### Framework

#### I value morality. The standard is maximizing well being.

#### All moral obligations revolve around potential consequences of actions

Sam Harris (NYT Bestselling author, BA in phil from Stanford, PhD in neuroscience from UCLA). The Moral Landscape: How Science Can Determine Human Values. 5 October 2010. p3. <http://notabenoid.com/book/22437/73890?Orig_page=3>

Here is my (consequentialist) starting point **all questions of value** (right and wrong, good and evil, etc.) **depend upon the possibility of experiencing such value. Without potential consequences at the level of experience**—happiness, suffering, joy, despair, etc.—**all talk of value is empty.** Therefore, **to say that an act is morally necessary**, or evil, or blameless, **is to****make** (tacit) **claims about its consequences in the lives of conscious creatures** (whether actual or potential). I am unaware of any interesting exception to this rule.Needless to say, **[For example,] if one is worried about pleasing God or His angels, this assumes that such** invisible **entities are** conscious(in some sense) and **cognizant of human behavior** It also generally assumes **[and] that it is possible to suffer their wrath or enjoy their approval**, either in this world or the world to come. **Even within religion**, therefore, **consequences and conscious states remain the foundation of all values.**

#### Utilitarianism comes first –approaches can *only* be ethical when they consider externalities.

Chandler ‘14

(David Chandler is Professor of International Relations at the Department of Politics and International Relations, University of Westminster – “Beyond good and evil: Ethics in a world of complexity” – International Politics, Vol. 51, No. 4 (2014), pp.441-457 – #CutWithKirby - Available at: http://www.davidchandler.org/wp-content/uploads/2014/10/International-Politics-Evil-PUBLISHED-2.pdf)

Self-reflexive ethics redistribute responsibility and emphasize the indirect, unintended and relational networks of complex causation. Collective problems are reconceived ontologically: as constitutive of communities and of political purpose. This is why many radical and critical voices in the West are drawn to the problems of 'side effects', of 'second-order' consequences - of a lack of knowledge of the emergent causality at play in the complex interconnections of the global world. The more these interconnections are revealed, though the work of self-reflexivity and self-reflection, the more ethical authority can be regained by governments and other agents of governance. We learn and learn again that we are responsible for the world, not because of our conscious choices or because our actions lacked the right ethical intention, but because the world's complexity is beyond our capacity to know and understand in advance. The unknowability of the outcomes of our action does not remove our ethical responsibility for our actions, it, in fact, heightens our responsibility for these second-order consequences or side effects. In a complex and interconnected world, few events or problems evade appropriation within this framing, providing an opportunity for recasting responsibility in these ways. The new ethics of indirect responsibility for market consequences can be seen (observed) clearly in the idea of environmental taxation, both state-enforced through interventions in the market and as taken up by both firms and individuals. The idea that we should pay a carbon tax on air travel is a leading example of this, in terms of governmental intervention, passing the burden of such problems on to 'unethical' consumers who are not reflexive enough to consider the impact of package holidays on the environment. At a broader level, the personalized ethico-political understanding that individuals should be responsible for and measure their own 'carbon footprint' shifts the emphasis from an understanding of broader inter-relations between modernity, the market and the environment to a much narrower understanding of personal indirect responsibility, linking all aspects of everyday decision making to the problems of global warming (see, for example, Marres, 2012). The shared responsibility for the Breivik murders is not different -ontologically - from the societally shared responsibility for global warming or other problematic appearances in the world. Through our actions and inactions we collectively constitute the frameworks in which others act and make decisions -failing to raise our voice against 'borderline racism' or extremism in a bar makes us indirectly responsible for acts of racism or extremism in the same way that failing to save water or minimize air travel makes us indirectly responsible for the melting polar ice caps.

#### Reject the “one percent” doctrine – it’s incoherent and makes policymaking impossible. Anything could potentially cause extinction – default to high probability impacts.

Meskill 9 — (David Meskill, professor at Colorado School of Mines and PhD from Harvard, “The "One Percent Doctrine" and Environmental Faith,” 12-9-2009, http://davidmeskill.blogspot.com/2009/12/one-percent-doctrine-and-environmental.html)

Tom Friedman's piece today in the Times on the environment (http://www.nytimes.com/2009/12/09/opinion/09friedman.html?\_r=1) is one of the flimsiest pieces by a major columnist that I can remember ever reading. He applies Cheney's "one percent doctrine" (which is similar to the environmentalists' "precautionary principle") to the risk of environmental Armageddon. But this doctrine is both intellectually incoherent and practically irrelevant. It is intellectually incoherent because it cannot be applied consistently in a world with many potential disaster scenarios. In addition to the global-warming risk, there's also the asteroid-hitting-the-earth risk, the terrorists-with-nuclear-weapons risk (Cheney's original scenario), the super-duper-pandemic risk, etc. Since each of these risks, on the "one percent doctrine," would deserve all of our attention, we cannot address all of them simultaneously. That is, even within the one-percent mentality, we'd have to begin prioritizing, making choices and trade-offs. But why then should we only make these trade-offs between responses to disaster scenarios? Why not also choose between them and other, much more cotidien [quotidian], things we value? Why treat the unlikely but cataclysmic event as somehow fundamentally different, something that cannot be integrated into all the other calculations we make?∂ And in fact, this is how we behave all the time. We get into our cars in order to buy a cup of coffee, even though there's some chance we will be killed on the way to the coffee shop. We are constantly risking death, if slightly, in order to pursue the things we value. Any creature that adopted the "precautionary principle" would sit at home - no, not even there, since there is some chance the building might collapse. That creature would neither be able to act, nor not act, since it would nowhere discover perfect safety.∂ Friedman's approach reminds me somehow of Pascal's wager - quasi-religious faith masquerading as rational deliberation (as Hans Albert has pointed out, Pascal's wager itself doesn't add up: there may be a God, in fact, but it may turn out that He dislikes, and even damns, people who believe in him because they've calculated it's in their best interest to do so). As my friend James points out, it's striking how descriptions of the environmental risk always describe the situation as if it were five to midnight. It must be near midnight, since otherwise there would be no need to act. But it can never be five \*past\* midnight, since then acting would be pointless and we might as well party like it was 2099. Many religious movements - for example the early Jesus movement - have exhibited precisely this combination of traits: the looming apocalypse, with the time (just barely) to take action.

### Contention 1: Access to Medicine

#### **Status quo pandemic management is plagued with inequality.**

Jenni Fink, 7-30-2021, "WHO warns world "blind to understanding" COVID spread, hurting ability to end pandemic," Newsweek, https://www.newsweek.com/who-warns-world-blind-understanding-covid-spread-hurting-ability-end-pandemic-1614722

