Durham this month and in a few weeks they will fill the bioreactor bag, ready to be transported to GlaxoSmithKline’s plant at Barnard Castle to be put into vials for distribution. “The first hurdle is showing it works and we don’t have that hurdle any more,” Erck said. But he added there were others still to overcome. “There’s the media that the cells have to grow in,” Erck said. “You grow them in these 2,000-litre bags, which are in short supply. Then you pour it out and you have to filter it, and the filters are in short supply. The little things count.” Novavax almost ran out of bags at one of its 20 factories earlier this year, but there had been no delays for the UK operation, according to Martin Meeson, global chief executive of Fujifilm Diosynth. “We started working on our part of the supply chain in summer last year,” he said. “We had to accelerate some of the investment here, but the commitment we made last summer to start manufacturing in February has been fulfilled.” Production of coronavirus vaccines is being ramped up. Production of coronavirus vaccines is being ramped up. Photograph: Christophe Archambault/AP Both Meeson and Erck said the UK’s vaccine taskforce had been helpful in sorting out supply issues so far, but other countries and other medical supplies might be affected. ABEC makes bioreactor bags at two plants in the US and two in Fermoy and Kells in Ireland, and delivered six 4,000-litre bags to the Serum Institute in India last year for its Covid vaccines. Brady Cole, vice-president of equipment solutions at ABEC, said: “We are hearing from our customer base of lead times that are pushing out to nine, 10, even 12 months to get bioreactor bags. We typically run out at 16 weeks to get a custom bioreactor bag out to a customer.” He said ABEC was still managing to fulfil orders at roughly that rate. “The bag manufacturing capacity can’t meet demand right now,” he added. “And on the component side, the tubes and the instruments and so forth that also go into the bag assembly – those lead times are also starting to get stretched as well. But the biggest problem we see is it really is just the ability to get bags in a reasonable amount of time.” ABEC expanded its factories last year and has now started making 6,000-litre bags, which are roughly the size of a minibus. Other firms including MilliporeSigma, part of German company Merck, have also been expanding their manufacturing facilities. American firm Thermo Fisher Scientific expects it will finish doubling its capacity this year. The US government has also blocked exports of bags, filters and other components so it can supply more Pfizer vaccines for Americans. Adar Poonawalla, the chief executive of the Serum Institute of India, said the restrictions were likely to cause serious bottlenecks. Novavax is hoping to avoid delays and “vaccine nationalism” by operating on four continents, with 20 facilities in nine countries. “One year ago, we had exactly zero manufacturing capacity,” Erck said. “We’re self-sufficient. The two main things we need to do are done in the UK. And in the EU we have plants in Spain and the Czech Republic and fill-and-finish in Germany and the Netherlands.” There was no need for vaccines to cross borders to fulfil contracts, he said. The Oxford/AstraZeneca vaccine was hit by a delay to a delivery of 5 million doses from India and a problem with a batch made in Britain, and the company has been dragged into a lengthy row between the UK and the EU over vaccine exports.

#### 2] Skill Disparities and Trade Secrets – Moderna proves IP isn’t the root cause.

Silverman 3-15 Rachel Silverman 3-15-2021 "Waiving vaccine patents won’t help inoculate poorer nations" <https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/> (Rachel Silverman is a policy fellow at the Center for Global Development)//Duong

Reality is more complicated, however. Because of the technical complexity of manufacturing coronavirus vaccines, waiving intellectual-property rights, by itself, would have **little effect**. It could even backfire, with companies using the move as an excuse to disengage from global access efforts. There are more effective ways to entice — and to pressure — companies to license and share their intellectual property and the associated know-how, without broadly nullifying patents. The Moderna vaccine illustrates the limits of freeing up intellectual property. Moderna announced in October that it would **not enforce IP rights** on its coronavirus vaccine — and yet it has **taken no steps to share information** about the vaccine’s design or manufacture, citing commercial interests in the underlying technology. Five months later, production of the Moderna vaccine remains entirely under the **company’s direct control** within its owned and contracted facilities. Notably, Moderna is also the only manufacturer of a U.S.- or British-approved vaccine not yet participating in Covax, a global-aid-funded effort (including a pledged $4 billion from the United States) to purchase vaccines for use in low- and middle-income countries. It is true, however, that activist pressure — including threats to infringe upon IP rights — can encourage originators to enter into voluntary licensing arrangements. So the global movement to liberate the vaccine patents may be useful, even if some advocates make exaggerated claims about the effects of waivers on their own. We focused on covid. Now our other patients are suffering. One reason patent waivers are unlikely to help much in this case is that vaccines are harder to make than ordinary drugs. Because most drugs are simple chemical compounds, and because the composition of the compounds is easily analyzable, competent chemists can usually reverse-engineer a production process with relative ease. When a drug patent expires, therefore — or is waived — generic companies can readily enter the market and produce competitive products, lowering prices dramatically. Vaccines, in contrast, are complex biological products. Observing their contents is insufficient to allow for imitation. Instead, to produce the vaccine, manufacturers need access to the developer’s “soft” IP — the proprietary recipe, cell lines, manufacturing processes and so forth. While some of this information is confidentially submitted to regulators and might theoretically be released in an extraordinary situation (though not without legal challenge), manufacturers are at an enormous disadvantage without the originator’s cooperation to help them set up their process and kick-start production. Even with the nonconsensual release of the soft IP held by the regulator, the process of trial and error would cause long delays in a best-case scenario. Most likely, the effort would end in expensive failure. Manufacturers also need certain raw ingredients and other materials, like glass vials and filtration equipment; overwhelming demand, paired with disruptive export restrictions, has constricted the global availability of some of these items.

