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### ADV---Innovation

#### Advantage 1 is Innovation

#### We are in an innovation crisis – new drugs are not being developed in favor of re-purposing old drugs to infinitely extend patent protection.

Feldman 19 [Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation, 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/>]/SidK + Elmer, recut by Cogito

In a perfect world, the system for conveying medications from their makers to patients should be designed to deliver the lowest-cost drugs. The system in the U.S. doesn’t even come close. Insurers should provide the lowest-cost and highest-quality drug benefit for each plan, public or private. But they don’t. Pharmacy benefit managers should use their volume buying power to obtain rebates that individuals could never obtain on their own and pass those rebates along to patients. But they don’t. Pharmacists, who know the prices of the drugs in their stock and who see patients’ cost-sharing amounts at the cash register, should be motivated to provide their customers with information on how to find the best deal so they can afford their medicines. But they aren’t. Doctors should make medication decisions that are in the best interests of their patients. But they often don’t. All of this occurs against the backdrop of a national conversation to lower drug costs and a policy to expedite and encourage vigorous competition in the pharmaceutical industry through the rapid entry of generic drugs as soon as patents expire. But even though the vast majority of prescriptions are filled with generic drugs, rising prices on existing brand-name drugs and sky-high prices for new drugs are swamping the savings from generics. Why isn’t the system working as it should? Some experts believe the U.S. can rein in drug process with value-based pricing, which aims to tie the prices we pay for drugs to the benefits they provide, either in terms of longer life or better quality of life. Others call for dismantling pharmacy benefit managers. Still others want large groups like Medicare to negotiate with drug companies for better drug prices. While each of these might help, they cannot solve the problem alone. Why? Because they do not reach the heart of the problem. As I explain in my new book, “Drugs, Money, and Secret Handshakes,” the government itself is giving pharmaceutical companies the power they are wielding through overly generous drug patent protection. Effective solutions must address that problem. Drug companies **have brought great innovations** to market. Society rewards innovation with patents, or with non-patent exclusivities that can be obtained for activities such as testing drugs in children, undertaking new clinical studies, or developing orphan drugs. The rights provided by patents or non-patent exclusivities provide a defined time period of protection so companies can recoup their investments by charging monopoly prices. When patents end, lower-priced competitors should be able to jump into the market and drive down the price. But that’s not happening. Instead, drug companies build massive patent walls around their products, extending the protection **over and over again**. Some modern drugs have an avalanche of U.S. patents, with expiration dates staggered across time. For example, the rheumatoid arthritis drug Humira is **protected by more than 100 patents**. Walls like that **are insurmountable**. Rather than rewarding innovation, our patent system is now largely repurposing drugs. Between 2005 and 2015, **more than three-quarters** of the drugs associated with new patents **were not new ones** coming on the market but existing ones. In other words, we are mostly churning and recycling. Particularly troubling, new patents can be **obtained on minor tweaks** such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit. 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.

#### Secondary patents create legal “minefields” that deter generic market entry

Gurgula 20 [Olga Gurgula, lecturer of intellectual property law at Brunel University London, 10-28-2020, "Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?," IIC - International Review of Intellectual Property and Competition Law, https://link.springer.com/article/10.1007/s40319-020-00985-0]/Kankee

Strategic patenting also has a chilling effect on follow-on innovation by generic competitors in the form of developing alternative versions of an off-patent compound. As was discussed earlier, the expiry of a basic patent that protects an active compound facilitates generic competition. This is because even if the product is still protected by process, specific form or formulation patents, generic companies may develop alternative ways of producing or formulating the product and start competing with the originator. In the absence of strategically accumulated patents by the originator, generic companies are typically open to innovating to launch alternative generic products as soon as the basic patent expires. However, by pursuing strategic patenting, originators may discourage generics from engaging in follow-on innovation because of the uncertainty about the patent protection and a fear of infringing on one of the numerous patents.Footnote96 In its Sector Inquiry Report, the Commission cited the following quote from one of the originators: The entire point of the patenting strategy adopted by many originators is to remove legal certainty. The strategy is to file as many patents as possible on all areas of the drug and create a “minefield” for the generics to navigate. All generics know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that your product will not infringe and you will not be the subject of an interim injunction.Footnote97 Therefore, as a result of creating an impenetrable ring of patent protection by the originator,Footnote98 generic competitors may be prevented from developing alternative generic versions of an off-patent compound. One of the examples revealed by the Commission during its Pharmaceutical Sector Inquiry was the filing by an originator company of “more than 30 patent families translating into several hundreds of patents in the Member States in relation to one product”, many of which were filed after the introduction of the product.Footnote99 This affected the intentions of several generic companies that planned to develop and bring their generic versions of the original product to the market.Footnote100 As a result, in addition to the already high barriers to entry into the pharmaceutical market due to patents that protect an existing product and the need to obtain a marketing authorisation, strategic patenting raises these entry barriers further, making it very difficult for generic companies to overcome them. This strategy, therefore, “may without further enforcement action by originator companies, … delay generic entry until the patent situation is clearer or even discourage more risk-sensitive generic companies from entering altogether”.Footnote101 Consequently, the fact that actual or potential competitors of originators would not be able to develop alternative generic products means that no one could enter the market and challenge originators’ monopoly positions. This results in a weakening of competition in the relevant market and a strengthening of the originator’s already dominant position. As Maggiolino put it, “patent accumulation … may work as a pre-emptive entry-deterrence strategy to protect monopoly power and … lower consumer welfare by allowing dominant firms to keep on charging over-competitive prices”.Footnote102 Therefore, when an array of accumulated secondary patents “blocks monopolists’ rivals from producing follow-on innovations, this strategy prevents the whole society from enjoying … these further innovations”.Footnote103 While practices that facilitate innovation are encouraged by competition law, practices that are aimed at blocking follow-on innovation by competitors should raise competition law concerns. Strategic Patenting is Considered Lawful Under the Current Approach

#### Pharma innovation is key to prevent devastating pandemics, bioterror, and ABR

Marjanovic and Fejiao 20 [Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge, and Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon, 2020, "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." RAND Corporation, https://www.rand.org/pubs/perspectives/PEA407-1.html]/Kankee

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, mak[ing] 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.

