### NC

#### The standard is minimizing existential risk

#### 1. Epistemological uncertainty

Jablonowski, 10 (Mark, April, Lecturer in Economics at the University of Hartford, “Implications of Fuzziness for the Practical Management of High-Stakes Risks,” International Journal of Computational Intelligence Systems, Vol.3, No. 1, JKS)

**“Danger” is an inherently fuzzy concept. Considerable knowledge imperfections surround** both **the probability of high-stakes exposures, and the assessment of their acceptability.** **This is due to the complex and dynamic nature of risk in the modern world**. ¶ **Fuzzy thresholds for danger are most effectively established based on natural risk standards. This means that risk levels are acceptable only to the degree they blend with natural background levels**. This concept reflects an evolutionary process that has supported life on this planet for thousands of years. By adhering to these levels, **we can help assure ourselves of thousands more.** While the level of such risks is yet to be determined, **observation suggest that the degree of human-made risk we routinely subject ourselves to is several orders of magnitude higher.** ¶ Due to the fuzzy nature of risk, we can not rely on statistical techniques. **The fundamental problem with catastrophe remains, in the long run, there may be no long run**. That is, **we can not rely on results “averaging out” over time.** With such risks, **only precautionary avoidance** (based on the minimax’ing of the largest possible loss) **makes sense. Combined with reasonable natural thresholds, this view allows a very workable approach to achieving safe progress**.

#### 2. Turns their offense – war/warming disproportionately harms minority populations who can’t access shelters or resources – material violence outweighs – it’s the reason we care about abstract theory.

#### 3. Precludes engaging in their method – no one can challenge structural violence if we are dead.

#### 4 – Totalization – even if you think life doesn’t matter and that some people have zero vtl you don’t get to make that decision for all people

#### 5 – Objectivity – body count is quantitative – VTL is subjective and can’t be weighed

### CP

#### CP: The member nations of the World Trade Organization should implement a one-and-done approach for patent protection.

#### That solves, it enables generics and access while maintaining incentives for 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.

#### Reforming the Patent Process would lower Drug Prices and incentivize Pharma Innovation by revitalizing the Market.

Stanbrook 13, Matthew B. "Limiting “evergreening” for a better balance of drug innovation incentives." (2013): 939-939. (MD (University of Toronto) PhD (University of Toronto))//Elmer

At issue in the Indian case was “evergreening,” a now widespread practice by the pharmaceutical industry designed to extend the monopoly on an existing drug by modifying it and seeking new patents.2 Currently, half of all drugs patented in Canada have multiple subsequent patents, extending the lifetime of the original patent by about 8 years.3 Manufacturers, in defence of these practices, predictably tout the advantages of new versions of their products, which often represent more potent isomers or salts of the original drugs, longer-lasting formulations or improved delivery systems that make adherence easier or more convenient. But the new versions are by definition “**me too” drugs**, and demonstration that the resulting **incremental benefits** in efficacy and safety are clinically meaningful **is often lacking**. Moreover, the original drugs have often been “blockbusters” used for years to improve the health of millions of patients. It seems hard to argue convincingly why such beneficial drugs require an upgrade, often just before their patents expire. Rather than the marginal benefits accrued from tinkering with already effective agents, patients worldwide are in desperate need of new classes of pharmaceuticals for the great many health conditions for which treatments are presently inadequate or entirely lacking. But developing truly innovative drugs is undeniably a high-risk venture. It is important and necessary that pharmaceutical companies continue to take these risks, because they are usually the only entities with sufficient resources to do so. Therefore, companies must continue to perceive **sufficient incentives** to continue investing in innovation. Indeed, there is evidence that the prospect of future evergreening has become part of the incentive calculation for innovative drug development.4 But surely it is perverse to extend unpredictably a period of patent protection that the government intended to be clearly defined and predictable, and to maintain incentives that drive companies to divert their **drug-development resources away from innovation**. **Current patent legislation may not be optimal** for striking the right balance between encouraging innovation and facilitating profiteering. Given the broad societal importance of patent legislation, ongoing research to enable active governance of this issue should be a national priority. In the last decade, Canada’s laws have been among the friendliest toward evergreening in the world.5 We should now reflect on whether this is really in our national interest. Governments, including Canada’s, would do well to take inspiration from India’s example and tighten regulations that currently facilitate evergreening. This might involve **denying future patents for modifications** that currently would receive one. An overall reduction in the duration of all secondary patents on a therapy might also be considered. Globally, a more flexible and individualized approach to the length of drug patents might be a more effective strategy to align corporate incentives with population health needs. Limits on evergreening would likely reduce the **extensive patent litigation** that contributes to the **high prices of generic drugs** in Canada.3 Reducing economic pressure on generic drug companies may facilitate current provincial initiatives to lower generic drug prices. As opportunities to generate revenue from evergreening are eliminated, research-based pharmaceutical companies would be left with no choice but to invest more in innovative drug development to maintain their profits.

