# Evergreening v4

## Advantage

#### Innovation low now – secondary patents gut the incentive and skyrocket price of Naloxone, HIV meds, insulin, and even basic allergy drugs – the only comprehensive study

AV 20 (“‘Evergreening’ Stunts Competition, Costs Consumers and Taxpayers.” Arnold Ventures, Arnold Foundation, 24 Sept. 2020, [www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/.)//LK](http://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/.)//LK) [Accessed 8/23/2021]

In 2011, Elsa Dixler was diagnosed with multiple myeloma. That August, she was prescribed Revlimid, a drug that had come on the market six years earlier. By January 2012, she went into full remission, where she has remained since. So long as Revlimid retains its effectiveness, she will take it for the rest of her life. “I was able to go back to work, see my daughter receive her Ph.D, and have a pretty normal life,” said Dixler, a Brooklyn resident who is now 74. “So, on the one hand, I feel enormously grateful.” But Dixler’s normal life has come at a steep financial cost to her family and to taxpayers. Revlimid typically costs nearly $800 per capsule, and Dixler takes one capsule per day for 21 days, then seven days off, and then resumes her daily dose, requiring 273 capsules a year. Since retiring from The New York Times at the end of 2017, she has been on Medicare. Dixler entered the Part D coverage gap (known as the donut hole) “within minutes,” she said. She estimates that adding her deductible, her copayment of $12,000, and what her Part D insurance provider pays totals approximately $197,500 a year. Revlimid should have been subject to competition from generic drug makers starting in 2009, bringing down its cost by many orders of magnitude. But by obtaining 27 additional patents, eight orphan drug exclusivities and 91 total additional protections from the U.S. Food and Drug Administration (FDA) since Revlimid’s introduction in 2005, its manufacturer, Celgene, has extended the drug’s monopoly period by 18 years — through March 8, 2028. “I cannot fathom the immorality of a business that relies on squeezing people with cancer,” Dixler said, noting her astonishment that Revlimid has obtained orphan drug protections when it treats a disease that is not rare and does not serve a very limited population. She also observed that Revlimid’s underlying drug is thalidomide, which has been around for decades. “They didn’t invent a new drug, rather, they found a new use for it,” she said. “The cost of Revlimid has imposed constraints on our retirement,” Dixler said, “but when I hear other people’s stories, I feel very lucky. A lot of people have been devastated financially.” Revlimid is a case study in a process known as “evergreening” — artificially sustaining a monopoly for years and even decades by manipulating intellectual property laws and regulations. Evergreening is most commonly used with blockbuster drugs generating the highest prices and profits. Of the roughly 100 best-selling drugs, more than 70 percent have extended their protection from competition at least once. More than half have extended the protection cliff multiple times. The true scope and cost of evergreening has been brought into sharper focus by a groundbreaking, publicly available, comprehensive database released Thursday by the Center for Innovation at the University of California Hastings College of Law and supported by Arnold Ventures. The Evergreen Drug Patent Search is the first database to exhaustively track the patent protections filed by pharmaceutical companies. Using data from 2005 to 2018 on brand-name drugs listed in the FDA’s Orange Book — a listing of relevant patents for brand name, small molecule drugs — it demonstrates the full extent of how evergreening has been used by Big Pharma to prolong patents and delay the entry of generic, lower-cost competition. “Competition is the backbone of the U.S. economy,” said Professor Robin Feldman, Director of the UC Hastings Center for Innovation, who spearheaded the database’s creation. “But it’s not what we’re seeing in the drug industry. “With evergreening, pharmaceutical companies repeatedly make slight, often trivial, modifications to drugs, dosage levels, delivery systems or other aspects to obtain new protections,” she said. “They pile these protections on over and over again — so often that 78 percent of the drugs associated with new patents were not new drugs coming on the market, but existing drugs.” In recent decades, evergreening has systematically undermined the Drug Price Competition and Patent Term Restoration Act of 1984, which created the generic drug industry. Commonly known as the Hatch-Waxman Act, it established a new patent and market exclusivity regime in which new drugs are protected from competition for a specified period of time sufficient to allow manufacturers to recoup their investments and earn a reasonable profit. When that protection expires, generic drug makers are incentivized to enter the market through a streamlined regulatory and judicial process. Drug prices typically drop by as much as 20 percent when the first generic enters the market, and with more than one generic manufacturer, prices can plummet by 80 to 85 percent. “Hatch-Waxman created an innovation/reward/competition cycle, but it’s been distorted into an innovation/reward/more reward cycle,” Feldman said. “To paraphrase something a former FDA commissioner once said, the greatest creativity in Big Pharma should come from the research and development departments, not from the legal and marketing departments.” Feldman led the development of the Evergreen Drug Patent Search in response to repeated requests from Congressional committees, members of Congress, state regulators and journalists for information about specific drugs and companies. “We want to make it so anyone can have the question about drug protections at their fingertips whenever they want,” Feldman said. “It’s designed to be easy and user-friendly, and to enhance public understanding about how competition may be limited rather than enhanced through the drug patent system.” The database was created through a painstaking process of combing through 160,000 data points to examine every instance where a pharmaceutical company