#### Bioweapons cause extinction

Millett & Snyder-Beattie ‘17. Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **Historically, disease events have been responsible for the greatest death tolls** on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to thinkthat existential risk from disease is unlikely. Such a disease would need to spreadworldwide to **remote populations**, overcome**rare genetic resistances**, and **evade detection**, cures, and **countermeasures**. Even evolution itself may work in humanity's favor: **Virulence and transmission is often a trade-off**, and so **evolutionary pressures** could push against maximally lethal wild-type pathogens.5,6 While skeptic arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also **historical examples of large human populations being almost entirely wiped out** by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include **native American tribes** exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But **many diseases are proof** of principle that **each worst-case attribute can be realized independently**. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, **natural evolution** would be an **unlikely** source for pathogens with the **highest possible levels of transmissibility, virulence, and global reach**. But **advances in biotech**nology might allow the creation of diseases that **combine such traits**. Recent controversy has **already emerged** over a number of **scientific experiments** that resulted in viruses with enhanced **transmissibility**, **lethality**, and/or the ability to overcome **therapeutics**.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a **long historical track record** of**state-run bioweapon research** applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, following a breakdown of the Biological Weapons Convention.25 and **m**utually **a**ssured **d**estruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The **possibility of a war** between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27 Non-state actors may also pose a risk, especially those with explicitly omnicidal aims. While rare, there are examples. The Aum Shinrikyo cult in Japan sought biological weapons for the express purpose of causing extinction.28 Environmental groups, such as the Gaia Liberation Front, have argued that “we can ensure Gaia's survival only through the extinction of the Humans as a species … we now have the specific technology for doing the job … several different [genetically engineered] viruses could be released”(quoted in ref. 29). Groups such as R.I.S.E. also sought to protect nature by destroying most of humanity with bioweapons.30 Fortunately, to date, non-state actors have lacked the capabilities needed to pose a catastrophic bioweapons threat, but this could change in future decades as biotechnology becomes more accessible and the pool of experienced users grows.31,32 What is the appropriate response to these speculative extinction threats? A balanced biosecurity portfolio might include investments that reduce a mix of proven and speculative risks, but striking this balance is still difficult given the massive uncertainties around the low-probability, high-consequence risks. In this article, we examine the traditional spectrum of biosecurity risks (ie, biocrimes, bioterrorism, and biowarfare) to categorize biothreats by likelihood and impact, expanding the historical analysis to consider even lower-probability, higher-consequence events (catastrophic risks and existential risks). In order to produce reasoned estimates of the likelihood of different categories of biothreats, we bring together relevant data and theory and produce some first-guess estimates of the likelihood of different categories of biothreat, and we use these initial estimates to compare the cost-effectiveness of reducing existential risks with more traditional biosecurity measures. We emphasize that these models are highly uncertain, and their utility lies more in enabling order-of-magnitude comparisons rather than as a precise measure of the true risk. However, **even with the most conservative models**, we find that reduction of **low-probability, high-consequence risk**s can be more cost-effective, as measured by **quality-adjusted life year** per dollar, especially when we account for the lives of future generations. This suggests that **despite** the **low probability** of such events, society **still ought to invest more in preventing** the most extreme possible **biosecurity catastrophes**.