### DA

**Pharma innovation is doing great now – answers all your warrants.**

Lisa Jarvis, 1-17-2020, (Based in Chicago, Lisa has been covering the biotech and pharmaceutical industries at C&EN since 2006. She writes feature articles that weave together the business and science of developing drugs, while also serving as pharmaceuticals editor for the magazine. She has a particular interest in rare diseases, innovative models for drug discovery, and emerging technologies.) "The new drugs of 2019," Chemical &amp; Engineering News, <https://cen.acs.org/pharmaceuticals/drug-development/new-drugs-2019/98/i3> //Jay

Although pharmaceutical companies last year were unable to top the record-shattering [59 new drugs approved in the US in 2018](https://cen.acs.org/pharmaceuticals/drug-development/new-drugs-2018/97/i3), they were still on a roll. In 2019, the Food and Drug Administration green-lighted 48 medicines, a crop that includes myriad modalities and many new treatments for long-neglected diseases. Taken together, the past 3 years of approvals represent drug companies’ most productive period in more than 2 decades. Still, some analysts caution that the steady flow of new medicines could mask troubling indications about the health of the industry. The year brought several notable trends. The first was an uptick in the number of novel mechanisms on display in the new drugs. Roughly 42% of the medicines were first in class, meaning they had new mechanisms of action; this is a jump over the prior 4 years, when that portion ranged between 32 and 36%. Another trend was the influx of newer modalities. While small molecules continue to account for the lion’s share of new molecular entities (NMEs), making up 67% of overall approvals in 2019, the list also includes several antibody-drug conjugates, an antisense oligonucleotide therapy, and a therapy based on RNA interference (RNAi). Yet another encouraging trend was the influx of innovative therapies for underserved diseases. Standout approvals include two new drugs for sickle cell anemia (Global Blood Therapeutics’ Oxbryta and Novartis’s Adakveo), an antibiotic for treatment-resistant tuberculosis (Global Alliance for TB Drug Development’s pretomanid), and a therapy for women experiencing postpartum depression (Sage Therapeutics’ Zulresso). “The quality of the drugs over the last decade or so has steadily improved since the depths of the innovation crisis 10–12 years ago,” says Bernard Munos, a senior fellow at FasterCures, a drug research think tank. “We’re seeing stuff that frankly would have looked like science fiction back then.” Those futuristic new therapies include [Novartis’s Zolgensma](https://cen.acs.org/articles/97/i22/FDA-approves-second-gene-therapy.html), a gene therapy for spinal muscular atrophy; Alnylam Pharmaceuticals’ Givlaari, the company’s second marketed RNAi-based therapy; and several critical vaccines for infectious diseases, including Ebola, smallpox, and dengue fever. Not all those edgy therapies appear in C&EN’s list. We track approvals granted through the FDA’s main drug approval arm, the Center for Drug Evaluation and Research; drugs like vaccines and gene therapies are generally reviewed through the agency’s Center for Biologics Evaluation and Research. The new-approvals list also doesn’t include several therapies that made their way to patients for the first time, even though the FDA doesn’t consider them new drugs. For example, the agency gave its green light to Johnson & Johnson’s Spravato, making it the first new treatment option for people with major depressive disorder in more than 50 years. The drug is the S enantiomer of ketamine, an N-methyl-D-aspartate receptor antagonist that had been long approved as an anesthetic, gained notoriety as a club drug, and was used for years off label to treat severe depression ([see page 18](https://cen.acs.org/biological-chemistry/neuroscience/Ketamine-revolutionizing-antidepressant-research-still/98/i3)). Also notable in 2019 was a slight dip in the number of cancer drugs, which in recent years typically made up more than a quarter of all new medicines. Last year’s 11 cancer treatments accounted for roughly 23% of approvals.

#### **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 and AMR 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.