added a new drug patent or exclusivity. “Most of it was done by hand,” Feldman said, “with multiple people reviewing it at every stage. And along the way we repeatedly made conservative choices. We erred on the side of underrepresenting the evergreen gain to be sure we were as fair and reasonable as possible.” Among the 2,065 drugs covered in Evergreen Drug Patent Search, there are many examples of the evergreening strategy used by pharma to delay the entry of competition, especially generics, often for widely prescribed drugs, including those used to treat heartburn, chronic pain, and opioid addiction. Nexium Before Nexium, there was Prilosec, a popular drug to treat gastroesophageal reflux disease (GERD). But its patent exclusivity was due to expire in April 2001. In the late 1990s, with a precipitous drop in revenue looming, Prilosec’s manufacturer, AstraZeneca, decided to develop a replacement drug. Using “one-half of the Prilosec molecule — an isomer of it,” the result was Nexium, which received approval in February 2001. Essentially an evergreened version of Prilosec, Nexium’s exclusivity was then extended by more than 15 years, as AstraZeneca received 97 protections stemming from 16 patents. These included revised dosages, compounds, and formulations. Feldman said that tinkering changes such as Nexium’s do not involve the substantial research and development required for a new drug, nor do they constitute true innovations, yet for a decade and a half, patients and taxpayers were forced to pay far more than was warranted for GERD relief. In fact, in 2016 — one year after patent exclusivity expired — Nexium still topped all drugs in Medicare Part D spending, totaling $1.06 billion. Suboxone Use of this combination of buprenorphine and naloxone for treating opioid addiction has exploded in the wake of the opioid epidemic. Since its approval, Suboxone’s manufacturer, Reckitt Benckiser (now operating as Indivior), extended its protection cliff eight times, gaining nearly two extra decades of exclusivity through early 2030. The drug maker gained six patents for creating a film version of the drug — notably around the time protection was expiring for its tablet version. (The therapeutic benefits of the film and tablet are identical.) An earlier version of Suboxone also obtained an orphan drug designation, despite an opioid epidemic that has expanded Suboxone’s customer base to millions of potential customers. Suboxone generates more than $1 billion in annual revenue and ranks among the 40 top-selling drugs in the U.S. Truvada When Truvada, commonly referred to as PrEP, was approved in 2004, this HIV-prevention drug was a breakthrough. But 16 years later — and 14 years after its original exclusivity was to expire — it retains its monopoly status. Truvada’s manufacturer, Gilead, has received 15 patents and 120 protections since it came on the market, extending its exclusivity for more than 17 years, until July 3, 2024. In countries where generic Truvada is available, PrEP costs $100 or less per month, compared to $1,600 to $2,000 in the U.S. As a result, Truvada is unaffordable to many people who need protection from HIV. Barred from access, they are left vulnerable to infection. “We’re establishing a precedent that a pharmaceutical company can charge whatever it wants even as it allows an epidemic to continue, and the government refuses to intervene,” said James Krellenstein, co-founder of the group PrEP4All. “That should scare every American. If it’s HIV today, it will be another disease tomorrow.” EpiPen First approved in 1987, the EpiPen has saved the lives of countless numbers of people with deadly allergies. But it is protected from competition until 2025 — 38 years after its introduction — because its owner, Mylan, has filed five patents, four since 2010, all involving tweaks to the automatic injector. The actual medication used, epinephrine, has existed for more than a century — the innovation here is in the delivery device. Because these small changes to the injector have maintained its monopoly for so long, the cost of an EpiPen package (containing two injectors) has risen from $94 when Mylan purchased the device to between $650 and $700 today. For many people, especially parents of children with severe reactions to common allergens like peanuts, EpiPen’s increasing price tag imposes an onerous financial burden. What Can Be Done As the Evergreen Drug Patent Search makes clear, the positive impact of Hatch-Waxman has been steadily and severely eroded by a regulatory system vulnerable to increasingly sophisticated forms of manipulation. “You might say that the patent and regulatory system has been weaponized,” Feldman said. “When billions of dollars are at stake, there’s a lot of money available to look for ways to exploit the legal system. And companies have become adept at this, as our work has found.” There are several key steps that Congress could take to restore the balance between innovation and competition that is the key to a successful prescription drug regulatory process. These may include: Imposing restrictions on the number of patents that prescription drug manufacturers can defend in court to discourage the use of anticompetitive patent thickets. Limiting the patentability of so-called secondary patents — which don’t improve the safety or efficacy of a drug — through patent and exclusivity reform. Reforming the 180-day generic exclusivity, which can currently be abused to block other competitive therapies. “The Evergreen Drug Patent Search provides the publicly available, evidence-based foundation that defines the extent of the problem, and it can be used to develop policies that solve the problem of anti-competitive patent abuses,” said Kristi Martin, VP of Drug Pricing at Arnold Ventures. “Our incentives have gotten out of whack,” Martin said. “The luxury of monopoly protection should only be provided to innovations that provide meaningful benefits in saving lives, curing illnesses, or improving the quality of people’s lives. It should not be provided to those gaming the system. If we can change that, we can save consumers, employers, and taxpayers many billions of dollars while increasing the incentives for pharmaceutical companies to achieve breakthroughs."