#### Bioterror causes nuclear miscalc

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3. Nuclear Deterrence in the Pandemic Era To this point, we have described the threat and control of biological weapons in a vacuum. The reality of biological weapons threats and their control is far more complex, however. For example, the Asia-Pacific is home to multiple nuclear-weapon states – how does their nuclear deterrent capability impact the threat and control of biological weapons? Furthermo4.re, natural outbreaks and pandemics might be misinterpreted as deliberate attacks, or used to mask them – how do we avoid nuclear escalation and potential brinksmanship when we are unable to discern an outbreak’s origin? In this section, we grapple with some of these real-world challenges in the Asia-Pacific, with the goal of deriving practical recommendations for regional stability and security. Nuclear doctrine and pandemic context. The pandemic context carries a neglected risk for the Asia-Pacific region: the risk that nuclear-weapon states operating in the region could not only mistake a natural pandemic or accidental biological release for an intentional biological weapons attack but compound this error by responding with a nuclear attack. After all, many of these states have published nuclear doctrines that declare that they are prepared to respond to biological weapons attacks with nuclear ones, leaving open the question of how and when such attacks would be attributed. In particular: United States. The United States has wrestled openly with the question of whether to retain the option of responding to a perceived BW attack with nuclear weapons but continues to maintain that option. In its 2010 Nuclear Posture Review (NPR), for example, the Obama administration debated whether to adopt a “universal policy that the ‘sole purpose’ of US nuclear weapons is to deter nuclear attack on the United States and our allies and partners,” but backed away from doing so in part because of the perceived need to deter biological weapons. Thus, while strengthening its ‘negative security assurances’ that “the United States will not use or threaten to use nuclear weapons against non-nuclear weapon states that are party to the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) and in compliance with their nuclear non-proliferation obligations,” the NPR included a caveat for biological weapons:[41] Given the catastrophic potential of biological weapons and the rapid pace of bio-technology development, the United States reserves the right to make any adjustment in the assurance that may be warranted by the evolution and proliferation of the biological weapons threat and U.S. capacities to counter that threat. The 2010 NPR went on to state that: In the case of countries not covered by this assurance–states that possess nuclear weapons and states not in compliance with their nuclear non-proliferation obligations–there remains a narrow range of contingencies in which U.S. nuclear weapons may still play a role in deterring a conventional or CBW attack against the United States or its allies and partners.” The Trump administration in its 2018 Nuclear Posture Review did not make explicit changes when it came to how it would respond to a potential biological attack. However, more generally it appeared to broaden the potential use of nuclear weapons, particularly against non-nuclear-weapon states: The United States would only consider the employment of nuclear weapons in extreme circumstances to defend the vital interests of the United States, its allies, and partners. Extreme circumstances could include significant non-nuclear strategic attacks. Significant non-nuclear strategic attacks include, but are not limited to, attacks on the U.S., allied, or partner civilian population or infrastructure, and attacks on U.S. or allied nuclear forces, their command and control, or warning and attack assessment capabilities. [42] It also pointed to “the proliferation of highly-lethal biological weapons” as a form of technological uncertainty that could change the threat environment and “dramatically affect U.S. nuclear force requirements, policy, and posture.”[43] Russia. Russia, likewise, has promulgated a military doctrine which retains the option of responding to a perceived biological attack with a nuclear one. [44] For example, its 2010 military doctrine stated that Russia “reserves the right to utilize nuclear weapons in response to the utilization of nuclear and other types of weapons of mass destruction against it and (or) its allies.”[45] In Early June 2020, Russia released a new document, titled “On Basic Principles of State Policy of the Russian Federation on Nuclear Deterrence,” that outlined the threats and circumstances that could lead to Russia’s use of nuclear weapons. The document lists a number of threats that Russia might face and circumstances under which it might consider the use of nuclear weapons. It indicates that Russia could order a nuclear strike in response to the “use of nuclear weapons or other types of weapons of mass destruction by an adversary against the Russian Federation and/or its allies.” [46] China. China continues to declare that it will not engage in the first use of nuclear weapons and has not carved out any exceptions.[47] In the past, this declaratory policy was buttressed by China’s small and largely un-mated arsenal. However, China has moved to a larger, more diverse arsenal, including naval systems where operational warheads are not separated from missiles. Concurrently, military experts in China are engaged in a growing debate about either abandoning the no-first-use doctrine altogether or carving out exceptions. Outsiders, meanwhile, increasingly question the credibility of Beijing’s no-first-use declaration. North Korea. North Korean suspicions of the United States and South Korea could lead the DPRK to mistake a natural outbreak/pandemic or laboratory accident for a deliberate nuclear attack. Ever since the Korean War, when it falsely accused the United States of employing BW,[48] Pyongyang has been primed for a biological attack from the United States or South Korea. Therefore, a natural outbreak (particularly if it appears first in the DPRK) is likely to be viewed as a deliberate attack until proven otherwise. And Pyongyang also is primed to believe that even in the case of a natural outbreak, the United States or the ROK can be expected to exploit the crisis as an opportunity for subversion and a threat to the regime. [49] India. India has long and loudly proclaimed that a cardinal principle of its nuclear doctrine is that it will not engage in the first use of nuclear weapons. However, it has been largely overlooked that for two decades this policy has included a significant caveat when it comes to biological weapons. India’s 2003 nuclear doctrine states that “in the event of a major attack against India, or Indian forces anywhere, by biological or chemical weapons, India will retain the option of retaliating with nuclear weapons.”[50] Interestingly, this caveat was not included in the initial draft doctrine India released after its 1998 nuclear tests. [51] Pakistan. Given India’s overwhelming conventional advantage, Pakistan has refused to renounce the first use of nuclear weapons. Government officials have not spoken specifically, however, on how Pakistan might respond to a chemical or biological attack. Whether and how these declaratory policies would play out under real-life circumstances is far from clear, however. These doctrines are primarily intended to communicate to potential adversaries as a form of deterrence; in the end, policymakers will decide, in the moment of crisis, how to respond to any outbreak and the possibility that it might stem from the use of biological weapons. Bioterrorism and nuclear escalation. As we have seen, deciding that an outbreak is natural, accidental, or intentional is highly challenging. Furthermore, this attribution challenge could be intentionally or unintentionally exacerbated by non-state actors to leverage nuclear escalation for their own purposes. For example, a millennial terrorist group such as Al Qaeda or ISIS could launch a biological attack against countries such as the United States, North Korea or Russia with hopes that it would be perceived as an attack by that country’s adversary, with consequent retaliation. Or Kashmiri militants with links to Pakistan could launch such an attack against India with or without support from Islamabad and with or without publicly acknowledging their responsibility. Alternatively, such militants could claim that what was in fact a natural outbreak on either side of the line of control was a BW attack, bringing nuclear escalation dynamics into play. The potential for the latter such effort is illustrated by a 1994 plague outbreak in Western India which was initially suspected to be a bioterrorist attack. [52] Discerning between natural and deliberate outbreaks. As described in the “detection” discussion above, there are two most likely scenarios in which a biological attack may play out: a detection system may be triggered, or human or animal populations may begin to fall ill. While the former scenario is largely specific to an attack (though false positives commonly occur due to detection of natural biological agents above expected background levels), the latter scenario requires that that the outbreak’s origin – natural versus deliberate[53] – be determined to inform nuclear deterrence and, potentially, escalation options. Initially, suspicion of a deliberate attack would likely be low in the absence of unique indicators (e.g., detection system alarm, law enforcement interdiction, allegation, tipoff, or visible substance such as a powder). Thus, a typical epidemiological investigation would most likely be conducted to determine the who, what, when, where, why and how of the outbreak. First, investigators would perform case histories and interviews to determine who is being infected, by what disease agent, when did infection occur, and in what location; this is called “descriptive epidemiology.” Investigators would then seek to determine how infection occurred and why by assessing (a) the epidemiological triangle for indicators of convergence that would enable spillover of the infecting agent from its natural reservoir to humans, and (b) the infecting agent genome for indicators of geographical and temporal spread; this is called “analytical epidemiology.” Throughout the investigative process, findings may suggest the possibility of a deliberate attack, as summarized in Figure 2. The epidemiological triangle is a simplified representation of the relationship between (1) a disease agent, typically in an animal reservoir; (2) a human host; and (3) the environment, which form the three points of a triangle. The lines of the triangle that connect these points can be long or short, and can be lengthened or shortened. The goal of the assessment is to determine whether the lines have shifted in a way that has brought the infecting agent (or its animal reservoir) into contact with the human host. Initially, assessment focuses on tracing back human cases to any known animal reservoirs, whether exposed through direct contact, consumption of byproducts, or another route. If no epidemiological link is apparent, investigators can seek to identify risk factors that might enable such exposure by asking the following key questions: Has the human population expanded into areas where the disease agent resides in animal reservoirs, for example due to wildlife trade, deforestation, or industrial farming? Has the disease agent expanded into human populations, for example due to animal reservoir overgrowth, vector population overgrowth (e.g., ticks, fleas), or interspecies spillover? Has the environment brought animal and human populations closer together, for example due to short-term meteorological shifts or longer-term climate shifts? Like the epidemiological triangle, the infecting agent’s genome may also hold clues to the outbreak’s origin. This is especially true for viral agents, and RNA viruses in particular, where mutations routinely occur as the virus replicates (i.e., reproduces, which requires infection of a host cell). Mutations that offer a selective advantage for the virus survive, providing a geospatial and temporal map of the outbreak based on prevailing mutations. By comparing the infecting agent’s genome with the genomes of well-characterized reference strains in the public domain, investigators can (1) identify the closest known relative of the infecting agent; and (2) determine whether the infecting agent’s genome has amassed mutations consistent with known patterns of natural emergence. Investigators can further determine whether the infecting agent’s genome so closely resembles a given reference strain that a period of limited or no replication is likely. Such so-called “frozen evolution,” when an infecting agent’s genome lacks the expected accumulation of mutations over time, suggests that alternative origin hypotheses such as a laboratory accident or deliberate attack must be explored.[54] Based on descriptive and analytical epidemiology findings, investigators may collect and/or analyze additional animal, human, or environmental samples with the goal of closing information gaps in the prevailing origin hypothesis. For example, if contact with an animal reservoir is suspected, investigators may collect animal or environmental samples at the suspected animal-human interface, whether a market, farm, abattoir, or in the wild; analysis of these samples may identify the reservoir or provide additional clues that can be traced back epidemiologically and genetically. “Banked” human samples predating the outbreak may also be tested to this end; often, such clinical samples are retained for extended periods of time, and may be revisited for further analysis, for example if they came from patients with clinical presentations resembling the current outbreak.[55] In addition, investigators may actively collect human samples that might indicate exposure or infection in so-called sentinel populations at the animal-human interface; for example, serological testing of hunters or wildlife traders may identify antibodies against the agent causing the current outbreak, indicating exposure that may then be traced back to an animal reservoir.[56] If findings of the outbreak investigation suggest the possibility of a deliberate attack, law enforcement must become involved either at the national level, possibly with support from other states, or at the international level under the UN Secretary General’s Mechanism (UNSGM), likely in coordination with other relevant international organizations such as the World Health Organization (WHO) or World Organisation for Animal Health (OIE). A law enforcement investigation would likely be initiated, involving additional sample collection, careful documentation of chain-of-custody, and analysis in an accredited laboratory to ensure the integrity of evidence in a court of law; supplementary evidence collection and examination; targeted patient and witness interviews; and coordination with intelligence officials regarding adversary capabilities and motivations. Despite a national or international investigative body’s best efforts, it may not be possible to definitely determine the origin of a particular outbreak. For example, a 1942 outbreak of tularemia among German and Soviet troops during the Battle of Stalingrad has been alternately attributed to natural and deliberate causes. The most widely accepted explanation cites natural convergence on the epidemiological triad as the likely cause: the war’s disruption of the local grain harvest led to population overgrowth of infected rodents, which passed the disease to both armies.[57] However, allegations that the outbreak was caused by a Soviet biological attack have persisted, including on the part of former Soviet bioweaponeers themselves.[58] A similar debate today might spark an unfounded nuclear escalation spiral, the evidentiary basis of which becomes lost in the “fog of war.” Similarly, imprecise analysis, for example the misinterpretation of environmental interferents as has commonly occurred with fielded biological detection devices,[59] might inadvertently lead to an asymmetric response. The risk of misattributing a natural event as a BW attack necessitates a deliberate, data-to-decisions approach that emphasizes degrees of certainty when determining proportional response. At a minimum, nuclear-weapon states must carefully consider how they operationalize doctrines the leave open the possibility of a nuclear response to a perceived BW attack. Asymmetric opportunities for exploitation of a natural outbreak or pandemic.