#### Actions that are targeted at singular medicines have perception-based spill-over effects that spark fear.

Asgari et al. ’21 (Nikou; writer for the Financial Times; 5-6-2021; “Pharma industry fears Biden’s patent move sets precedent”; Financial Times; <https://www.ft.com/content/f54bf71b-87be-4290-9c95-4d110eec7a90>; Accessed: 8-31-2021; AU)

Profits in the pharmaceutical industry are **protected** by a **fortress of patents** that guarantee drugmakers a stream of income until they expire. On Wednesday, Joe Biden broke with decades of US orthodoxy and **made a crack in the wall**. His administration’s decision to support a **temporary waiver of Covid-19 vaccine** patents prompted instant outrage in the pharmaceutical sector, which argues that the move **rides roughshod** over their intellectual property rights and will **discourage US innovation** while sending jobs abroad. “Intellectual property is the **lifeblood** of biotech, it’s like oxygen to our industry,” said Brad Loncar, a biotech investor. “If you take it away, you don’t have a biotech sector.” Biden’s top trade adviser Katherine Tai said that while the US government still “believes strongly” in intellectual property protections, it supported waiving patents for Covid-19 vaccines to help boost global production of jabs. The move comes as some countries, including India, struggle to tackle further waves of the virus even as others have rolled out successful vaccination campaigns that are driving down infections, hospitalisations and deaths. The waiver proposal was put forward at the World Trade Organization in October and has since been supported by more than 60 countries who say worldwide vaccine production must increase dramatically. Washington’s support marks a pivotal step in making the proposal a reality and Tai said the US would engage in negotiations to hammer out the details at the WTO. Tedros Adhanom Ghebreyesus, the WHO’s director-general, told the Financial Times the decision was a “monumental moment” in the fight against Covid-19. “I am not surprised by this announcement. This is what I expected from the administration of President Biden.” However, the pharma industry did not expect it; the US has tended to fiercely protect domestic companies’ intellectual property rights in trade disputes. Industry leaders described the decision as a heavy blow for innovation that would do little to boost global production because there is a shortage of manufacturing facilities and skilled employees. In an earnings call Thursday, Stéphane Bancel, chief executive of Moderna, said a patent waiver “will not help supply more mRNA vaccines to the world any faster in 2021 and 2022, which is the most critical time of the pandemic”. “There is no idle mRNA manufacturing capacity in the world,” he said. “The administration’s steps here are very unnecessary and damaging,” said Jeremy Levin, chair of biotech trade association Bio. “Securing vaccines rapidly will not be the result, and worse yet, it sets a principle that companies who invested in new tech will stand the risk of having that taken away.” Shares in the big makers of Covid-19 vaccines were hit by the announcement. Frankfurt-listed shares in BioNTech closed down 12 per cent on Thursday while Moderna and Novavax pared losses after tanking on Wednesday in New York, trading 2.4 per cent lower and 1 per cent lower, respectively. CanSino Biologics, a Chinese private company that developed a single-shot adenovirus-vectored vaccine with Chinese military researchers, fell 14 per cent on Thursday. Fosun Pharma, which has a deal to supply BioNTech vaccines in China, lost 9 per cent. Sven Borho, a managing partner at OrbiMed Advisors, a healthcare investment company, said pharma executives feared the administration’s **move set a precedent** that would make it easier to suspend patents in the future. “They are worried **in the long term** that this is a foot in the door — ‘OK, we did it with Covid-19, **let’s do it with the next crisis**, and the next one’,” he said. “And **then suddenly** it’s a cancer drug patent that needs to be invalidated. They fear it is a mechanism that sets the stage for actions in the future.” Peter Bach, director of Memorial Sloan Kettering’s Center for Health Policy and Outcomes, said there was a potential trade-off that pitted the **imminent need** to contain the pandemic against the risk that drugmakers **would be more cautious** when investing in **pioneering therapies** in the future.

### Case

#### The AFF’s demand to “take control” of medicines from “member states of the World Trade Organization through patent expiration” collapses the WTO and leads to global structural violence.