A lack of testing for COVID-19 in parts of the world is preventing countries from having a clear picture of how the virus is spreading and therefore hurting the world's chances at fighting the virus and ending the pandemic, according to the World Health Organization. Health inequities throughout the world have plagued the global response to COVID-19 from the outset and WHO has pushed higher income countries to help lower income countries in the interest of ending the pandemic. Along with restricted access to vaccines, lower income countries have struggled to have sufficient testing, meaning the virus is likely going undetected in certain areas, further enabling its ability to spread. Low testing rates is "leaving the world blind to understanding where the disease is and how it's changing," Dr. Tedros Adhanom Ghebreyesus, director general of the WHO said on Friday during a press briefing. Without improving global testing rates, Ghebreyesus said the world can't "fight the disease" or mitigate the risk it poses to people around the globe. who blind covid spread cases On Friday, the World Health Organization warned the world is "blind" to how COVID-19 is spreading because of a lack of testing in certain places. WHO Director-General Tedros Adhanom Ghebreyesus attends a daily press briefing on the new coronavirus dubbed COVID-19, at the WHO headquaters on March 2, 2020, in Geneva. FABRICE COFFRINI//AFP/GETTY IMAGES NEWSWEEK NEWSLETTER SIGN-UP > One of Ghebreyesus' biggest frustrations with the pandemic response is the failure to evenly distribute the vaccine around the world. In some countries, like the United States and other higher-income nations, significant portions of the population have been vaccinated. While those large vaccinated populations help reduce the spread of the virus in some areas, other countries, especially those in Africa, haven't been able to vaccinate even 10 percent of their population. This puts the entire world at risk because when the virus is able to spread throughout communities it has the ability to mutate, thereby increasing the possibility that a mutation could evade the vaccines. It's a scenario public health officials have been warning about for months and Ghebreyesus said on Friday that "hard won gains are in jeopardy" or have already been lost because the virus has been able to spread. Nearly 30 countries have high or rising oxygen needs and the shortage of life-saving oxygen could lead to increased deaths. More than 196 million cases of COVID-19 have been reported around the world, according to a Johns Hopkins University tracker, and more than 4.2 million people have died. Ghebreyesus suspected the number of cases would top 200 million within the next two weeks and warned that health systems in many countries are being overwhelmed. Preventing hospitals from exceeding capacity was a massive concern when the pandemic first broke out and a year later, parts of the U.S. are having their health systems strained as the more transmissible Delta variant spreads. On Thursday, Arkansas Governor Asa Hutchinson declared a public health emergency that allows the state to bring in health care workers from outside Arkansas and makes it easier for retired health care workers and medical students to become licensed. The goal is to help alleviate stress on health care systems and Hutchinson said they've had people waiting in ambulances because there wasn't an open spot in a hospital. That strain will only become more exacerbated if a mutation occurs that evades the vaccine, as inoculations have proven effective at helping to keep people out of the hospital. Ghebreyesus warned that more variants will emerge if global access to vaccines and testing doesn't improve. "The pandemic will end when the world chooses to end it. It is in our hands. We have all the tools we need. We can prevent this disease. We can test for it and we can treat it," Ghebreyesus said.

#### Historical data proves our thesis– up to 80% of all new patents are not new drugs but old ones.

**Feldman 2** Robin Feldman 18, May your drug price be evergreen, Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, Pages 590–647, <https://doi.org/10.1093/jlb/lsy022> Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation (Study Notes: Presenting the first comprehensive study of evergreening, this article examines the extent to which evergreening behavior—which can be defined as artificially extending the protection cliff—may contribute to the problem. The author analyses all drugs on the market between 2005 and 2015, combing through 60,000 data points to examine every instance in which a company added a new patent or exclusivity.)//sid

The study results demonstrate definitively that the pharmaceutical industry has strayed far from the patent system's intended design. The patent system is not functioning as a time-limited opportunity to garner a return, followed by open competition. Rather, companies throughout the industry seek and obtain repeated extensions of their competition-free zones. Moreover, the incidence of such behavior has steadily increased between 2005 and 2015, especially on the patent front and for certain highly valuable exclusivities. Most troubling, the data suggest that the current state of affairs **is harming innovation** in tangible ways. Rather than creating new medicines—sallying forth into new frontiers for the benefit of society—**drug companies are focusing their time and effort extending the patent life of old products.** **This**, of course, **is not the innovation one would hope for**. The greatest creativity at pharmaceutical **companies should be in the lab, not in the legal department**.115 The following sections describe the results obtained through our analysis in detail, but below are the key takeaways from the study: Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. In fact, **78% of the drugs associated with new patents** in the FDA’s records **were not new drugs** coming on the market, but existing drugs. In some years, the percentage reached as high as 80%. Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70% extended their protection at least once, with more than 50% extending the protection cliff more than once. Looking at the full group, almost **40% of all drugs** available on the market **created additional market barriers by having patents or exclusivities added** to them. Many of the drugs adding to the Orange Book are ‘serial offenders’—returning to the well repeatedly for new patents and exclusivities. Of the drugs that had an addition to the Orange Book, 80% of those had an addition to the Orange Book on more than one occasion, and almost half of these drugs had additions to the Orange Book on four or more occasions. The number of drugs with a high quantity of added patents in a single year has substantially increased. For example, the number of drugs with three or more patents added to them in one year has doubled. Similarly, the number of drugs with five or more added patents has also doubled. Overall, the quantity of patents added to the Orange Book has more than doubled, increasing from 349 patents added in the year 2005 to 723 in 2015. The number of drugs that had a patent added to them in the Orange Book almost doubled. There were striking increases in certain exclusivities, such as orphan drug exclusivity, new patient population exclusivity, and new product exclusivity. In particular, the number of drugs with an added orphan drug exclusivity tripled. In addition, the number of times a use code was added to a patent more than tripled, suggesting that this has become a new favored game. To provide a broad sense of the types of metrics we are using, some could be characterized as ‘intensity’ measures, which capture the breadth and depth of patent and exclusivity activity in the industry. Another set of our metrics can be characterized as ‘temporal’ measures, which evaluate whether there are any trends in the behavior under examination across time during our 11-year timeframe from 2005 to 2015.

#### IP protections are vital to resolve vaccine deficiencies. History disproves all pro patent arguments

Kumar, PhD, 7-12-21

(Rajeesh, Associate Fellow Manohar Parrikar Institute for Defence Studies and Analysis, https://www.idsa.in/issuebrief/wto-trips-waiver-covid-vaccine-rkumar-120721)