### ADV---Drug Prices

#### Advantage 2 is Drug Prices

#### Excessive patents are the key driver of the drug pricing crisis

Rajkumar 20 [S. Vincent Rajkumar, Professor of Medicine at the Mayo Clinic, 2020, “The high cost of prescription drugs: causes and solutions,” Blood and Cancer, https://www.nature.com/articles/s41408-020-0338-x]/Kankee

Global spending on prescription drugs in 2020 is expected to be ~$1.3 trillion; the United States alone will spend ~$350 billion1. These high spending rates are expected to increase at a rate of 3–6% annually worldwide. The magnitude of increase is even more alarming for cancer treatments that account for a large proportion of prescription drug costs. In 2018, global spending on cancer treatments was approximately 150 billion, and has increased by >10% in each of the past 5 years2. The high cost of prescription drugs threatens healthcare budgets, and limits funding available for other areas in which public investment is needed. In countries without universal healthcare, the high cost of prescription drugs poses an additional threat: unaffordable out-of-pocket costs for individual patients. Approximately 25% of Americans find it difficult to afford prescription drugs due to high out-of-pocket costs3. Drug companies cite high drug prices as being important for sustaining innovation. But the ability to charge high prices for every new drug possibly slows the pace of innovation. It is less risky to develop drugs that represent minor modifications of existing drugs (“me-too” drugs) and show incremental improvement in efficacy or safety, rather than investing in truly innovative drugs where there is a greater chance of failure. Causes for the high cost of prescription drugs Monopoly The most important reason for the high cost of prescription drugs is the existence of monopoly4,5. For many new drugs, there are no other alternatives. In the case of cancer, even when there are multiple drugs to treat a specific malignancy, there is still no real competition based on price because most cancers are incurable, and each drug must be used in sequence for a given patient. Patients will need each effective drug at some point during the course of their disease. There is seldom a question of whether a new drug will be needed, but only when it will be needed. Even some old drugs can remain as virtual monopolies. For example, in the United States, three companies, NovoNordisk, Sanofi-Aventis, and Eli Lilly control most of the market for insulin, contributing to high prices and lack of competition6. Ideally, monopolies will be temporary because eventually generic competition should emerge as patents expire. Unfortunately, in cancers and chronic life-threatening diseases, this often does not happen. By the time a drug runs out of patent life, it is already considered obsolete (planned obsolescence) and is no longer the standard of care4. A “new and improved version” with a fresh patent life and monopoly protection has already taken the stage. In the case of biologic drugs, cumbersome manufacturing and biosimilar approval processes are additional barriers that greatly limit the number of competitors that can enter the market. Clearly, all monopolies need to be regulated in order to protect citizens, and therefore most of the developed world uses some form of regulations to cap the launch prices of new prescription drugs. Unregulated monopolies pose major problems. Unregulated monopoly over an essential product can lead to unaffordable prices that threaten the life of citizens. This is the case in the United States, where there are no regulations to control prescription drug prices and no enforceable mechanisms for value-based pricing. Seriousness of the disease High prescription drug prices are sustained by the fact that treatments for serious disease are not luxury items, but are needed by vulnerable patients who seek to improve the quality of life or to prolong life. A high price is not a barrier. For serious diseases, patients and their families are willing to pay any price in order to save or prolong life. High cost of development Drug development is a long and expensive endeavor: it takes about 12 years for a drug to move from preclinical testing to final approval. It is estimated that it costs approximately $3 billion to develop a new drug, taking into account the high failure rate, wherein only 10–20% of drugs tested are successful and reach the market7. Although the high cost of drug development is a major issue that needs to be addressed, some experts consider these estimates to be vastly inflated8,9. Further, the costs of development are inversely proportional to the incremental benefit provided by the new drug, since it takes trials with a larger sample size, and a greater number of trials to secure regulatory approval. More importantly, we cannot ignore the fact that a considerable amount of public funding goes into the science behind most new drugs, and the public therefore does have a legitimate right in making sure that life-saving drugs are priced fairly. Lobbying power of pharmaceutical companies Individual pharmaceutical companies and their trade organization spent approximately $220 million in lobbying in the United States in 201810. Although nations recognize the major problems posed by high prescription drug prices, little has been accomplished in terms of regulatory or legislative reform because of the lobbying power of the pharmaceutical and healthcare industry. Solutions: global policy changes There are no easy solutions to the problem of high drug prices. The underlying reasons are complex; some are unique to the United States compared with the rest of the world (Table 1).Patent reform One of the main ways to limit the problem posed by monopoly is to limit the duration of patent protection. Current patent protections are too long, and companies apply for multiple new patents on the same drug in order to prolong monopoly. We need to reform the patent system to prevent overpatenting and patent abuse11. Stiff penalties are needed to prevent “pay-for-delay” schemes where generic competitors are paid money to delay market entry12. Patent life should be fixed, and not exceed 7–10 years from the date of first entry into the market (one-and-done approach)13. These measures will greatly stimulate generic and biosimilar competition. Faster approval of generics and biosimilars