Narlikar 18 Amrita Narlikar 3-5-2018 "A Trade War on the Poor" <https://archive.is/sD9sf#selection-1337.0-1340.0> (President of the GIGA German Institute of Global and Area Studies and a professor at the University of Hamburg.)//Elmer

Recurrent deadlocks have plagued the Doha negotiations since their launch in 2001, damaging the credibility of the organization that oversees this unfortunate negotiation process. The WTO’s Ministerial Conference in Nairobi in 2015, which coincided with the 20th anniversary of the WTO’s founding, should have been a moment for celebration. Instead, it turned out to be an embarrassment: for the first time the Ministerial Declaration reflected not consensus but fundamental division over whether even to reaffirm the Doha mandates, which had sought to launch an ambitious round of multilateral trade liberalization with a close eye on development issues. At its Ministerial Conference in Buenos Aires, in 2017, the WTO sank to a new low: this conference was unprecedented in its failure to even produce a Ministerial Declaration. The WTO seems to be whimpering its way to an inglorious end. And if the global trading mechanism does indeed collapse, the consequences will be adverse for **all parties**, but especially so for the poorest of the world. PUNISHING DEVELOPING COUNTRIES AND THE POOREST PEOPLE In 2010, the Millennium Development Goals reached one of its targets, of **cutting extreme poverty by half**. The most important factor that contributed to this achievement was economic growth in many developing countries, especially China and India. Although such growth was fueled by several factors, **one critical driver was international trade**. Extensive research shows that the countries and regions that harnessed the opportunities afforded by low tariffs and open markets did particularly well, aided as they were by a reliable system of enforceable trade rules—all negotiated, monitored, and implemented under the auspices **of the WTO**. Still, between 600 million and 700 million people currently live under $1.90 per day and are concentrated in middle-income and lower-income developing countries. For instance, 4.5 percent of Brazilians live below the extreme poverty line, six percent do in India, and 34 and 42 percent do in Afghanistan and Nigeria. Much work still has to be done to address the concerns of the poor worldwide, and a minimal step toward this would be to ensure **continued market access** for developing countries and to maintain the **predictability of tariff and non-tariff barriers**. If the WTO collapses, rich countries would easily be able to **crank up tariffs against poorer countries**, while introducing many **other protectionist measures to discourage imports**. Developing countries, which have experienced growth through exports, and have adapted their production chains to export markets, would be hit hard. A decline in their exports would directly affect their producers and workers in the affected industries, resulting **in losses for poor people** who can least afford such losses. The costs, moreover, would go beyond the immediate job losses and price hikes in basic goods. The first fundamental benefit that poor countries derive from the WTO is that they get a relatively level playing field for negotiating with more powerful countries. Outside the WTO, in bilateral and regional settings, it is much easier to coerce countries into accepting harsh terms in a trade deal, such as through stringent environmental and labor standards that they would find virtually impossible to meet. In contrast, the institutional setting of the WTO offers developing countries some indispensable advantages. Formally, all members in the WTO have **one vote each** (very different from voting procedures at the UN Security Council and the International Monetary Fund). This is **a powerful equalization tool**, which is rendered all the more potent by the fact that consensus-based decision-making allows even the smallest and weakest player de jure veto power. Informally, having an audience within the institution, and a range of partners to work with, enables **poor countries to form coalitions** with like-minded states. Some powerful coalitions have emerged over the years, which have allowed poor and middle-income countries to band together (sometimes also with developed countries) to punch considerably above their weight in the Doha negotiations. One example is **the G-33. It began as a coalition of 33 developing countries including China, India, Indonesia, Nigeria, Pakistan, and others, but now comprises 47 members and has managed to resist calls for greater market opening for agricultural products in developing economies**. **The G-20, a coalition led by Brazil, China, and India at the time of its founding, which now includes 23 developing countries, has demanded more ambitious market opening for agricultural products in developed country markets**. Without the WTO, developing countries would have neither the institutional rules to protect them nor the support of coalitions to enhance their bargaining power. The second important benefit that developing countries derive from the WTO is its Dispute Settlement Mechanism (DSM), which allows members to take another member “to court” over violating trade rules. In the event a judgment is made, the WTO can then authorize retaliatory measures against the responding party. Even though there are several deterrents that might make poor countries reluctant to make use of this facility (including the fact that bringing a dispute against a rich country requires extensive technical and legal know-how, and low-income countries sometimes lack the resources and capacity to initiate a case), the figures show considerable learning and growing effectiveness on their part. While the United States and the European Union have been the most avid users of the DSM (they have brought 115 and 97 cases, respectively, since 1995), many large developing countries have also frequently lodged complaints. China, for example, has brought 15 cases; India, 23; and Brazil, 31. Nor should one assume that the DSM has been the stomping ground of only developed countries and rising powers. David has sometimes taken on Goliath. Ecuador, for example, filed a complaint against U.S. action against its shrimp exports in 2005, and won, despite the extreme asymmetry of power. Allow the WTO to wither away and the world returns to **a system of unchecked power politics.