In October 2020, India and South Africa had submitted a proposal to the World Trade Organization (WTO), suggesting a waiver of certain provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for the “prevention, containment and treatment of COVID-19”. The proposal seeks the waiver of “the implementation, application, and enforcement of sections 1, 4, 5 and 7 of part II of the TRIPS agreement”, which are stipulations referring to copyright, industrial design, patents, and undisclosed information (trade secrets).1 The proponents of the proposal argue that a waiver will enable timely and equitable access to affordable health products and technologies, including vaccines. Though many member countries had supported and co-sponsored the proposal, a small but influential group of countries, mainly Australia, Canada, the European Union (EU), Japan, the United Kingdom (UK) and the United States (US), opposed it. They argued that existing exceptions under the TRIPS Agreement are sufficient to address the concerns mentioned in the proposal. This resulted in sidelining of the waiver proposal for months. However, on 5 May 2021, the Joseph Biden administration announced its support for waiving intellectual property protections for COVID-19 vaccines.2 It was a significant step towards breaking the seven-month gridlock, and led to many more countries modifying their position on the waiver proposal. On 25 May 2021, the co-sponsors of the waiver proposal submitted a revised proposal that specified the scope of the waiver as applying to “health products and technologies” and also added a section on the proposed duration of the waiver, i.e., three years.3 At present, more than 100 countries, including the US and China support this proposal. The principal opponent of the waiver is the EU and in June 2021, it submitted an alternative proposal to the TRIPS Council, which requested to keep TRIPS’ provisions intact and focused on compulsory licensing and removing vaccine export restrictions to address the concerns raised by India and South Africa.4 The EU proposal also stated that the TRIPS Agreement does not prevent countries from taking measures to protect public health.5 At the meeting of the TRIPS Council on 8–9 June 2021, the member states agreed to text-based negotiations focusing on two proposals tabled by members. The members also decided to hold a series of meetings till the end of July 2021 to take stock of the text-based negotiations. However, the latest developments show that the waiver discussions hit a hurdle due to a split between the developed and developing countries over the negotiation text. This brief discusses how TRIPS becomes a barrier to the equitable access of COVID-19 vaccines. It also examines how a waiver will help India in its fight against COVID-19 at home and abroad. TRIPS and its Exceptions TRIPS, a comprehensive multilateral agreement on Intellectual Property (IP), was an outcome of the Uruguay Round (1986–94) of negotiations of the General Agreement on Tariffs and Trade (GATT). The Agreement came into force on 1 January 1995 and offers a minimum standard of protection for Intellectual Property Rights (IPR).6 In WTO, IPR are divided into two main categories. First, copyright and related rights (Articles 9 to 14, Part II of the TRIPS Agreement). Second, industrial property that includes trademarks, geographical indications, industrial designs, patents, integrated circuit layout designs, and undisclosed information (Articles 15 to 38, Part II of the TRIPS Agreement).7 Article IX.3 and IX.4 of the Marrakesh Agreement Establishing the WTO deals with TRIPS waivers. Article IX.3 says that in “exceptional circumstances” the Ministerial Conference may waive off an obligation imposed on WTO member countries.8 Such a decision requires the support of three-fourths of the WTO membership. According to Article IX.4, any waiver granted for more than one year will be reviewed by the Ministerial Conference. Based on the annual review, the Conference may extend, modify, or terminate the waiver. The TRIPS Agreement provides some flexibility primarily in the form of compulsory licensing and research exceptions through Articles 30 and 31. While Article 30 permits WTO members to make limited exceptions to patent rights, Article 31 provides a detailed exception, provided certain conditions are met. Compulsory licensing is the process of granting a license by a government to use a patent without the patent holder's consent. Article 31 permits granting compulsory license under circumstances such as “national emergencies”, “other circumstances of extreme urgency”, “public noncommercial use”, or against “anti-competitive” practices.9 In addition to these original waivers, the Declaration on the TRIPS Agreement and Public Health, adopted at the 2001 Doha Ministerial Meeting, also recognises some exceptions, for instance, in situations of a public health emergency, member countries have the freedom to determine the grounds upon which compulsory licenses are granted. Similarly, under Article 66.1, the least developed countries (LDCs) are given waivers for implementing TRIPS on pharmaceuticals till 1 January 2033. COVID-19 and TRIPS Waiver Two significant factors rekindled the debate on TRIPS waiver for essential medical products—first, vaccine inequity, and second, the insufficiency of existing waiver provisions in fighting the COVID-19 pandemic. COVID-19 is an exceptional circumstance, and equitable global access to the vaccine is necessary to bring the pandemic under control. However, the world is witnessing quite the reverse, i.e., vaccine nationalism. Vaccine nationalism is “my nation first” approach to securing and stockpiling vaccines before making them available in other countries. A TRIPS waiver would be instrumental in addressing the growing inequality in the production, distribution, and pricing of the COVID-19 vaccines. Vaccine Inequity According to Duke Global Health Innovation Center, which monitors COVID-19 vaccine purchases, rich nations representing just 14 per cent of the world population have bought up to 53 per cent of the most promising vaccines so far. As of 4 July 2021, the high-income countries (HICs) purchased more than half (6.16 billion) vaccine doses sold globally. At the same time, the low-income countries (LICs) received only 0.3 per cent of the vaccines produced. The low and middle-income countries (LMICs), which account for 81 per cent of the global adult population, purchased 33 per cent, and COVAX (COVID-19 Vaccines Global Access) has received 13 per cent.10 Many HICs bought enough doses to vaccinate their populations several times over. For instance, Canada procured 10.45 doses per person, while the UK, EU and the US procured 8.18, 6.89, and 4.60 doses per inhabitant, respectively.11 Source:“Tracking COVID-19 Vaccine Purchases Across the Globe”, Duke Global Health Innovation Center, Updated 9 July 2021. Consequently, there is a significant disparity between HICs and LICs in vaccine administration as well. As of 8 July 2021, 3.32 billion vaccine doses had been administered globally.12 Nonetheless, only one per cent of people in LICs have been given at least one dose. While in HICs almost one in four people have received the vaccine, in LICs, it is one in more than 500. The World Health Organization (WHO) notes that about 90 per cent of African countries will miss the September target to vaccinate at least 10 per cent of their populations as a third wave looms on the continent.13 South Africa, the most affected African country, for instance, has vaccinated less than two per cent of its population of about 59 million. This is in contrast with the US where almost 47.5 per cent of the population of more than 330 million has been fully vaccinated. In Sub-Saharan Africa, vaccine rollout remains the slowest in the world. According to the International Monetary Fund (IMF), at current rates, by the end of 2021, a massive global inequity will continue to exist, with Africa still experiencing meagre vaccination rates while other parts of the world move much closer to complete vaccination.14 This vaccine inequity is not only morally indefensible but also clinically counter-productive. If this situation prevails, LICs could be waiting until 2025 for vaccinating half of their people. Allowing most of the world’s population to go unvaccinated will also spawn new virus mutations, more contagious viruses leading to a steep rise in COVID-19 cases. Such a scenario could cause twice as many deaths as against distributing them globally, on a priority basis. Preventing this humanitarian catastrophe requires removing all barriers to the production and distribution of vaccines. TRIPS is one such barrier that prevents vaccine production in LMICs and hence its equitable distribution. TRIPS: Barrier to Equitable Health Care Access The opponents of the waiver proposal argue that IPR are not a significant barrier to equitable access to health care, and existing TRIPS flexibilities are sufficient to address the COVID-19 pandemic. However, history suggests the contrary. For instance, when South Africa passed the Medicines and Related Substances Act of 1997 to address the HIV/AIDS public health crisis, nearly 40 of world’s largest and influential pharma companies took the South African government to court over the violation of TRIPS. The Act, which invoked the compulsory licensing provision, allowed South Africa to produce affordable generic drugs.15 The Big Pharma also lobbied developed countries, particularly the US, to put bilateral trade sanctions against South Africa.16 Similarly, when Indian company Cipla decided to provide generic antiretrovirals (ARVs) to the African market at a lower cost, Big Pharma retaliated through patent litigations in Indian and international trade courts and branded Indian drug companies as thieves.17 Another instance was when Swiss company Roche initiated patent infringement proceedings against Cipla’s decision to launch a generic version of cancer drug, “erlotinib”. Though the Delhi High Court initially dismissed Roche's appeal by citing “public interest” and “affordability of medicines,” the continued to pressure the generic pharma companies over IPR. 18 Likewise, Pfizer’s aggressive patenting strategy prevented South Korea in developing pneumonia vaccines for children.19 A recent document by Médecins Sans Frontières (MSF), or Doctors Without Borders, highlights various instances of how IP hinders manufacturing and supply of diagnostics, medical equipment, treatments and vaccines during the COVID-19 pandemic. For instance, during the peak of the COVID-19 first wave in Europe, Roche rejected a request from the Netherlands to release the recipe of key chemical reagents needed to increase the production of diagnostic kits. Another example was patent holders threatening producers of 3D printing ventilators with patent infringement lawsuits in Italy.20 The MSF also found that patents pose a severe threat to access to affordable versions of newer vaccines.21 Source:“COVID-19 Vaccine R&D Investments”, Global Health Centre, Graduate Institute, Geneva, Updated 9 July 2021. The opponents of the TRIPS waiver also argue that IP is the incentive for innovation and if it is undermined, future innovation will suffer. However, most of the COVID-19 medical innovations, particularly vaccines, are developed with public financing assistance. Governments spent billions of dollars for COVID-19 vaccine research. Notably, out of $6.1 billion in investment tracked up to July 2021, 98.12 per cent was public funding.22 The US and Germany are the largest investors in vaccine R&D with $2.2 billion and $1.5 billion funding. Source:“COVID-19 Vaccine R&D Investments”, Global Health Centre, Graduate Institute, Geneva, Updated 9 July 2021. Private companies received 94.6 per cent of this funding; Moderna received the highest $956.3 million and Janssen $910.6 million. Moreover, governments also invested $50.9 billion for advance purchase agreements (APAs) as an incentive for vaccine development. A recent IMF working paper also notes that public research institutions were a key driver of the COVID-19 R&D effort—accounting for 70 per cent of all COVID-19 clinical trials globally.23 The argument is that vaccines are developed with the support of substantial public financing, hence there is a public right to the scientific achievements. Moreover, private companies reaped billions in profits from COVID-19 vaccines. Source: Katharina Buchholz, “COVID-19 Vaccines Lift Pharma Company Profits”, Statista, 17 May 2021. One could argue that since the US, Germany and other HICs are spending money, their citizens are entitled to get vaccines first, hence vaccine nationalism is morally defensible. Nonetheless, it is not the case. The TRIPS Agreement includes several provisions which mandates promotion of technology transfer from developed countries to LDCs. For instance, Article 7 states that "the protection and enforcement of IP rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."24 Similarly, Article 66.2 also mandates the developed countries to transfer technologies to LDCs to enable them to create a sound and viable technological base. The LMICs opened their markets and amended domestic patent laws favouring developing countries’ products against this promise of technology transfer. Another argument against the proposed TRIPS waiver is that a waiver would not increase the manufacturing of COVID-19 vaccines. Indeed, one of the significant factors contributing to vaccine inequity is the lack of manufacturing capacity in the global south. Further, a TRIPS waiver will not automatically translate into improved manufacturing capacity. However, a waiver would be the first but essential step to increase manufacturing capacity worldwide. For instance, to export COVID-19 vaccine-related products, countries need to ensure that there are no IP restrictions at both ends – exporting and importing. The market for vaccine materials includes consumables, single-use reactors bags, filters, culture media, and vaccine ingredients. Export blockages on raw materials, equipment and finished products harm the overall output of the vaccine supply chain. If there is no TRIPS restriction, more governments and companies will invest in repurposing their facilities. Similarly, the arguments such as that no other manufacturers can carry out the complex manufacturing process of COVID-19 vaccines and generic manufacturing as that would jeopardise quality, have also been proven wrong in the past. For instance, in the early 1990s, when Indian company Shantha Biotechnics approached a Western firm for a technology transfer of Hepatitis B vaccine, the firm responded that “India cannot afford such high technology vaccines… And even if you can afford to buy the technology, your scientists cannot understand recombinant technology in the least.”25 Later, Shantha Biotechnics developed its own vaccine at $1 per dose, and the UNICEF (United Nations Children’s Emergency Fund) mass inoculation programme uses this vaccine against Hepatitis B. In 2009, Shantha sold over 120 million doses of vaccines globally. India also produces high-quality generic drugs for HIV/AIDS and cancer treatment and markets them across the globe. Now, a couple of Indian companies are in the last stage of producing mRNA (Messenger RNA) vaccines.26 Similarly, Bangladesh and Indonesia claimed that they could manufacture millions of COVID-19 vaccine doses a year if pharmaceutical companies share the know-how.27 Recently, Vietnam also said that the country could satisfy COVID-19 vaccine production requirements once it obtains vaccine patents.28 Countries like the United Arab Emirates (UAE), Turkey, Cuba, Brazil, Argentina and South Korea have the capacity to produce high-quality vaccines but lack technologies and know-how. However, Africa, Egypt, Morocco, Senegal, South Africa and Tunisia have limited manufacturing capacities, which could also produce COVID-19 vaccines after repurposing. Moreover, COVID-19 vaccine IPR runs across the entire value chain – vaccine development, production, use, etc. A mere patent waiver may not be enough to address the issues related to its production and distribution. What is more important here is to share the technical know-how and information such as trade secrets. Therefore, the existing TRIPS flexibilities, such as compulsory and voluntary licensing, are insufficient to address this crisis. Further, compulsory licensing and the domestic legal procedures it requires is cumbersome and not expedient in a public health crisis like the COVID-19 pandemic.