#### Low return on investment for ABR patents decks US response – firms focus on higher cost drugs instead

Emanuel 19 [Ezekiel J. Emanuel, oncologist, a bioethicist, and a vice provost of the University of Pennsylvania, 05-23-2019, “Big Pharma’s Go-To Defense of Soaring Drug Prices Doesn’t Add Up,” Atlantic, https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/]/Kankee

Exorbitant drug prices have two bad effects. First, high costs mean that lots of patients are unable to take their medications. A recent study in the Journal of Clinical Oncology assessed patients’ access to 38 different oral cancer drugs and found that 13 percent of cancer patients did not buy approved chemotherapy drugs if they had a co-payment of $10 a month, while 67 percent did not when they had to pay $2,000 or more. Another study showed that 25 percent of diabetic patient underuse their insulin because of cost. Second, the high drug prices distort research priorities, emphasizing financial gains and not health gains. Cancer drugs are routinely priced at about $120,000 to $150,000 a year, and more than 600 cancer drugs are now being tested on humans. This can lead to great societal benefits: The United States is expected to face 1.76 million new cancer cases and more than 600,000 cancer deaths in 2019 alone. But many of the drugs that companies are pursuing have low promise, where the health gains are small—weeks of added life, not big cures. While even this short extra time can be valuable to individual families, too much investment in oncology means not enough in drugs for other illnesses whose treatments cannot be so highly priced. Consider antibiotics. The Centers for Disease Control and Prevention ranks antibiotic-resistant infections as one of the nation’s top health threats. An estimated 2 million Americans become infected with such bacteria each year, and 23,000 die. A superbug that is resistant to all known antibiotics is an imminent threat. Yet because antibiotics are generally cheap, [but] for most pharmaceutical and biotechnology companies they are not a primary focus. The Pew Charitable Trusts reports that only about 42 new antibiotics with the potential to treat serious bacterial infections were in clinical development for the U.S. market in December 2018. Six hundred drugs for cancer and only 42 for serious infections seems like profit maximization, not a case of sensible research priorities that reflects “value in preventing and treating disease.” The simple explanation for excessive drug prices is monopoly pricing. Through patent protection and FDA marketing exclusivity, the U.S. government grants pharmaceutical companies a monopoly on brand-name drugs. But monopolies are a recipe for excessive prices. A company will raise prices until its profits start to drop. To address the problem of high prices and reduced access to drugs, Johnson & Johnson advocates eliminating rebates to pharmacy benefit managers and insurers, which would increase price transparency and lower patient co-pays. But it would not necessarily lower total drug prices. The proposal avoids the standard economic response to monopoly pricing: price regulation. Every other developed country regulates drug prices, often through price negotiations pegged to cost-effectiveness analysis or some other measure of clinical benefit. Will R&D go down if the United States follows this model? Not necessarily. Remember, the high drug prices fund R&D but also marketing, manufacturing, administrative expenses, and profits at the companies. Lower revenue from lower drug prices could reduce marketing, administration, and excessive profits before R&D costs have to be reduced. Where cuts are made is up to drug companies. Their claims of lower R&D costs appear designed to generate fear, but as some former executives themselves have acknowledged, there is no necessary link between a decline in drug prices and a decline in R&D. Drug companies could make other choices that maximally improve the health of all Americans.

#### Only innovation now solves AMR super-bugs -- timeframe’s key.

Sobti 19 [Dr. Navjot Kaur Sobti is an internal medicine resident physician at Dartmouth-Hitchcock-Medical Center/Dartmouth School of Medicine and a member of the ABC News Medical Unit. May 1, 2019. “Amid superbug crisis, scientists urge innovation”. <https://abcnews.go.com/Health/amidst-superbug-crisis-scientists-urge-innovation/story?id=62763415>] Dhruv