** The costs, moreover, would not necessarily be limited to the “global South” and its poorest people. FROM WIN-WIN TO LOSE-LOSE Even if a WTO collapse would strike the poorest nations the hardest, rich countries will not escape its impact, as the resulting protectionism would greatly hurt poor consumers in developed economies. They would lose access to cheap and competitive imports from developing countries, including essential items such as fruits and vegetables, garments, footwear, and other items on which the average person spends a large proportion of his or her disposable income. The impact of increased tariffs on employment, however, would be, at best, mixed. Any gains would be restricted to specific sectors. For instance, a tariff increase on steel imports may see job increases in that particular industry—although tariffs would not save the job losses that have occurred due to technological innovation—but many other U.S. industries that rely on steel imports, such as producers of cars or electrical machinery, would see their production costs rise. This, in turn, would negatively affect their domestic and international competitiveness, profit margins, and their ability to hire and pay wages. Further, it is unlikely that other countries will accept such treatment sitting down. Retaliatory action could potentially go considerably beyond the steel and steel-consuming sector. China is the second-largest market for agricultural exports from the United States; if China increased trade barriers against soybeans, coarse grains, meat products, and cotton, it could hurt U.S. jobs across several sectors. Of course, such measures by China would be welfare-reducing for its own consumers too, who benefit from these key and competitive U.S. imports. Almost all parties would thus end up in an entirely unnecessary and sad lose-lose situation. In sum, a trade war would be a lose-lose for all, but particularly the poorest in developed and rising powers. EXPLAINING THE MESS There is widespread perception that current U.S. trade policy is the main cause for the mess that has become the WTO, given Trump’s anti-free-trade rhetoric, the United States’ current backseat role in the WTO negotiations, and its attempt to hobble the organization’s DSM by blocking new appointments to its Appellate Body. Unfortunately, the miseries of the WTO run much deeper. The United States’ protectionist leanings predate the election of Trump. The Obama administration, for example, imposed a fivefold increase on steel imports duties from China, dabbled in the rhetoric of protecting U.S. workers, showed great reluctance to make concessions in the Doha negotiations, and precipitated a fundamental turn away from the WTO’s multilateralism via its commitment to the mega-regionals of the Trans-Atlantic Trade and Investment Partnership (TTIP) and Trans-Pacific Partnership (TPP). The institutional processes of the WTO have also failed its members. Decision-making still relies on consensus diplomacy, a great idea in principle, but unwieldy for a 160-member organization with wildly divergent interests and worldviews. The principle of “single undertaking”—nothing is agreed until everything is agreed—has allowed different interests to hold the wide-ranging Doha negotiations to ransom. The organization needs new rules to adapt to the changing balance of power and the changing needs of the time, and it has failed abysmally on this front. Rising powers, such as China and India, must take some share of the blame for the WTO’s failures. Through much of the Doha negotiations, the larger developing countries were quick to demand greater market access in developed countries, but were unwilling to open up their own markets in return. As the BRICs have moved up the development ladder, demands that these developing countries take on more international responsibility have understandably increased. This means showing greater readiness to make reciprocal concessions toward developed countries and among themselves, too. China has been talking the talk on this, but it has yet to open up its own markets. Other middle-income developing countries should also share this responsibility. If they did, at best, this move could bring the United States back to the negotiating table. At the very least, such action would help preserve some **essential trade opportunities** for the remaining members of the WTO. Both rich and poor members of the WTO would do well to recognize the gains from multilateral trade, but they must also acknowledge and address the domestic costs that international trade generates in specific sectors at home. A failure to do so in the past has contributed significantly to a misguided resentment against the WTO. Correcting this could have a transformative and positive effect on the organization. Even though Trump alone cannot be blamed for the looming collapse of the WTO, the current panic that he has generated over a WTO collapse and impending trade wars might galvanize the organization to set itself on the right course.