#### They’re endemic to the industry & 80% of patents were not for new drugs – their stats ignore the quality of the innovation which is nonexistent

Robin 18 (Robin Feldman, 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 [Robin Feldman, Hastings College of the Law, University of California])//LK](https://doi.org/10.1093/jlb/lsy022%20%5bRobin%20Feldman,%20Hastings%20College%20of%20the%20Law,%20University%20of%20California%5d)//LK) [Accessed 8/23/21]

IV.A. Overview 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](javascript:;) 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. IV.B. Number of drugs that had patents and/or exclusivities added to them in the Orange Book, compared to the total number of drugs available As an initial inquiry, we wanted to determine the extent to which companies are adding patents and exclusivities to drugs. Is this a limited activity, confined to well-worn anecdotes that everyone repeats, or does it occur throughout the industry? Our results demonstrate that adding patents and exclusivities is a common behavior, endemic to pharmaceuticals. In fact, between 2005 and 2015, almost 40% of all drugs available on the market had patents, exclusivities, or other changes added to them. Table [1](javascript:;) shows the total number of FDA-approved drugs available on the market in each year of our study. Table [2](javascript:;) shows the number of drugs that had a patent or exclusivity added to them as a percentage of the total number of drugs. The figure is broken down in terms of the number of drugs with an added patent, the number of drugs with an added exclusivity, and the number of drugs that had any relevant change made to it (which includes not only adding a patent and/or exclusivity, but also other significant changes such as adding a use code.)

#### Little revenue goes to RND—ignore their lies told by big pharma

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 //LK [RCT]

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.