[The United Nations](https://abcnews.go.com/Politics/amal-clooney-angelina-jolie-speak-us-weighed-vetoing/story?id=62574726) has called antimicrobial resistance a “global crisis.” With the [rise in superbugs](https://abcnews.go.com/Health/superbug-fungus-global-health-threat-600-us-infected/story?id=62297532) across the globe, common infections are becoming harder to treat, and lifesaving procedures riskier to perform. Drug-resistant infections result in about 700,000 deaths per year, with at least 230,000 of those deaths due to multidrug resistant tuberculosis, [according to a groundbreaking report from the World Health Organization (WHO).](https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf?ua=1) Given that antibiotic resistance is present in every country, antimicrobial resistance (AMR) now represents a global health crisis, according to the UN, which has urged immediate, coordinated and global action to prevent a potentially devastating health and financial crisis. With the rising rates of AMR -- including antivirals, antibiotics, and antifungals -- estimates from the WHO show that AMR may cause 10 million deaths every year by 2050, send 24 million people into extreme poverty by 2030, and lead to a financial crisis as severe as the on the U.S. experienced in 2008. Antimicrobial resistance develops when germs like bacteria and fungi are able to “defeat the drugs designed to kill them,” according to the Centers for Disease Control and Prevention. Through a biologic “survival of the fittest,” germs that are not killed by antimicrobials and continue to grow. WHO explains that “poor infection control, inadequate sanitary conditions and inappropriate food handling encourage the spread” of AMR, which can lead to “superbugs.” Those superbugs require powerful and oftentimes more expensive antimicrobials to treat. Examples of superbugs are far and wide, and can range from drug-resistant bacteria like Pseudomonas aeruginosa and Staphylococcus aureus to fungi like Candida. These bugs can cause illnesses that range from pneumonia to urinary tract and sexually transmitted infections. According to the WHO, AMR has caused complications for nearly 500,000 people with tuberculosis, and a number of people with HIV and malaria. The people at the [highest risk for AMR](https://www.who.int/news-room/detail/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed) are those with chronic diseases, people living in nursing homes, hospitalized in the ICU or undergoing life-saving treatments such as organ transplantation and cancer therapy. These people often develop infections, which can become antimicrobial-resistant, rendering them difficult, if not impossible, to treat. [(MORE: Melissa Rivers talks about her father's suicide with Dr. Jennifer Ashton)](https://abcnews.go.com/Health/melissa-rivers-talks-fathers-suicide-dr-jennifer-ashton/story?id=62733179&cid=clicksource_26_null_headlines_hed) The CDC notes that “antibiotic resistance has the potential to affect people at any stage of life,” including the “healthcare, veterinary, and agriculture industries, making it one of the world’s most urgent public health problems." AMR can cause prolonged hospital stays, billions of dollars in healthcare costs, disability, and potentially, death. “The most important thing is to understand and embrace the interconnectedness of all of this,” said Dr. Robert Redfield, director of the CDC, in a recent interview with ABC News’ Dr. Jennifer Ashton. It’s not just our countries that are connected.” Research has shown that superbugs like Candida auris “came from multiple places, at the same time. It wasn’t just one organism that [evolved]” in a single location, Redfield added. Given longstanding concerns about antimicrobial misuse leading to AMR, physicians have embraced a medical approach called antibiotic stewardship. This encourages physicians to carefully evaluate which antibiotic is most appropriate for their patient, and discontinue it once it is no longer medically needed. WHO has also highlighted that the inappropriate use of antimicrobials in agriculture -- such as on farms and in animals -- may be an underappreciated cause of AMR. Noting these trends, the WHO has urged for “coordinated action...to minimize the emergence and spread of antimicrobial resistance.” It urges all countries to make national action plans, with a focus on the development of new antimicrobial medications, vaccines, and careful antimicrobial use. Redfield emphasized the importance of vaccination during the global superbug crisis, stating that “the only way we have to eliminate an infection is vaccination.” He added that investing in innovation is key to solving the crisis. While WHO continues to advocate for superbug awareness, they warn that AMR has reversed “a century of progress in health.” The WHO added that “the challenges of antimicrobial resistance” are “not insurmountable,” and that coordinated action will “help to save millions of lives, preserve antimicrobials for generations to come and secure the future from drug-resistant diseases.”

#### Extinction - generic defense doesn’t apply.

Srivatsa 17 Kadiyali Srivatsa 1-12-2017 “Superbug Pandemics and How to Prevent Them” <https://www.the-american-interest.com/2017/01/12/superbug-pandemics-and-how-to-prevent-them/> (doctor, inventor, and publisher. He worked in acute and intensive pediatric care in British hospitals)//Elmer