#### 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.

#### That causes extinction C/A 1NC Srivatsa

#### Nitty gritty debates on details of medicine and health policy is key to knowledge generation of constructive strategies to solve oppression.

Galea 18, Sandro. Healthier: Fifty thoughts on the foundations of population health. Oxford University Press, 2017. (Professor of Public Health at Boston University)//Elmer

How should we in academic public health engage with the issue of racism, at both interpersonal and structural levels? How might we best mitigate its effects? I suggest four possible approaches. First, we must tackle racism at the community level. In this capacity, some of us may choose to express solidarity with affected groups, participating in public shows of support. Such actions ensure that the issue of racism moves to the forefront of the public debate and stays there. Indeed, peaceful public statements of concern about a pressing social issue always have a place in an open society, and our responsibility to make these statements is not in any way inconsistent with our role as members of an academic community. Given that we are members of this community, my second suggestion relates to how our scholarship may pave the way for progress on this issue. The work of **knowledge generation** can help **inform acute social needs**, developing **constructive strategies** to help solve the urgent problems of our time—problems such as racism. This nudges us toward a scholarship of consequence, where we aim to shed light on the root causes of racial divides and the link between racism and the health of the public. To do this, **we must prioritize our research questions** accordingly. By focusing on what matters most, and orienting our scholarship toward areas of inquiry that tackle the foundational drivers of population health, we stand to make a real difference in creating a fairer, less racially fraught society. Third, we are charged at our various institutions with **fostering an education environment that both teaches** the foundations of our field and prepares students to engage with evolving issues of contemporary **public health** importance. That calls for an education that is **dynamic** and **reflexive**, but also one that is encouraging and respectful of the **sharing of ideas.** Such an academic climate does much to advance the goals of engendering **mutual understanding and identifying solutions** grounded in diversity of experience, opinion, and perspective. It is not enough to merely acknowledge disparities; we need to engage in difficult, sometimes uncomfortable discussions about these issues in order to understand one another and improve the often unacceptable conditions our scholarship makes all too apparent to us. Finally, insofar as public health centers around shaping the conditions that make people health, and insofar as those conditions depend on the introduction of health in all sectors, we need to work toward a health conversation that extends well beyond the walls of academia. This agitates for an engagement with the public conversation around the issue of racism wherever the conversation may arise. Public health’s unique perspective, informed by its scholarship, is well positioned to influence how we understand racism and its consequences for the well-being of populations. By clarifying the links between racism and health by making them unignorable in the public debate, we can then begin to advance solutions. Needless to say, racism and hate of any kind are intolerable, even when we do not take into account their health consequences. But health, as a universal aspiration, can serve as a clarifying lens for action, elevating the importance of creating a society free of racism, where health will no longer be determined by the color of a person’s skin. The actions of a committed, activist public health will go far toward bringing this about.

### T

#### Interpretation: the affirmative should only garner offense from the hypothetical implementation of the resolution through a specific policy action.

#### CX and the 1AC prove there’s no I-meet – anything new in the 1AR is either extra-T since it includes the non-topical parts of the Aff or effects-T since it’s a future result of the advocacy which both link to our offense.

#### “Resolved” means to enact by law.

Words & Phrases ’64

(Words and Phrases; 1964; Permanent Edition)

Definition of the word “resolve,” given by Webster is “to express an opinion or determination by resolution or vote; as ‘it was resolved by the legislature;” It is of similar force to the word “enact,” which is defined by Bouvier as meaning “to establish by law”.

#### [4] Standards to Prefer:

#### First - Fairness – radically re-contextualizing the resolution lets them defend any method tangentially related to the topic exploding Limits, which erases neg ground via perms and renders research burdens untenable by eviscerating predictable limits. Procedural questions come first – debate is a game and it makes no sense to skew a competitive activity as it requires effective negation which incentivizes argument refinement, but skewed burdens deck pedagogical engagement.

#### Second - Clash – Allowing them any ground precludes stasis and decks pre-round research forcing a race to the margins to skirt clash. Negation distinguishes debate necessitating iterative testing and engagement which is key to creates better advocacies.

#### Third – SSD – Read it on the neg solves your offense and creates better discussions b/c aff engagement

#### TVA – [Read an aff that defends implementation via the government while keeping the advantage the same] proves they aren’t mutually exclusive and a DA to the TVA proves neg ground.

#### Prefer Competing Interpretations – reasonability is arbitrary and causes a race to the bottom. This means reject Aff Impact Turns predicated on their theory since we weren’t able to adequately prepare for it.