### Contention 2: Drug Prices

#### Intellectual property protections keep drug prices high.

Amin 18 Tahir Amin 6-27-2018 "The problem with high drug prices isn't 'foreign freeloading,' it's the patent system" [High drug prices caused by US patent system, not 'foreign freeloaders' (cnbc.com)](https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html) <https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html> (co-founder of nonprofit I-MAK.org)//Elmer

**'Evergreening'** Instead of going to new medicines, the study finds that 74 percent of new patents during the decade went to drugs that already existed. It found that 80 percent of the nearly 100 best-selling drugs extended their exclusivity protections at least once, and 50 percent extended their patents more than once—with the effect of **prolonging** the **time before generics** could reach the market **as drug prices continued to rise**. The strategy is called “evergreening”: drug makers add on new patents to prolong a drug’s exclusivity, even when the additions aren’t fundamentally new, non-obvious, and useful as the law requires. One of the most expensive cancer drugs on the market, **Revlimid**®, is a case in point: **priced at** over $**125,000** per year of treatment, Celgene has sought **105 patents** on Revlimid®, many of which have been granted, extending its monopoly until the end of 2036. That gives the Revlimid® patent portfolio a lifespan of 40 years, which is being used to block or deter generic competitors from entering the market. But a recent I-MAK analysis finds that several of Celgene’s patents are mere add-ons—not fundamentally new to deserve a patent. And because of the thicket of patents around Revlimid®, **payers** are **projected to spend $45 billion** **in excess costs** on that drug alone as compared to what they could be paying if generic competitors were to enter when the first patent expires in 2019. Meanwhile, Celgene is also among the pharmaceuticals that have been recently scolded by the FDA for refusing to share samples with generic makers so they can test their own products against the brands in order to attain FDA approval. **In the absence of** genuine **competition** in the U.S. prescription drug market, **monopolies are yielding reckless pricing schemes and prohibitively expensive drugs** for Americans (and people around the world) who need them. In 2015, for example, U.S. Senators Wyden and Grassley found after an 18-month bipartisan investigation that the notorious $84,000 price tag for the hepatitis C drug made by Gilead was based on “a pricing and marketing strategy designed to maximize revenue with little concern for access or affordability.” Gilead’s subsequent hepatitis C drug Harvoni® was introduced to the market at a still higher cost of $94,500. Who benefits when drugs are priced so high? Not the 85 percent of Americans with hepatitis C who are still not able to afford treatment.