#### Independently, it’s the root cause of AIDS backsliding – kills millions each year

Frontline AIDS (“How Patents Affect Access to Hiv Treatment.” Frontline AIDS, 2 October 2019, frontlineaids.org/how-patents-affect-access-to-hiv-treatment/)//LK [Accessed 8/25/2021] \*pppy = per person per year

Since the world acknowledged the global AIDS epidemic in the 1980s much has changed. With better treatment and prevention options, AIDS is no longer seen as a death sentence. Better treatment for co-infections, particularly multi-drug resistant tuberculosis (MDR-TB) and for viral hepatitis have also emerged in the past decade. However, despite the huge progress made, 1.7 million people acquired HIV last year and 770,000 died of AIDS-related illness. For those people – the parents, children, siblings, and friends who unnecessarily lost their lives – the declarations of success are hollow. UNAIDS, which NGOs have been criticising for years for its unduly optimistic reporting, has now acknowledged in its 2019 Epidemic Update that “the annual number of HIV infections has increased in three regions: Eastern Europe and Central Asia (29% increase), Middle East and North Africa (10% increase) and Latin America (7% increase)”. HIV advances that had been made, are now reversing. The over-positive reporting resulted in a serious side-effect. Donors, with competing priorities, bought into the success narrative, and overall global funding for AIDS was reduced. Investment in the HIV responses of low- and middle-income countries decreased by $900 million in just one year. We must act now to ensure the response is fully funded and barriers to accessing medicines, including to second and third line HIV treatment and co-infection treatments, are effectively tackled. Frontline AIDS and the International Treatment Preparedness Coalition (ITPC) have released a joint report looking at one of these crucial barriers – the problem with patents in middle-income countries (MICS). In 2019, people aren’t dying because the drugs for treating HIV, MDR-TB, hepatitis C and many other diseases don’t exist. People are dying because they can’t access them. With an increasing focus on voluntary mechanisms to provide access to medicines, the problem with patents in MICs is being seriously over-looked; as are the legitimate tools that governments can use to increase access and availability and decrease prices. The use of legal mechanisms like TRIPS flexibilities by governments has proven highly effective; in the use of these legal tools, governments, global health agencies and civil society all have an essential role to play. It will not be possible to achieve a sustainable response to HIV without tackling intellectual property (IP) barriers, particularly in MICs. The problem with patents One of the most critical barriers that has existed since treatment for HIV was first approved relates to patents. Patenting of medicines has increased considerably since 2005. More worrying is the trend of ‘evergreening’ patents. Evergreening is a tactic used by pharmaceutical companies to extend their exclusivity over a medicine by applying for, and usually getting, multiple, overlapping patents on a single medicine. Most medicines are covered by several patents, known as patent ‘thickets’ and are used to delay or complicate generic production. Over-pricing as a result of unmerited and extended monopolies puts a huge strain on health budgets. While in theory a government may commit to universal access, in reality the budget may not stretch. Prices for HIV treatment can vary from under $100 to tens of thousands of dollars per person per year (pppy) – for the same drug. Take dolutegravir (DTG) for example. In July 2019, the World Health Organization (WHO) recommended all countries immediately adopt DTG-based regimens as the preferred first-line treatment for HIV. Prices pppy range from $75 for countries that are in a ‘voluntary license’, up to $9656 for those that are not. Middle-income, high burden Typically, MICs are worst affected by the patent problem. Nearly 38 million people live with HIV and a majority of them live in MICs. The countries’ income classification means they are frequently left out of pricing deals or voluntary agreements and have funding reduced by health and development agencies, and so face the dual burden of high prevalence and high costs. Evergreening is just one of the tactics employed by pharmaceutical companies to maintain monopolies and pave the way for this arbitrary pricing. Our report details other tactics as well as how they can be legitimately challenged. Within the Sustainable Development Goals themselves our recommendations are backed. SDG3b reaffirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) regarding flexibilities to protect public health, and, in particular, provide access to medicines for all. Unless TRIPS flexibilities are more routinely put into practice we risk undermining the commitments made to the HIV response.

#### We control uniqueness – innovation is low now and it solves disease, bioterror & antimicrobial resistance. The response to COVID is the exception, not the rule.