### 1NC – Infectious Diseases turn

#### Forcing factory production results in unsafe manufacturing and forces trade-offs with medicines for other infectious diseases.

Szabo et. Al 21 Liz Szabo et. Al 21 [Liz Szabo (Liz Szabo, a senior correspondent and enterprise reporter who focuses on the quality of patient care, has covered medicine for two decades.)]. "Why Even Presidential Pressure Might Not Get More Vaccine to Market Faster." Kaiser Health News, 1-26-2021, Accessed 8-5-2021. https://khn.org/news/article/ramping-up-covid-vaccine-production-could-take-months-even-with-bidens-best-tool-to-pressure-companies/ // duongie

Americans are dying of covid-19 by the thousands, but efforts to ramp up production of potentially lifesaving vaccines are hitting a brick wall. Vaccine makers Moderna and Pfizer-BioNTech are **running their factories full ti**lt and are under enormous pressure to expand production or collaborate with other drug companies to set up additional assembly lines. That pressure is only growing as new viral variants of the virus threaten to launch the country into a deadlier phase of the pandemic. President Joe Biden has said he plans to invoke the Cold War-era authority of the Defense Production Act to provide more vaccines to millions of Americans. Consumer advocates — who had called for Donald Trump to use the Defense Production Act more aggressively as president — are now asking Biden to do the same. But even forcing companies to gear up production won’t **provide much-needed doses anytime soon**. Expanding production lines takes time. Establishing lines in repurposed facilities can take months. “The big problem is that even if you can get the raw material and get the infrastructure set up, how do you get a company that is already producing at maximum capacity to go beyond that maximum capacity?” said Lawrence Gostin, a professor of global health law at Georgetown University. Ordering the companies to work 24/7 “would be a naïve solution,” said Dr. Nicole Lurie, a senior adviser to the CEO of the Coalition for Epidemic Preparedness Innovations, an international group that finances vaccines for emerging diseases. “They’re probably already doing that to the extent they have the raw materials.” Lurie added, “If you completely wear people out, mistakes happen. You **have to balance speed with quality and safety.”** The technological challenges involved are daunting, and the companies haven’t been forthcoming about what’s needed to overcome any supply shortfalls. “We don’t know what the holdup is. Is it capacity? Raw materials? People? Glass vials? We just don’t know what the bottleneck is,” said Erin Fox, senior director of drug information and support services at the University of Utah Health Hospitals. Forcing other companies to start making the vaccines might not work either, Gostin said. “I’m not sure if Biden could require a private company to transfer its technology to another company,” Gostin said. “That is highly questionable legally. … President Biden’s room for maneuvering isn’t as great as people think.” Drug companies define “trade secrets” broadly, Fox said. “In general, drug companies don’t have to tell me who is making their product, where it’s made, the location of the factory. … That’s considered proprietary.” Part of the challenge relates to how these vaccines are made. The first two authorized products use lipid nanoparticles to deliver a snippet of the coronavirus’s genetic material — called messenger RNA, or mRNA — into cells. The viral genes teach our cells how to make proteins that stimulate an immune response to the novel coronavirus. Messenger RNA is fragile and breaks down easily, so it needs to be handled with care, with specific temperatures and humidity levels. The vaccines “are not widgets,” said Lurie, who served as assistant secretary for preparedness and response at the Department of Health and Human Services during the Obama administration. Every step, experts say, to get vaccines to market has its complexities: obtaining raw materials; building facilities to precise specifications; buying single-use products, such as tubing and plastic bags to line stainless steel bioreactors; and hiring employees with the requisite training and expertise. Companies also must pass safety and quality inspections and arrange for transportation. The Defense Production Act, for instance, would allow the government to commandeer a plant that already has a fermenter — there are plenty in the biotech industry — to expand production. But that’s just the first stage in making an mRNA vaccine and, even then, it would take about a year to get going, said Dr. George Siber, a vaccine expert who is on the advisory board of CureVac, a German mRNA vaccine company. Companies would first have to do a breathtakingly thorough cleaning to prevent cross-contamination, Siber said. Next, they would need to set up, calibrate and test equipment, and train scientists and engineers to run it. Finally, Siber said, unlike a drug, whose components can be tested for purity, there’s no way to be sure a vaccine produced in a new facility is what it claims to be without testing it on animals and people. “Making vaccines is not like making cars, and quality control is paramount,” said Dr. Stanley Plotkin, a vaccine industry consultant credited with inventing the rubella vaccine. “We are expecting other vaccines in a matter of weeks, so it might be faster to bring them into use.” However, even that will require patience. Johnson & Johnson, expected to announce clinical trial results this month, has said that it won’t be able to deliver as many shots as planned because of manufacturing delays. The company did not confirm a manufacturing delay and declined to respond to questions. AstraZeneca’s vaccine, also funded in part by U.S. taxpayers, is in use already in the United Kingdom and India, but the Food and Drug Administration has raised questions about its late-stage trial, so it may not be available here until the spring. Novavax, another U.S.