#### High Drug Prices forces patients to go underground for drugs.

Bryant 11 Clifton Bryant 2011 “The Routledge Handbook of Deviant Behaviour” (former professor of sociology at VA Tech)//Elmer

Now, the field of medicine is able to achieve seemingly miraculous results, through organ transplantation, reviving patients who have been "clinically" dead, and curing supposedly "incurable diseases." Medical miracles are not cheap, however, and the costs of medical care and drugs have risen (and continue to rise) at a near-astronomical rate. Consequently, neither private medical insurance plans nor Medicare will now cover certain procedures, treatments, and medicines. In the future, with continuing reform of the US healthcare system, even fewer procedures, treatments, and medications might will be covered. Certainly, some medical treatment will be "rationed," and particular categories of people (such as the elderly) may be systematically denied the coverage they need. As a result of all this, medical- and health-related crime and deviance will inevitably rise. Medical insurance, Medicare, and Medicaid fraud, which is already prevalent today, will increase exponentially. Smugglers will "bootleg" ever more pharmaceuticals into the US, and a large, thriving, nationwide black market will develop for those who cannot afford to buy uncovered medications. More medicines and diagnostic equipment will be stolen, and back- street medical procedures using such stolen equipment may well be offered for cash with no questions asked. Armed robberies of valuable pharmaceuticals from drug stores and super- markets will increase, too. Bribery to obtain insurance-uncovered or rationed medical care (or, indeed, any kind of medical care where demand exceeds supply) will likely mushroom. This is actually common in some countries around the world. Counterfeiting expensive pharmaceuticals will be prevalent, and medical frauds of all kinds will be very widespread. Many of these frauds will be directed at the elderly population as it continues to increase in size. The elderly will be particularly vulnerable because they are most likely to be denied coverage for certain medical procedures or treatments. For instance, private health insurance and Medicare will both refuse to cover a woman in her mid-80s for potentially life-saving heart-bypass surgery. As a result, she will be a prime candidate for victimization by medical fraud that offers her affordable, but bogus, treatment. There is already a thriving international black market in human organs (Schepper-Hughes 2009). Kidneys are obtained from poor individuals in impoverished countries for relatively modest sums of money. This cash allows the donors to purchase luxuries, such as a small automobile, educate their children, or simply sustain their families for a few months. The organs are sometimes transferred quickly to a hospital in the donor's own country for transplant surgery. But on other occasions they are transported to the US or another Western country. In the US, obtaining an organ for transplantation in this fashion is illegal. Nevertheless, the practice will undoubtedly increase greatly in the future. Where medical care and medicines become exorbitantly expensive, cheaper ways to obtain them, even when these are illicit, will be sought. Where there are shortages of medical care or medicines, perhaps because of rationing, other means of obtaining them, even if deviant, will surely be employed. As the cost and the difficulty of obtaining medical care and medicines increase, the implications for increased crime and deviance become almost limitless.

#### Counterfeit drugs kill millions.

Greenberger 20 Phyllis E. Greenberger 12-3-2020 "Counterfeit Medicines Kill People" <https://www.healthywomen.org/health-care-policy/counterfeit-medicines-kill-people/who-suffers-because-of-counterfeit-drugs> (HealthWomen’s Senior Vice President of Science & Health Policy)//Elmer

**Over 1 million people die each year from fake drugs**. COVID-19 Have you ever had a hard time getting a prescription filled? Or maybe you've had to wrestle with your insurance provider to get them to pay for a medication vital for your health? Worse, maybe you're one of the 27.5 million uninsured Americans who find it difficult to get health care, let alone obtain the prescription drugs you may need. If you've had any of these experiences, then perhaps you've turned to the internet to buy medications that would require a prescription. While legal online pharmacies do exist, many online pharmacies are fraudulent, selling counterfeit medications, and millions of people have fallen victim to these scammers. Make no mistake: **Counterfeit medicine is not real**. The **active ingredients** that help you stay healthy may be **missing** **or diluted** to levels that are no longer potent. This **can be dangerous and even life-threatening**, as people rely on their medications to keep them well, and sometimes even alive. Many counterfeit medicines aren't even drugs at all, but rather **snake oil cures that make people sick** — they may even **contain** **dangerous ingredients such as heavy metals, highway paint or even rat poison.** The World Health Organization (WHO) estimates that over 1 million people die each year from these substandard drugs. It's estimated that more than 10% of all pharmaceuticals in the global supply chain are counterfeit in normal times, and during COVID-19, the increased use of telehealth and the appearance of fraudulent doctors has led to a surge in drug fraud. In October of this year, Peter Pitts, president of the Center for Medicine in the Public Interest, a nonpartisan research organization, said pharmaceutical fakery was a "spreading cancer." Counterfeiting is a major problem that requires the federal government to step up to slow — and eventually prevent — its spread. It's also vital that consumers know exactly what's at stake when taking these fake drugs. Who suffers because of counterfeit drugs? Expensive prescription medications and generic drugs in nearly every therapeutic class may be counterfeited. Out of $4.3 billion worth of counterfeit medications seized between 2014 and 2016, 35% were marked as antibiotics. Some of the other most common culprits in counterfeit medicine are used to "treat" HIV/AIDS, erectile dysfunction and weight loss. No matter what condition or disease the counterfeit medication is intending to treat, the outcome can be disastrous. **Counterfeit medications exacerbate other existing health crises**. The United States, for example, is in the midst of an opioid epidemic that is killing 130 people per day. As of 2018, counterfeit drugs containing illegally imported fentanyl (a powerful opioid) had contributed to this tragedy by causing deaths in 26 states. The U.S. Department of Justice found that, in at least one case, these counterfeit drugs had been sold through a fraudulent online pharmacy.

### Contention 3: Innovtion

#### The current pharmaceutical industry is hindering innovation.

Mazzucato 18 [Mariana Mazzucato, 10-17-2018, "Opinion," Washington Post, https://www.washingtonpost.com/news/theworldpost/wp/2018/10/17/pharmaceutical/]/ISEE

The global pharmaceutical industry is no longer innovating. Research shows that 78 percent of patents approved by the U.S. Food and Drug Administration correspond to medications already on the market, while those disease areas not considered growth markets are ignored. From 2000 to 2011, only 4 percent of newly-approved products globally were designed to treat neglected diseases that affect lower- and middle-income countries. Part of the problem is how pharmaceuticals use the patent system. Instead of creating new drugs, they extend existing patents beyond the initial 20-year protection set by the United States and use gimmicks, such as overly-wide patents, to block knowledge creation and issue patents for what is essentially the same drug. Losec, for example, which is produced by AstraZeneca to treat heartburn and ulcers, was later tweaked and placed under a new name. This enabled the company to issue a new patent for the barely modified medication, effectively extending the company’s monopoly on this type of drug well beyond the period granted by the original patent. What’s more, while taxpayers are largely footing the bill for drug research, pharmaceuticals are reaping all the gains. Sofosbuvir, which treats hepatitis C, emerged from over 10 years of U.S. taxpayer-funded research — through the Department of Veterans Affairs and the National Institutes of Health. But when the private biotech company Gilead Sciences later acquired the drug, it priced a 12-week course of pills at $84,000 in the U.S. market. By the end of 2017, Sofosbuvir had generated over $50 billion in sales. Sofosbuvir is not an exception. The U.S. taxpayer has funded research for every single one of the 210 new drugs that the FDA approved between 2010-16. Yet the companies that have access to this research are increasingly viewing pharmaceuticals in the same way that banks view their financial product — opportunities for short-term returns. Large pharma companies spend more on share buybacks to boost share prices (and stock options — the main way that executives get paid) than on research and development. Pfizer, for example, spent $139 billion on share buybacks and dividends in the past decade — and just $82 billion on research and development in the same period. (The chief executive’s pay was also a reported $27.9 million in 2017.)

#### While patents first-glance may seem like a good idea, the problem is that many corporations use them to get rid of rivals, functionally monopolizing the market. As a result, medical innovation has slowed down tremendously.