Marjanovic and Feijao 20 (Marjanovic, Sonja and Carolina Feijao, Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement. Santa Monica, CA: RAND Corporation, 2020. <https://www.rand.org/pubs/perspectives/PEA407-1.html)//LK> [Accessed 8/30/31]

We need to ensure scalable and sustainable approaches for pharmaceutical innovation in response to infectious disease threats to public health As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism con-text.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterror-ism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions. The COVID-19 pandemic is a game-changer among global public health threats. The risk to human life (both in terms of morbidity and quality of life), the economic risks, the epidemiology of the disease and speed of escalation have led to a crisis-response by many governments around the world. This has in turn influenced the immediate indus-try efforts. Many other infectious disease threats may not manifest as crises in the short term and in the same way as COVID-19, but they could nevertheless escalate. They are not considered to be crises from a short term perspective because they are contained to specific regions and affect fewer people at present – or are re-emerging (e.g. Ebola) – or their impacts have not yet materialised at a scale that would qualify as an immediate crisis (e.g. growing risks of antimi-crobial resistance to some infectious pathogens). However, such diseases and issues are recognised as global threats that could become crises in the future.13 The emerging threats raise important policy questions about how government and the pharmaceutical industry can work together to ensure that pharmaceutical industry innovation is incentivised sustainably and at scale. This is important to help mitigate against current and emerging threats becoming crises further down the line. At present, there are no clear and specific criteria to determine when a disease can trigger the types of healthcare-innovation-re-lated policy actions that have been deployed in response to the COVID-19 crisis. For example, this applies to criteria for securing financial resources for innovation-related activities, reforming regulation to accelerate trials and regulatory approval processes, and securing reimburse-ment mechanisms that help enable industry engagement and the search for rapid solutions. The WHO guidance on what constitutes a pandemic phase does provide guidance on national policy response options, but not specifically as they relate to healthcare innovation activity.14 There are also questions as to whether such policy initiatives and incentives should only be applied in crisis situations, or also as part of proactive government and industry efforts to innovate in the areas of public health threats in order to prevent future global calamities. A crisis and ‘emergency mode’ response may be inevitable for some diseases, but more can be done to mitigate against the need for such a response – especially in cases where emerging threats and their consequences can be foreseen and are known to be a risk. We need to anticipate and act now in terms of how we plan and incentivise better for the future, and how we distinguish between different types of infectious disease threats and phases in framing incentives and regulation.

#### 3 Impacts:

#### 1] Antimicrobial resistance triggers extinction.

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

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

#### 2] Innovation is key to treat neglected tropical diseases – that revives global health diplomacy

Hotez 16, Peter J. Blue marble health: an innovative plan to fight diseases of the poor amid wealth. JHU Press, 2016. (Sabin Vaccine Institute and Texas Children’s Hospital Center for Vaccine Development, Departments of Pediatrics and Molecular Virology and Microbiology)//Elmer //LK [RCT 9/15/2021]