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. And the problem is already here. In the summer of 2011, a 43-year-old woman with complications from a lung transplant was transferred from a New York City hospital to the Clinical Center at the National Institutes of Health (NIH), in Bethesda, Maryland. She had a highly resistant superbug known as Klebsiella pneumoniae carbapenemase (KPC). The patient was treated and eventually discharged after doctors concluded that they had contained the infection. A few weeks later, a 34-year-old man with a tumor and no known link to the woman contracted KPC while at the hospital. During the course of the next few months, several more NIH patients presented with KPC. Doctors attacked the outbreak with combinations of antibiotics, including a supposedly powerful experimental drug. A separate intensive care unit for KPC patients was set up and robots disinfected empty rooms, but the infection still spread beyond the intensive care area. Several patients died and then suddenly all was silent on the KPC front, with doctors convinced they had seen the last of the dangerous bacterium. They couldn’t have been more mistaken. A year later, a young man with complications from a bone marrow transplant arrived at NIH. He became infected with KPC and died. This superbug is now present in hospitals in most, if not all U.S. states. This is not good. This past year an outbreak of CRE (carbapenem-resistant enterobacteriaceae) linked to contaminated medical equipment infected 11 patients and killed two in Los Angeles area hospitals. This family of bacteria has evolved resistance to all antibiotics, including the powerful carbapenem antibiotics that are often used as a last resort against serious infections. They are now so resilient that it is virtually impossible to remove them from medical tools such as catheters and breathing tubes placed into the body, even after cleaning. Then we have gonorrhea, chlamydia, and other sexually transmitted diseases that we cannot treat and that are spreading all over the world. Anyone who has sex can catch these infections, and because most people may not exhibit any symptoms they spread infections without anyone knowing about it. Sexually transmitted diseases used to be treatable with antibiotics, but in recent years we have witnessed the rise of multi-drug resistant STDs. Untreated gonorrhea can lead to infertility in men and women and blindness and other congenital defect in babies. As is well known, too, we have witnessed many cases of drug-resistant pneumonia. These problems have arisen in part because of simple mistakes healthcare professionals repeatedly make. Let me explain. Neither superbugs nor common bacterial infections produce any special symptoms indicative of their cause. Rashes, fevers, sneezing, runny noses, ear pain, diarrhea, vomiting, coughing, fatigue, and weakness are signs of common and minor illnesses as well as uncommonly deadly ones. Therefore, the major problem for clinicians is to identify a common symptom that may potentially be an early sign of a major infection that could result in an epidemic. We know that dangerous infections in any given geographical area do not start at the same time. They start with one victim and gradually spread. But that victim is only one among hundreds of patients a doctor will typically see, so many doctors will miss patients presenting with infections that are serious. They will probably identify diseases that kill fast, but slow-spreading infections such as skin infections that can lead to septicemia are rarely diagnosed early. In addition, I have seen doctors treating eczema with antibiotic cream, even though they know that bacteria are resistant to the majority of these drugs. This sort of action encourages simple infections to spread locally, because patients are therefore not instructed to take other, more useful precautions. On top of that, some people are frivolous about infections and assume doctors are exaggerating the threat. And some people are selfish. Once I was called to see a passenger during a flight who had symptoms consistent with infection. He boarded the plane with these symptoms, but began to feel much worse during the flight. I was scared, knowing how infections such as Ebola can spread. This made me think about a way to screen passengers before they board a flight. Airlines could refund a traveler’s ticket, or issue a replacement, in case of sickness—which is not the policy now. We currently have no method to block infectious travelers from boarding flights, and there are no changes in the incentive system to enable conscientious passengers to avoid losing their money if they responsibly miss a flight because of illness. Speaking of selfishness, I once saw a mother drop her daughter off at school with a serious bout of impetigo on her face. When I asked her why she had brought her daughter to school with a contagious infection, she said she could not spare the time to keep her at home or take her to the doctor. By allowing this child to contact other children, a simple infection can become a major threat. Fortunately, I could see the rash on the girl’s face, but other kids in schools may have rashes we cannot see. Incorrect diagnosis of skin problems and mistaken use of antibiotics to treat them is common all over the world, and so we are continually creating superbugs in our communities. Similarly, chest infections, sore throats, and illnesses diagnosed as colds that unnecessarily treated with antibiotics are also a major threat. By prescribing antibiotics for viral infections, we are not only helping bacteria develop resistance, but we are also polluting the environment when these drugs are passed in urine and feces. All of this helps resistant bacteria to spread in the community and become an epidemic. Ebola is very difficult to transmit because people who are contagious have visible and unusual symptoms. However, the emerging infections and pandemics of the future may not have visible symptoms, and they could break out in highly populous countries such as India and China that send thousands of travelers all over the world every day. When a person is infected with a contagious disease, he or she can expect to pass the illness on to an average of two people. This is called the “reproduction number.” Two is not that high a number as these things go; some diseases have far greater rates of infection. The SARS virus had a reproduction number of four. Measles has a reproduction number of 18. One person traveling as an airplane passenger and carrying an infection similar to Ebola can infect three to five people sitting nearby, ten if he or she walks to the toilet. The study that highlighted this was published in a medical journal a few years ago, but the airline industry has not implemented any changes or introduced screening to prevent the spread of infections by air travel passengers, a major vehicle for the rapid spread of disease. It is scary to think that nobody knows what will happen when the world faces a lethal disease we’re not used to, perhaps with a reproduction number of five or eight or even ten. What if it starts in a megacity? What if, unlike Ebola, it’s contagious before patients show obvious symptoms? Past experience isn’t comforting. In 2009, H1N1 flu spread around the world before we even knew it existed. The Questions Remains Why do seemingly intelligent people repeatedly do such collectively stupid things? How did we allow this to happen? The answer is disarmingly simple. It is because people are incentivized to prioritize short-term benefits over long-term considerations. It is what social scientists have called a “logic of collective action” problem. Everyone has his or her specialized niche interest: doctors their patients’ approval, business and airline executives their shareholders’ earnings, hospitals their reputations for best-practice hygienics, homemakers their obligation to keep their own families from illness. But no one owns the longer-term consequences for hundreds of millions of people who are irrelevant to satisfying these short-term concerns. Here is an example. At a recent Superbug Super Drug conference in London that I attended, scientists, health agencies, and pharmaceutical companies were vastly more concerned with investing millions of dollars in efforts to invent another antibiotic, claiming that this has to be the way forward. Money was the most pressing issue because, as everyone at the conference knew, for many years pharmaceutical companies have been pulling back from antibiotics research because they can’t see a profit in it. Development costs run into billions of dollars, yet there is no guarantee that any new drug will successfully fight infections. At the same conference Dr. Lloyd Czaplewski spoke about alternatives to antibiotics, in case we cannot come up with new ones fast enough to outrun superbug evolution. But he omitted mention of preventive strategies that use the internet or communication software to help reduce the spread of infections among families, communities, and countries. It is madness that we don’t have a concrete second-best alternative to new antibiotics, because we need them and we need them quickly. Of course, this is why we have governments, which have been known occasionally in the past as commonwealths. Governments are supposed to look out for the wider, common interests of society that niche-interested professionals take no responsibility for, and that includes public health. It is why nearly every nation’s government has an official who is analogous to the U.S. Surgeon General, and nearly every one has a public health service of some kind. Alas, national governments do not always function as they should. Several years ago physician and former Republican Senator Bill Frist submitted a proposal to the Senate for a U.S. Medical Expeditionary Corps. This would have been a specialized organization that could coordinate and execute rapid responses to global health emergencies such as Ebola. Nothing came of it, because Dr. Frist’s fellow politicians were either too shortsighted or too dimwitted to understand why it was a good idea. Or perhaps they simply realized that they could not benefit politically from supporting it. Plenty of mistakes continue to be made. In 2015, a particularly infectious form of bird flu ripped through 14 U.S. states, leading farmers to preventively slaughter nearly 40 million birds. The result of such callous and unnecessary acts is that, instead of exhausting themselves in the host population of birds, the viruses quickly find alternative hosts in which to survive, and could therefore easily mutate into a form that can infect humans. Earlier, during the 1980s, AIDS garnered more public attention because a handful of rich and famous people were infected, and because the campaign to eradicate it dovetailed with and boosted the political campaign on behalf of homosexual rights. Methicillin resistant Staphylococcus aureus (MRSA) in hospitals, by far the bigger threat at the time, was virtually ignored. Some doctors knew that MRSA would bring us to our knees and kill millions of people worldwide, but pharmaceutical companies and device and equipment manufacturers ignored these doctors and the thousands of patients dying in hospitals as a result of MRSA. They prioritized the wrong thing, and government did not correct the error. And that is partly how antibiotic-resistant infection went from an obscure hospital problem to an incipient global pandemic. Politics well outside the United States plays several other roles in the budding problem that we are confronting. Countries often will not admit they have a problem and request help because of the possible financial implications in terms of investment and travel. Guinea did not declare the Ebola epidemic early on and Chinese leaders, worried about trade and tourism, lied for months in 2002 about the presence of the SARS virus. In 2004, when avian influenza first surfaced in Thailand, officials there displayed a similar reluctance to release information. Hospitals in some countries, including India, are managed and often owned by doctors. They refuse to share information about existing infections and often categorically deny they have a problem. Reporting infections to public health authorities is not mandatory, and so hospitals that fail to say anything are not penalized. Even now, the WHO and the CDC do not have accurate and up-to-date information about the spread of E. coli or other infections, and part of the reason is that for-profit hospitals are reluctant to do anything to diminish their bottom line. Syria and Yemen are among those countries that are so weak and fragmented that they cannot effectively coordinate public healthcare. But their governments are also hostile to external organizations that offer relief. Part of the reason is xenophobia, but part is that this makes the government look bad. Relatedly, most poor-nation governments do not trust the efficacy of international institutions, and think that cooperating with them amounts to a re-importation of imperialism. They would rather their own people suffer and die than ask for needed help. That brings us to the level of international public health governance. Alas, sometimes poor-country governments estimate the efficacy of international institutions accurately. The WHO’s Ebola response in 2014-15 was a disaster. The organization was slow to declare a public health emergency even after public warnings from Médecins Sans Frontières, some of whose doctors had already died on the front line. The outbreak killed more than 28,000 people, far more than would have been the case had it been quickly identified. This isn’t just an issue of bureaucratic incompetence. The WHO is under-resourced for the problems it is meant to solve. Funding comes from voluntary donations, and there is no mechanism by which it can quickly scale up its efforts during an emergency. The result is that its response to the next major disease outbreak is likely to be as inadequate as were its responses to Ebola, H1N1, and SARS. Stakeholders admit that we need another mechanism, and most experts agree that the world needs some kind of emergency response team for dangerous diseases. But no one knows how to set one up amid the dysfunctional global governance structures that presently exist. Maybe they should turn to Bill Frist, whose basic concept was sound; if the U.S. government will not act, perhaps some other governments will, and use the UN system to do so. But as things stand, we lack a health equivalent of the military reserve. Neither government leaders nor doctors can mobilize a team of experts to contain infections. People who want to volunteer, whether for government or NGO efforts, are not paid and the rules, if any, are sketchy about what we do with them when they return from a mission. Are employers going to take them back? What are the quarantine rules? It is all completely ad hoc, meaning that humanity lacks the tools it needs to protect itself. And note, by the way, the contrast between how governments prepare for facing pandemics and how they prepare for making war. War is not more deadly to the human race than pandemics, but national defense against armed aggression is much better planned for than defense against threats to public health. There is a wealth of rules regarding it, too. Human beings study and plan for war, which kills people both deliberately and accidentally, but they do not invest comparable effort planning for pandemics, which are liable to kill orders of magnitude more people. To the mind of a medical doctor, this is strange. Creating Conditions for Infections to Spread Superbug infections spread for several interlocking reasons. Some are medical-epidemiological. Most of the infections of the past thirty years have started in one place and in one family. As already noted, they spread because many infectious diseases are highly contagious before the onset of symptoms, and because it is difficult to prevent patients who know they are sick from going to hospitals, work, and school, or from traveling further afield. But again, one reason for the problem is political, not medical. Many governments have no strategies in place to prevent pandemics because they are unwilling to tell their people how infections spread. They don’t want to worry people with such talk; it will make them, they fear, unpopular. So governments may have mountains of bureaucracy with great heaps of rules and regulations concerning public health, but they are generally unwilling to trust their own citizens to use common sense on their own behalf. This, too, seems very strange. Until now, no one has come forward to help us develop strategies to educate people how to identify and prevent the spread of infection to their families and communities. The majority of stakeholders have also been oblivious to the use of new technologies to help reduce the spread of these infections. There are some exceptions. In a fun blog post called Preparedness 101: Zombie Apocalypse, the CDC uses the threat of a zombie outbreak as a metaphor to encourage people to prepare for emergencies, including pandemics. It is well meaning and insightful, yet when my colleagues and I try to discuss ways of scaling up the CDC’s example with doctors and nurses, they shut down. Nobody plans for an actual crisis partly because it is too scary and hence paralyzing to think about. But it is also because it is not most health professionals’ job; it is not what they are trained and paid to do. It is always someone else’s job, except that it has turned out to be nobody’s job. Worse, the situation is not static. While we sit paralyzed, superbugs are evolving. Epidemiological models now predict how an algorithmic process of disease spread will move through the modern world. All urban centers around the entire globe can become infected within sixty days because we move around and cross borders much more than our ancestors did, thanks to air travel. A new pandemic could start crossing borders before we even know it exists. A flu-like disease could kill more than 33 million people in 250 days.3