-funded vaccine maker, has been plagued by delays and only recently began recruiting volunteers for its big trial. Merck, the most recent company to get federal support for covid vaccines, announced Monday it was scrapping its two candidates after they failed to produce adequate immune response in early tests. “None of the vaccine makers are manufacturing at the volume they ultimately want to be at,” Lurie said. “They all have manufacturing delays.” Pfizer, which has committed 200 million doses to the U.S. government by the end of July, said last week it expected “no interruptions” in shipments from its primary U.S. covid manufacturing plant in Kalamazoo, Michigan. Pfizer spokesperson Sharon Castillo said the company has expanded manufacturing facilities and added more suppliers and contract manufacturers. Those efforts, and the company’s announcement that its five-dose vials actually contain an extra dose, mean “we can potentially deliver approximately 2 billion doses worldwide by the end of 2021.” The U.S. government also has an option to acquire another 400 million doses of the Pfizer-BioNTech vaccine, though the company declined to provide details on that option when asked. But countries around the world are competing for the same supplies and raw materials, Gostin said. Biden could use the Defense Production Act “to force Pfizer to prioritize U.S. contracts, but that would be politically risky,” given that other countries could retaliate by hoarding supplies. Although Pfizer is an American company, it has partnered with BioNTech, of Germany, to make its covid vaccine. “That would lead to a global mess.” Trying to corner the world market on vaccine ingredients or supplies would look bad, experts say, given that the United States just this week joined Covax, an international venture to source and distribute vaccines, in an effort to ensure poor countries aren’t left behind. Paradoxically, the rush to get vaccines to market may have resulted in a less efficient manufacturing process. Vaccine companies typically spend months making their factories run as efficiently as possible, as well as finding an ideal dose and the most effective interval between doses, Lurie said. Given the urgency of the pandemic, however, they delayed parts of this process and launched straight into mass production. Pfizer angered European countries last week when it paused vaccine production at a Belgian plant to upgrade its capacity. Pfizer said the weeklong closure would decrease vaccine deliveries to Europe for three to four weeks before boosting supplies in February. The move doesn’t affect U.S. vaccine supplies. “The U.S can’t necessarily readily access stuff that’s being held for vaccines in other countries,” Lurie said. And forcing other companies to make covid vaccines could jeopardize production of **other important shots,** such as measles, said Dr. Amesh Adalja, a senior scholar at the Johns Hopkins Center for Health Security. Routine childhood immunization rates have fallen during the pandemic, raising the risk of epidemics. Using the act to prioritize covid vaccine manufacturing has already disrupted supplies of at least one drug, Fox noted. In December, Horizon Therapeutics warned doctors and patients to expect a shortage of a drug called Tepezza, used to treat thyroid-related eye disease, because its manufacturer was ordered to prioritize covid shots. Lawmakers and consumer advocates such as Public Citizen called on the government to use the Defense Production Act more aggressively. In a letter sent earlier this month, Sen. Elizabeth Warren (D-Mass.) and Rep. Katie Porter (D-Calif.) said Moderna should share its technique for stabilizing its vaccine at normal refrigerator temperatures, without “ultracold” freezers. Moderna officials have said the intrinsic differences in the two companies’ mRNA material make that technology hard to share. Besides, they say, Pfizer has declined to share data with Moderna. Pfizer has declined to comment on the issue. Since Moderna’s effort is federally funded, the government presumably has march-in rights and could take over production, said Mike Watson, former president of Moderna subsidiary Valera, in an email. “The reality is that however far you push production capacity, you sooner or later reach a bottleneck.” Experts say it’s not as simple as demanding that glassmaker Corning step up and make glass vials, for example. Of course, the vials will need to meet rigorous requirements. But there’s also this: The U.S. is facing a shortage of mined sand, the main component needed to make glass vials.