**Gubby 19** [Hellen Gubby, professor at the Rotterdam School of Management at Amarus University with a PhD in law, 9-6-2019, "Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective," Wiley Online Library, https://onlinelibrary.wiley.com/doi/10.1111/1758-5899.12730]/Kankee

As the economy has largely shifted from industrial manufacturing to high-tech, life science and information processing industries, intellectual property has become more and more important. **Corporations have become increasingly aware** **of the potential of the patent**, **not just as a shield to protect against imitation, but as a strategic tool to block competition** **and dominate markets**. Patents have come to have a broader strategic function in which **innovation may only play a small part**. Although many patents do not produce any income: ‘In terms of strategy, though, the patent can be much more valuable’ (Macdonald, 2004, p. 143). Patent strategy is directly related to the business context. The Carnegie Mellon Survey of the US manufacturing sector in 1994 revealed that **firms often used patents as strategic tools, rather than** as simply **a means of protecting an invention from wrongful imitation** (Cohen et al., 2000). In their examination of motives to patent, Blind et al. (2009) recognised that, although protection from imitation was still the most important factor, ‘the importance of the strategic motives to patent are confirmed’ (Blind et al., 2006, p. 671). Patent strategies **The decision to patent has become** in part uncoupled from the original core purpose of the patent: **to protect an invention from unfair imitation by other market participants**. **Larger firms, with the capital assets to pay for the cost of patenting, use their patent portfolios strategically**. **Patents have become** useful as **bargaining chips; they provide leverage**. **Large patent portfolios are a means to get access to important co-operations or cross-licensing arrangements** (Blind et al., 2009, p. 431). Yet while building **the portfolio** requires enormous legal costs, it **contributes little to research incentives**. Furthermore, **these** **portfolios** can be used not just to oblige competitors to take licences, but also the terms of these licences can **restrict competitors to certain areas of technology** (Barton, 2000). **Larger firms** **can** afford to play the ‘wrap around’ strategy. Instead of **apply**ing **for** a single patent to cover an invention, other **patents** are filed **around the main patent**. **These** **related** **patents lock down the discrete features of an invention**. **The tactic hinders entry to the market**. **Competitors will be put to time, effort and cost to fight their way through all the relevant patents covering the technology**. Furthermore, **the chance** that **the competitor's invention may infringe one of the many claims in one of the many patents is high**. Not only can **damages be awarded for infringement, but also an injunction**. **Injunctions prevent the party accused of infringement from producing any products that require the use of the tech**nology **covered by the infringed patent and all infringing products are removed from the market.** Patents may be used simply to block competitors. **Using a patent as a blocking strategy is common practice** (Neuhäusler, 2012). **Defensive blocking is used to protect a firm's own freedom to operate**: **it does not want to be shut out by the patents of its rivals**. An offensive blocking strategy is where **patents are filed to cover products or processes that the firm does not intend to practice itself, but which could be viable alternatives to competitors**. **By patenting all conceivable alternatives, research by competitors that might threaten their own technological lead can be thwarted**. As in general **a patentee is under no obligation to license out its technology to another, the strategy can deter market entry or new product launch.** This offensive blocking of competitors by means of **patents**, ‘is clearly a case of the patent system being used for purposes other than for which it was originally intended’ (Blind, 2009, p. 436). However, both defensive and offensive **blocking** should be a policy concern, as they **can reduce economic** **efficiency**. **Defensive patenting increases cost to firms without necessarily producing any benefit and offensive patenting can reduce technological progress and increase consumer costs by reducing competition** (Thumm, 2004, p. 533). Using data from a large-scale survey of patent applications, Torrisi discovered that **a substantial share of patents remained unused and a substantial number of patent applications were filed to block other patents**. There were institutional differences; there were more unused patents in Japan and the EU than in the USA. Although cautious to make generalisations about unused patents, as some unused patents are there to ensure freedom to operate or simply because of management inefficiency, Torrisi et al. did conclude that: ‘[**o**]**ur results highlight that there might be substantial benefits that patent owners draw from being able to keep patent rights unused**. These would have to be balanced against possible harm imposed on other economic agents’ (Torrisi et al., 2016; , p. 1384). These strategies show a disconnect with the original purpose of the patent system. Patent strategies impact on innovation, and this in turn impacts on society. Concern was already expressed quite forcibly some years ago by Turner: Surely when the framers of the [US] Constitution empowered Congress to grant monopolies to ‘promote the progress of science and the useful arts’, they did not envision the beneficiaries of this grant would use it to bury new technologies to protect market share or capital investments. (Turner, 1998, p.209) Administrative failures Patent offices have been struggling to cope with the increasing number of patent applications: in 2017, more than 3 million patent applications were filed worldwide (WIPO, 2018). This influx has resulted in substantial application backlogs, with an increasingly long time between the patent filing and the patent grant: five years is not unusual. Complaints of poor quality control have been made concerning the US Patent and Trademark Office as well as the European Patent Office (Abbott, 2004; Mabey, 2010). The WIPO recognised a consistent upward trend in patent filings is putting patent offices under enormous pressure (WIPO, 2017, p. 13). Why are these administrative failings dangerous from a societal perspective? **Patents** **grant a monopoly that can impact innovative processes for 20 years or more**. **Patents have been granted that should not have been granted**. **When an overly broad patent is granted, this can block further innovation by others**. **Broad patents may mean** that **access to vital research is not available because** the **results** of that research **are covered by patent claims**. In particular, **broad** basic **patents on fundamental research** **can block and deter follow-on** **research**. **The incentive to innovate is reduced** (Barton, 2000; Henry and Stiglitz, 2010).1 Back in 1966, the societal implication of overly broad grants was expressed clearly by the US Supreme Court when it rejected a broad claim covering a group of chemicals: ‘**Such a patent may confer power to block off whole areas of scientific development** without compensating benefits to the public.’2

#### Reject Negative Turns – they’re pharmaceutical lies – the Plan isn’t anti-Patent, just pro-innovation – breaking down secondary patents is key.

* AT Advantage CPs to solve Drug Prices

Radhakrishnan 16 Priti Radhakrishnan 6-14-2016 "Pharma’s secret weapon to keep drug prices high" <https://www.statnews.com/2016/06/14/secondary-patent-gilead-sovaldi-harvoni/> (Priti Radhakrishnan is cofounder and director of the Initiative for Medicines, Access & Knowledge (I-MAK), a US-based nonprofit group of scientists and lawyers working globally to get people lifesaving medicines. Before founding I-MAK, she worked as a health attorney in the US, Switzerland, and India.)//Elmer

Skyrocketing drug prices are forcing states to take **unprecedented measures** to rein in health care spending. Vermont just became the nation’s first state to require prescription drug pricing transparency. The New York and Massachusetts attorneys general have launched investigations into major pharmaceutical companies’ and insurers’ drug pricing policies and strategies. These **are important steps**. **But** they **ignore a key driver of the problem: secondary patents**. Familiar to only a few people inside the insular world of intellectual property law, secondary patents work like this: Companies file for additional, defensive patents to thicken the protection around their original base patents. These additional patents **rarely represent anything new in terms of science**. Instead, their **purpose is to** **prolong** **a** company’s **monopoly** and, along with that, its ability to charge high prices for its drugs. Some drugs have dozens of secondary patents. Abbott Labs, for example, has over 108 patents on its HIV drug Kaletra. Take the case of Sovaldi, a treatment for hepatitis C developed by Gilead Sciences. In the United States, Gilead prices Sovaldi at up to $1,000 a pill, or about $84,000 for a complete course of treatment. This pricing strategy helped Gilead clear $18 billion in profits last year, while taxpayer-funded Medicaid programs, state health programs, and patients have trouble affording this astronomically priced drug. Sovaldi is comprised of a base compound — sofosbuvir — for which the pharma giant has filed three patents. On top of that, Gilead has pursued an additional 24 patents, with more likely to come. My organization, the Initiative for Medicines, Access & Knowledge (I-MAK), aims to ensure that people with hepatitis C and HIV around the world get the medicines they need to survive and lead healthy lives. We have evaluated Gilead’s patent portfolio and found that, based on US and international patent law, Gilead does not deserve any of its 27 patents for Sovaldi. Both the base and secondary patents for the drug are based on old science and commonly known techniques. Yet because of its defensive patenting strategy, Gilead will maintain an iron lock on its market share and charge exorbitantly high prices to Americans with hepatitis C until well into the 2030s. Harvoni, another medication that treats hepatitis C, combines sofosbuvir and a drug called ledipasvir. Currently, Harvoni has 27 secondary patents. If these were removed, people in the US could access far cheaper versions of the same drug as soon as 10 years earlier. Based on I-MAK’s conservative estimates, this could open access to treatment for millions of people in the US, saving patients and payers like Medicare and Medicaid $5 billion over an eight-year period. In the US, Harvoni is priced at $94,000 for a course of treatment. In middle-income, high-population countries like Argentina, Brazil, and China, people are forced to pay thousands of dollars for sofosbuvir. Stripping away unmerited patents would reduce drug costs and increase access for millions of people in the US and around the world. **Pharmaceutical companies love to claim that winnowing** their armada of **patents would be a disincentive to innovation** and would limit research into new drugs. **Don’t believe it**. **The industry devotes shockingly little funding to research and development**. Companies **spend** roughly **one-third** of their revenues **on marketing** **and only half as much on research** and development, while spending big on armies of lawyers to devise and defend secondary patents and other so-called “life cycle management” strategies. Drug **research funding** has been **declining for more than a decade**, **while** strategies of **secondary patenting have steadily increased.** We support patents — just not those that are unmerited and that unjustly prolong companies’ market power and prevent legitimate competition.