We also need to better understand how these NTDs are actually transmitted within US borders, and I think it is extremely important to learn more about the links between these diseases and poverty. As I noted earlier, a drive through Houston’s Fifth Ward provides some insights, as one can quickly identify predisposing risk factors, including stray animals, dilapidated houses without window screens, standing water and discarded tires, and other evi- dence of environmental degradation, but we need to conduct careful epidemiological studies to really understand the links between poverty and NTDs, as well as animal reservoirs for illnesses such as Chagas disease and others. All of this presents an important research and development agenda for the NTDs in the United States. There are no point-of-care diagnostic tests available for most of the NTDs endemic to the nation, so blood from pa- tients must be sent to the CD С or other specialty research laboratories in order to establish a diagnosis for these conditions. As I sometimes point out to general audiences, when you go to your physician and get blood work done, there is no box to check off for toxocariasis or Chagas disease as there is for blood chemistries or other routine tests. We need diagnostic tests that are easily accessible to physicians and nurses. We also need new and improved treatments and vaccines. Because the NTDs are poverty-related diseases, they often fly below the radar screen of the major pharmaceutical companies and are not prioritized. Thus, the drugs used to treat these illnesses are not widely available, so typically the CDC has to be contacted in order to access them. In addition, many of these medicines were developed decades ago and produce a lot of side effects. For instance, the two medicines for Chagas disease—benznidazole and nifurtimox—cause skin rashes, diarrhea, and other unpleasant or even dangerous symptoms and illnesses. Patients using these medications have to interrupt their treatments up to 20% of the time. Moreover, these drugs cannot be used by pregnant women. Currently, new innovations for NTDs like Chagas dis- multinational ease still rely on nonprofit PDPs. The Geneva-based Drugs pharmaceutical for Neglected Diseases Initiative is leading efforts to de- companies have velop new and safer Chagas disease medicines [60], while shown little or modest at our National School of Tropical Medicine the Sab in interest in American Vaccine Institute and Texas Childrens Hospital Center for NTDs. As a result, new Vaccine Development (Sabin PDP) is working to develop products are being a therapeutic vaccine that could be used alongside exist- developed in the ing treatments [61]. These efforts rely on major philan- nonprofit sector. thropic donors. In our case at the Sabin PDP, they include the Kleberg Foundation, the Carlos Slim Foundation, the Southwest Electronic Energy Medical Research Institute, and Texas Childrens Hospital. Summary Points 1. In the United States, 45.3 million people live below the poverty line, roughly the same number of impoverished Americans alive during the early 1960s when Michael Harrington wrote The Other America. Approximately 20 million Americans now live in extreme poverty at one-half the US poverty level, and approximately 5 million are living on less than $2 per day 2. American poverty concentrates in specific areas, especially in southern states, with Texas having the largest numbers who live in poverty Important areas in the South include the Gulf Coast, border areas with Mexico, the Mississippi Delta, and Appalachia. 3. Approximately 12 million Americans are infected with NTDs, led by toxocariasis and trichomoniasis—which disproportionately affect African Americans—and Chagas disease (American trypanosomiasis) and cysticercosis—which disproportionately affect people of Hispanic origin. Toxoplasmosis is another important NTD. Toxocariasis, cysticercosis, and toxocariasis exert important mental health effects on impoverished Americans. Many of these NTDs are transmitted within US borders (autochthonous infections). 4. Arboviral infections are also important NTDs, led by dengue fever in Gulf Coastal areas and West Nile virus infection. WNV can cause chronic, persistent viral infections linked to chronic neurologic and renal disease. 5. There is an urgent need to promote awareness about the NTDs, especially for physicians and other health-care providers. 6. New policies are needed to expand surveillance for the NTDs affecting the United States. New legislation has been adopted in Texas, while additional bills are being introduced in the US Congress. Epidemiological studies are also needed to better understand how these diseases are transmitted and how they are linked to extreme poverty in the American South and elsewhere. 7. There is an urgent need for new “control tools” for American NTDs, including point-of-care diagnostics, antiparasitic and antiviral drugs, and vaccines. Many of these products are being developed by nonprofit PDPs rather than pharmaceutical companies. he G20 "A Theory of Justice" In his landmark 1971 book A Theory of Justice, the Harvard political philosopher John Rawls articulates two overriding principles of a just and fair society, namely, (1) “equality in the assignment of basic rights and duties” and (2) allowance of some social and economic inequalities, but only if they ultimately benefit “the least advantaged members of society” [1]. In terms of Rawls’s worldview, I believe that finding widespread NTDs among the extreme poor (and least-advantaged) who live amidst wealth—the central tenet of blue marble health—might represent one of the most jarring affronts to what he terms “justice as fairness” Because NTDs are now widespread among the leastadvantaged members of the worlds wealthiest economies, and they represent a major basis for thwarting their future growth, it is urgent for these nations, especially the G20 countries, to adopt strong internal policies to combat these diseases. I envision a three-pronged strategy to best address the G20 s (and Nigeria’s) poorest citizens afflicted by NTDs: 1. Each of the G20 nations and Nigeria has the capacity to fully understand the extent of these diseases within their own borders and then provide their own impoverished populations access to essential medicines used in mass drug administration to target helminth infections, in addition to trachoma, leprosy, yaws and scabies, and to provide treatments for other high-disease burden NTDs, including leishmaniasis and Chagas disease. The G20 countries and Nigeria Three major steps are required to effectively address blue marble health. 