#### That turns the Case – limited care and medicine for other infectious diseases will go to white, privileged populations leaving minorities and those in the global south vulnerable to unnecessary deaths.

### 1NC – Quality turn

#### IP laws are key to prevent the development and spread of counterfeit drugs.

**Mercurio 21:** Mercurio, Bryan [the Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law] “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review”, *Virginia Journal of International Law Online (Forthcoming 2021),* Feb 12, 2021

The protection of IP not only provides incentives to innovators to create, but also plays a crucial role in ensuring the safety of vaccines and helping to prevent the importation of fraudulent and dangerous goods. Unlike the typical pharmaceutical industry, the vaccine market is not a free and open market.69 Vaccines contain biological products made from living organisms and the risk of failure in vaccine development and production is high. 70 Moreover, the manufacturing process for vaccines is **much more** complex as it requires the use of facilities and equipment with a high degree of specialization.71 The complexity of vaccine products implies that more time and regulatory requirements are needed in order to make or “copy” the vaccine production process. Therefore, the innovator should be expected to make conscious and meticulous decisions as to when and to whom to issue licenses, as this is the most responsible way to bring their technologies to the world and safeguard global health. In addition, as the COVID-19 pandemic continues there has been a noticeable increase in the circulation of fake medicines around the world. According to the International Criminal Police Organization (Interpol), **organized crime groups have been producing fake drugs and medical products and selling them for lucrative profits in developing countries.72 With the development of COVID-19 vaccines on the market, a rapid rise in the illegal sale of fake items is expected**, according to the United Nations Office on Drugs and Crime (UNODC).73 Counterfeits of the legitimate products provide false promises of protection and could lead to disastrous consequences, including worsened illness and death for the individual and the retardation of herd immunity for the population at large. Effective and proactive IP procurement is essential and useful in mitigating the risks of counterfeit and substandard medicines. IP enforcement measures play a significant role in preventing these fake and illicit medicines from circulating in the market. While important during normal times, IP enforcement can take on an enhanced role of safeguarding the public during this critical period of time. Waiving all COVID-19 related IPRs raises the risk of unsafe or fake vaccines circulating in supply channels and being sold to unsuspecting governments, putting millions of human lives at risk and reducing trust in vaccines.

#### TURNS CASE – counterfeits cause major health crises – Niger proves.

**Williams & McKnight 14:** Williams, LaKeisha [Drug Information Specialist, Xavier University of Louisiana College of Pharmacy, New Orleans, Louisiana] McKnight, Ellen [PharmD Candidate, 2017, Xavier University of Louisiana College of Pharmacy, New Orleans, Louisian] “The Real Impact of Counterfeit Medications” June 19, 2014 AA

**Counterfeiting drugs is not only illegal, but it is also a major public health concern.** **Counterfeit drugs often contain the correct ingredients in incorrect quantities**; however, **they may also contain** either a wrong API—which may even be **toxic**—or no active **substance** at all.15 **Treatment with ineffective counterfeit drugs such as antibiotics can lead to the emergence of resistant organisms and may have a deleterious effect on a wide section of the population.** In extreme cases, **counterfeit drugs may even cause death**.3 **For example,** it has been estimated that between **60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit** vaccine containing only chloramphenicol, an antibiotic that is generally combined with another medication, which may have resulted in more than 100 fatal infections.17, 18 As a consequence of such damaging effects, **counterfeit drugs may erode public confidence in healthcare systems, healthcare professionals, the suppliers and sellers of genuine drugs, the pharmaceutical industry, and national drug regulatory authorities**.4

#### Quality Control DA: massive expansion of medicines leads to significantly worse medicines being manufactured since it costs more to develop good medicines this will lead to worse medicines being produced since they must be produced at a higher scale.