### ADV---Solvency

#### Advantage 3 is Solvency

#### Plan – The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by implementing a one-and-done approach for patent protection.

#### The Plan solves Evergreening.

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

Particularly troubling, new patents can be **obtained on minor tweaks** such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit.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.

### ADV---Framing

#### Advantage 4 is Framing

#### The standard is maximizing expected well-being.

#### 1] Actor Specificity

#### a) Different actors have distinct responsibilities – governments are abstract entities lacking personal identity and can’t know their impact on specific individuals

#### b) Aggregation – governments evaluate policy tradeoffs and degrees of wrongness of actions

#### 2] Fairness and Education – frameworks are topicality interpretations of the word “ought” so they must be theoretically justified –

#### a) Util doesn’t arbitrarily moot 6 minutes of 1AC offense and forcing a 1AR restart

#### b) Real World – policymakers use util to model impacts – outweighs since education is the reason schools fund debate

#### 3] Extinction First – life is the prerequisite to value

Bostrom 12 [Nick Bostrom, Faculty of Philosophy & Oxford Martin School University of Oxford. Existential Risk Prevention as Global Priority. 2012. www.existential-risk.org/concept.html]

These reflections on moral uncertainty suggest an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate. Our present understanding of axiology might well be confused. We may not now know — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet be able to imagine the best ends of our journey. If we are indeed profoundly uncertain about our ultimate aims, then we should recognize that there is a great option value in preserving — and ideally improving — our ability to recognize value and to steer the future accordingly. Ensuring that there will be a future version of humanity with great powers and a propensity to use them wisely is plausibly the best way available to us to increase the probability that the future will contain a lot of value. To do this, we must prevent any existential catastrophe.

#### 4] Prefer Aff Reasonability –

#### a) Substance crowd-out – competing interps leads to endless frivolous theory with arbitrary self-serving interps instead of stopping actual abuse

#### b) 1AR Time Skew – 4 minutes is too short to reasonably answer T and substance given the 6 minute 2NR collapse to 1 argument

#### 5] No RVIs

#### a) Chilling Effect – RVIs make worse theory debaters fear theory debates in the face of actual abuse

#### b) Logic – You shouldn’t win a chess match by *not* flipping the chess board