#### Patents incentivize Negative Innovation.

Feldman 21, Robin C., et al. "Negative innovation: when patents are bad for patients." <https://www.nature.com/articles/s41587-021-00999-0.pdf> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//Elmer

Patent law in the United States is historically premised on advancing the interests of society. From the store of productive activity available to all, the government restricts some activities for a limited time in hopes this will redound to the benefit of all by incentivizing innovation1 . The law thereby restricts competition, forgoing the concomitant advantages of the free market, but only during the patent period. After that time, the law expects that competition will enter, driving down prices and spurring new innovation. From this perspective, US patent law centers on the benefit to the public, with the inventor’s reward providing the vehicle for accomplishing this jurisprudential goal. In the health care space, these incentives have resulted in extraordinary success stories, but the **same incentives** can also **result in** a range of undesirable consequences, including excessive development of **similar (but not better) products** (‘me-too drugs’), the focus on drugs for diseases that affect wealthy people and wealthy countries rather than diseases that disproportionately affect the poor and developing nations, and a lack of innovation for types of medicines that may return fewer profits, such as antibiotics2–4 . Similarly, drug companies will **not research the utility of a known** (**and hence unpatentable) chemical**, since the ability to obtain patent protection is central to their business model5 . Past literature has highlighted these problems but has largely overlooked the problem of ‘**negative innovation’**, in which **patent** law **drives innovation into spaces that are affirmatively harmful to patients**. By this, we mean **scenarios** **whereby** **patents create incentives to bring a product to market in a way that is** relatively **harmful to consumers**, and the existence of a patent (and the associated rents) discourages the patentee from taking steps to improve the product so as to prevent the adverse health outcomes. Of course, there are other patent-driven situations of problematic utility, including scenarios that result in purely financial harms, such as drugs that are no better than existing options but are more expensive; scenarios where a small, heightened risk of direct physical harm is offset by lower prices for the drug in question6 ; and scenarios where there is no existing product on the market and inadequate incentives to develop such a product, so any physical harm is the result of the underlying disease or illness7 . Finally, there is a general concern that inadequate new information about existing products is generated in the current system8 . All of these scenarios are different in kind from negative innovation, which results in a harmful (but profitable) product. We focus on this dangerous but overlooked space of the patent landscape, wherein patents themselves lead fairly directly to patient harm. What does negative innovation look like? We highlight a particularly pernicious example, the case of Imbruvica (ibrutinib); suggest the likelihood of broader problems; and outline various strategies for preventing such outcomes going forward. The case of ibrutinib Ibrutinib, a small molecule drug discovered by Pharmacyclics (now a subsidiary of AbbVie), is an irreversible inhibitor of Bruton’s tyrosine kinase (BTK), a key regulator of B cell signaling and growth. It is approved by the US Food and Drug Administration for multiple indications and is most commonly used to treat B cell cancers, such as chronic lymphocytic leukemia. While ibrutinib is effective, it, like all anticancer agents, is toxic. It is all the more puzzling, then, that ibrutinib’s recommended dosage appears to be substantially higher than necessary to achieve the necessary therapeutic effect—or at least, what evidence is available points to that conclusion9 . Problematic incentives created by the patent system make this result unfortunately unsurprising. The basic story is disheartening but simple. Early studies published by Pharmacyclics showed efficacy at low doses (partial response at 1.25 milligrams per kilogram body weight, approximately 40% response at 2.5 mg kg–1, and no relationship of response to dose between 2.5 and 12.5 mg kg–1)10. These reports were shared by Pharmacyclics in a conference abstract in 200911,12 and a press release in 201013. An early patent application by Pharmacyclics (US 2012/0087915 A1) accordingly claimed a full range of doses. Trials to support approval by the US Food and Drug Administration (FDA) continued. In July 2013, ibrutinib received accelerated approval for mantle cell lymphoma based on a 66% response rate in 111 patients treated at 560 mg daily. Notably, the 2013 FDA review included an analysis of the relationship of ibrutinib dose and trough plasma concentration to both response and toxicity. This analysis demonstrated no relationship with response: “Dose-response relationship for BTK occupancy and clinical response in the phase 1 dose escalation trial showed that maximum BTK occupancy and maximum response were achieved at doses of ≥ 2.5 mg/kg (≥ 175 mg for average weight of 70 kg)”14—far below the approved dosage of 560 mg. Meanwhile, the FDA also granted accelerated approval for previously treated chronic lymphocytic leukemia on 12 February 2014 on the basis of a 58% response rate in 48 patients treated at a dose of 420 mg daily. Thus, there were now two different doses approved for ibrutinib, with the labeled dose based solely on the dose that was used in the single-arm studies supporting the accelerated approvals. Furthermore, in the context of that approval, the FDA reiterated its assessment that the labeled dose was higher than necessary and included the explicit suggestion to study lower doses: “However, the proposed dose is 2.4-fold higher than the lowest dose that resulted in maximum BTK occupancy and maximum clinical response. Dose-response relationship for ORR and BTK occupancy from phase 1 study suggested that maximum ORR and maximum occupancy was achieved at doses of ≥ 2.5 mg/kg (≥ 175 mg for average weight of 70 kg) [see Pharmacometrics review in DARRTS dated 11/01/2013]. The sponsor should thus consider exploring lower doses in future development programs.”15 Those lower doses have not, to our knowledge, been rigorously explored in clinical trials—an unfortunate outcome for patients, since if a lower dose is just as effective with lower side effects, treatment would be safer and better. However, if the lower dose were found to provide better patient outcomes and resulted in a change in the labeled dose, it is likely that the labeled dose would not be covered by the patent. Thus, generic competitors might be able to enter the market sooner, once the primary compound patent lost exclusivity. In fact, the process at the US Patent and Trademark Office (USPTO) and the limits of the granted patents encourage the patent holder to avoid such information entirely. The patent examiner evaluating Pharmacyclics’ method of treatment patents found lower doses obvious on the basis of the 2009 and 2010 conference and press release disclosures, which occurred more than a year before the relevant patent was filed. **Only the highest doses**—420 mg and higher—**were granted** in the issued method of **treatment patent16**. **Patent law thus created incentives to pursue a higher, more toxic dose rather than the lower doses the FDA suggested be explored**. And, adding insult to injury, **once the patent was issued** with narrower claims covering the high doses only, **the drug sponsor** not only lacked incentives to explore the possibility of lower doses, it **had an active incentive not to explore** those **doses** **because evidence that lower doses were safe** and effective **would** sharply **reduce the economic significance of the method of treatment patent** it had narrowly managed to obtain. The patent holder already knew it could not get protection on a lower dose––the USPTO had rejected lower doses as obvious–– so any evidence of the importance of lower doses would have undermined the value of the company’s patent-protected, higher-dose product. Broader possibilities Although ibrutinib is only one example, we are concerned that it may be an indicator of a broader problem, one that either lies ahead or is already lurking. More generally, consider combination products with two drugs at fixed dosages. Many treatment method patents exist in which an independent claim specifies a dose, nominally designed to increase patient adherence but often at a much higher cost17,18. The result is that a prescriber cannot adjust the dosage for only one of the two drugs or discontinue only one component. It is possible, perhaps likely, that some of these combination regimens mirror the dosage issue with ibrutinib, in which the incentives of the patent system have encouraged the development of a drug in a form that is suboptimal for patient health in certain circumstances. This would not be the first time in history that combination medications have proven problematic. More than 50 years ago, a US Senate investigation found that certain combination antibiotics products— developed in an effort to bring something ‘new’ to the market—were useless or dangerous19. Nor is ibrutinib the only time in history that medications have been sold at higher dosages than appropriate for safety and efficacy. Millions of women received the birth control pill Enovid (mestranol/ noretynodrel), containing ten times the necessary dose, before studies pointed to a concerning risk of blood clots19. In another sign of negative innovation, **Gilead** Sciences is alleged to have **intentionally delayed a less-toxic version of its HIV medicine** **until just a few years before the original version’s patent expiration20**. Unfortunately, the pernicious impact of patent incentives described above means that not only are these situations possible, but it is hard to know how frequent or how serious these situations are. Pharmacyclics did not follow the recommendation from the FDA and others to study lower doses. Because its method of treatment patents were tied to the higher dose, they had no economic incentive to do such research— any information on safer dosing outside the scope of the issued claims would undermine the value of their existing patent, and they would be unable to get a new patent for the safer dose on grounds of obviousness. The safety data are starting to emerge anyway, albeit from sources other than the company9.