### 1NC – Drug Prices turn

#### Low prices independently cause AMR.

Babu and Suma 6 Babu, Varsha, and C. Suma. "Antibiotic pricing: when cheaper may not be better." Clinical infectious diseases 43.8 (2006): 1085-1086. (Government Primary Health Center)//Elmer

To The Editor—Antibiotics in India have always been cheaper in absolute terms thanks to weak patent laws that have been in effect until recently. Because a direct translation of drug prices from US dollars to Indian rupees (INR) would have rendered most new antibiotics inaccessible to the vast majority of Indians, such patent violations were subtly encouraged. Even despite this, we were caught unaware when pharmaceutical representatives approached our primary care center in rural India, claiming that a 5-day course of levofloxacin would henceforth cost the patient ∼INR 20 (<$0.50). Reluctant to accept such a statement at face value, we consulted the CIMS Updated Prescriber's Handbook [1], a popular index of pharmaceutical drugs available in India. Here, we discovered that a 5-day course of oral levofloxacin (500 mg once daily) cost anywhere from INR 19.5 to INR 475 ($0.50–$10.50), with most companies pricing their brand at <$1 for a full course. The same course in the United States would cost >$100. Intrigued, we did some more research and came up with the following results. The cheapest 5-day courses of first-line antibiotics, such as oral amoxicillin (500 mg thrice daily) or oral erythromycin (500 mg 4 times daily), cost INR 45 ($1) and INR 90 ($2), respectively. On the other hand, the cost of a 3-day course of oral azithromycin (500 mg daily) was one-half that of a course of erythromycin. Despite the obvious price advantage to the patients, we find this trend troubling. **Lower prices** often **lead to wider prescription of a given drug**, especially in resource-limited settings. **If** second-line **antibiotics**—such as levofloxacin and azithromycin—**are made available at lower prices** than first-line antibiotics, **there is a high probability of their overuse and subsequent development of resistance**. In the face of **very low costs of medication**, patients are unlikely to complain of escalating medical expenses. The issue assumes more gravity when one considers the fact that levofloxacin is an important second-line drug for the treatment of tuberculosis [2]. Its widespread use in the community **is likely to lead to emergence of resistance** **among** **mycobacteria** **and** delayed diagnosis of **tuberculosis** [3]—an occurrence that India, with its large population of tuberculosis-affected patients, cannot afford. We believe we have encountered a situation where **low prices of antibiotics are likely to cause more harm than good**. In the post World Trade Organization treaty scenario, governments in resource-limited countries should use their privileges of essential drug control to ensure that the costs of first-line antibiotics remain lower than those of second-line drugs. Such a government-instituted ladder in antibiotic pricing is essential to prevent the misuse of antibiotics in the community and to ensure that antibiotic resistance is kept at low levels.

#### AMR is an existential threat – it’s non-linear and has an invisible tipping point.

Silverman 16 Rachel Silverman 4-19-2016 “Confronting Antimicrobial Resistance: Can We Get to Collective Action?” <https://www.cgdev.org/blog/confronting-antimicrobial-resistance-can-we-get-collective-action> (MPhil with Distinction in Public Health @ the University of Cambridge, Senior Policy Analyst and Assistant Director of Global Health Policy @ the Center for Global Development, focusing on global health financing and incentive structures)//Elmer

Antimicrobial resistance is already causing huge harm – and the worst is yet to come. To open the panel, Dr. Chan issued a serious warning about the size and scope of the AMR threat: “everyone will be affected if we do not address this problem.” AMR is already responsible for an estimated 700,000 global deaths each year, 50,000 of which take place in the US and Europe. Extensively drug-resistant (XDR) tuberculosis—cases where the most effective first- and second-line drugs are rendered useless—infected an estimated 47,000 people worldwide in 2014, only one ‘last-line’ antimicrobial is available to reliably treat gonorrhea, and few new antimicrobial drugs are in the development pipeline. According to the latest review, AMR could cause 10 million deaths each year by 2050, with knock-on effects draining many trillions from the global economy. Summers suggested that AMR and potential pandemics, alongside climate change and nuclear proliferation, represent the top three existential threats to life on earth as we know it. And as Dr. Chan explained, the worst-case scenario implies the end of modern medicine as we know it. Even worse, Summers suggested that AMR seems like a “quintessential non-linear phenomenon, and therefore more dangerous.” Year by year the effects are small and mostly invisible. Butat some point in the future they could suddenly become catastrophic, like a “levee that doesn’t hold and unleashes a flood.” Dr. Chan concurred that “the tipping point is not predictable because…microbes are invisible. We don’t even know when they’re going to make the switch” to become resistant to existing drugs.