#### 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

#### Disease is a non-linear, existential risk - encompasses AND outweighs other threats

Pamlin and Armstrong 15 Dennis Pamlin and Stuart Armstrong February 2015 “Global Challenges: 12 Risks that threaten human civilization: The case for a new risk category” https://web.archive.org/web/20171006070112/https://api.globalchallenges.org/static/wp-content/uploads/12-Risks-with-infinite-impact.pdf (Dennis Pamlin, Executive Project Manager Global Risks, Global Challenges Foundation, and Stuart Armstrong, James Martin Research Fellow, Future of Humanity Institute, Oxford Martin School, University of Oxford)//Re-cut by Elmer

3.1 Current risks Pandemic 3.1.4 Global **A pandemic** (from Greek πᾶν, pan, “all”, and δῆμος demos, “people”) is an epidemic of infectious disease that has spread through human populations across a large region; for instance several continents, or even **worldwide**. Here only worldwide events are included. A widespread endemic disease that is stable in terms of how many people become sick from it is not a pandemic. 260 84 Global Challenges – Twelve risks that threaten human civilisation – The case for a new category of risks 3.1 Current risks 3.1.4.1 Expected impact disaggregation 3.1.4.2 Probability Influenza subtypes266 Infectious diseases have been one of the **greatest causes of mortality in history**. Unlike many other global challenges pandemics have happened recently, as we can see where reasonably good data exist. **Plotting** historic epidemic **fatalities** on a log scale **reveals** that these tend to follow **a power law with a small exponent**: many plagues have been found to follow a power law with exponent 0.26.261 These kinds of power laws are **heavy-tailed**262 **to a significant degree**.263 In consequence most of the fatalities are accounted for by the top few events.264 If this law holds for future pandemics as well,265 then **the majority** of people who **will die** from epidemics will likely die **from the single largest pandemic**. Most epidemic fatalities follow a power law, with some extreme events – such as the Black Death and Spanish Flu – being even more deadly.267 There are other grounds for suspecting that such a highimpact epidemic will have a **greater probability than usually assumed**. **All the features** of an extremely devastating disease **already exist** in nature: essentially **incurable** (Ebola268), nearly **always fatal** (rabies269), **extremely infectious** (common cold270), and **long incubation periods** (HIV271). **If a pathogen** were to emerge that somehow **combined these** features (and **influenza** has **demonstrated antigenic shift**, the **ability to combine features from different viruses272**), **its death toll would be extreme**. Many relevant features of **the world have** **changed** considerably, **making past comparisons problematic**. The modern world has better sanitation and medical research, as well as national and supra-national institutions dedicated to combating diseases. Private insurers are also interested in modelling pandemic risks.273 Set against this is the fact that **modern transport** and **dense** human **population** allow infections to spread much more rapidly274, and there is the potential for urban slums to serve as breeding grounds for disease.275 Unlike events such as nuclear wars, pandemics would not damage the world’s infrastructure, and initial survivors would likely be resistant to the infection. And there would probably be survivors, if only in isolated locations. Hence the risk of a civilisation collapse would come from the **ripple effect** of the fatalities and the policy responses. These would include **political and agricultural disruption** as well as economic dislocation and damage to the world’s trade network (including the food trade). Extinction risk is only possible if the aftermath of the **epidemic fragments** and diminishes **human society to the extent that recovery becomes impossible277 before humanity succumbs to other risks (such as** **climate** change **or further pandemics**). Five important factors in estimating the probabilities and impacts of the challenge: 1. What the true probability distribution for pandemics is, especially at the tail. 2. The capacity of modern international health systems to deal with an extreme pandemic. 3. How fast medical research can proceed in an emergency. 4. How mobility of goods and people, as well as population density, will affect pandemic transmission. 5. Whether humans can develop novel and effective anti-pandemic solutions.

#### We’re on the Brink – new diseases are emerging.

Deccan Herald 21 1-4-2021 Deccan Herald "New deadly virus 'Disease X', much more fatal than COVID-19, could affect humans: Scientists" (Indian English language daily newspaper published from the Indian state of Karnataka by The Printers Mysore Private Limited, a privately held company owned by the Nettakallappa family. It has seven editions printed from Bengaluru, Hubballi, Davanagere, Hosapete, Mysuru, Mangaluru, and Kalaburagi)//Elmer

A **woman** in a remote town in the Democratic Republic of Congo has been **showing** symptoms of hemorrhagic fever, which scientists fear may be a **sign of a new deadly virus, termed ‘Disease X’,** which could be **as contagious as** **COVID**-19 virus **but have Ebola’s fatality** **rate of** 50-**90 per cent**. Disease X, where the ‘X’ standard for ‘unexpected’, has been termed by the World Health Organization (WHO) as hypothetical for now. But the woman in Ingende has been tested for many diseases, including Ebola, but they have all come out negative. Scientists now fear this could be **that deadly virus**, one of many that **could emerge from the** African tropical **rainforests**. “We are now **in a world where new pathogens will come out**. And that is what **constitutes** a **threat for humanity**,” Professor Jean-Jacques Muyembe Tamfum, the scientist who helped discover the Ebola virus in 1976 told CNN, adding that **these new viruses** could be **much deadlier than Covid-19**. The scientist has warned of **many** animal-based **viruses** or those viruses that **can jump the species barrier** and infect humans. He said that Covid-19 is among those diseases, along with rabies and yellow fever.