141 142 Blue Marble Health need to allocate resources and implement programs to achieve universal coverage for these diseases. 2. Each of the G20 nations and Nigeria has the capacity to conduct research and development for new NTD biotechnologies; they need to allocate resources toward this goal. 3. Both activities should be conducted within an overall framework of health system strengthening. Mass Drug Administration in the G20 A good place to revisit MDA among the G20 countries is to more closely examine the six G20 countries with positive worm indices—Brazil, China, India, Indonesia, Mexico, and South Africa—in addition to Nigeria. Together these countries account for one-half of the worlds helminth infections [2]. An analysis of WHO s PCT database reveals that most of these nations are severely underachieving when it comes to providing MDA for people who require regular and periodic treatment for their intestinal helminth infections, schistosomiasis, and LF. Shown in table 11.1 is WHO’s estimate of the percentage that received treatment in 2013 [3-5]. Overall, the G20 nations affected by helminth infections and Nigeria perform poorly when it comes to treating their affected populations through MDA. In terms of specific countries in Latin America, Brazil is reaching only approximately one-third of its children and population at risk. And although Mexico provides complete coverage for intestinal worms, it—as previously mentioned—neither diagnoses nor treats hundreds of thousands (and possibly millions) of people with Chagas disease. In Africa, Nigeria’s MDA reaches less than 25% of its children at risk for helminth infections, and there is no information about schistosomiasis coverage in South Africa forthcoming from WHO. However, as Dr. Eyrun Kjetland (who works extensively in South Africa) has pointed out, female genital schistosomiasis remains widespread there, in part because praziquantel has been mostly unavailable in the country, owing to its drug importation laws. Schistosomiasis and other NTDs are still found among the poor in the Kingdom of Saudi Arabia. The entire MENA region severely underdiagnoses most of its NTDs, including leishmaniasis. In Asia, Indonesia largely does not promote widespread deworming for its children, and only a small percentage of its population receives treatment for LF, while India does only marginally better. Indonesia also suffers from high rates of yaws, which can also be targeted by MDA using the antibiotic azithromycin. Similarly in India, the vast majority of its children do not have access to regular and periodic deworming, and only about one-half of the population receives MDA for LF. India also has the worlds largest numbers of leprosy cases. This disease can also be attacked through MDA using a multidrug therapy regimen. WHO does not present information on China, either because it has not been determined or is unavailable. However, China has made great strides in reducing its schistosomiasis prevalence since 1949, and it has eliminated LF. Similarly, Japan and South Korea have achieved significant success both in economic development and in reducing or eliminating its NTDs. 144 Blue Marble Health Key common factors for poor performance in meeting MDA targets are vast geographies, decentralization of health care, inadequate resource allocation, and lack of political will. Overall, the six G20 countries with positive worm indices, together with Nigeria, have the means and capacity to eliminate LF within their own borders, while greatly reducing the disease burdens of their intestinal helminth infections and schistosomiasis through MDA. Some of the key common factors for poor performance in meeting MDA targets are vast geographies, decentralization of health care that results in fragmentation of drug delivery, inadequate resource allocation, and lack of political will and commitment. What about G20 countries affected by NTDs but without a positive worm index? In the United States, the 12 million Americans infected and living with NTDs are largely unrecognized, undiagnosed, and untreated. The United States also does very little in terms of conducting active surveillance for Chagas disease (and other major NTDs), and only a tiny percentage of its population receives access to diagnosis and treatment—the same is true for Argentina. In both North America and Europe, toxocariasis and other parasitic zoonotic infections are seldom diagnosed and treated. Minimal information is available on eastern ------------------- Europeans, Turks, and Russians with intestinal worms or zoonotic NTDs or their access to diagnosis and treatment. NTDs remain widespread among Aboriginal Australians, including intestinal helminth infections and scabies—both of which can be targeted through MDA. Thus, the current status of access to essential medicines for people living in poverty and with NTDs among the G20 countries and Nigeria can be summarized as abysmal. The fact that so few are being treated through MDA programs is especially sad, given its low costs. As previ- ------------------- ously mentioned, there are approximately 1.07 billion treatments required among the populations at greatest risk in the G20 countries and Nigeria. At a cost of 50 cents per person per year, approximately $500 million would be required—that is, a dollar amount representing a tiny percentage (<0.001%) of the $65 trillion combined economy of these countries. The bottom line is that each of these nations has the internal capacity to provide these low-cost treatments to its impoverished populations. WHO has now launched a Universal Health Coverage (UHC) initiative that builds on its 1978 “Health for All” Alma-Ata declaration and the MillenThe current status of access to essential medicines for people living in poverty and with NTDs among the G20 countries and Nigeria can be summarized as abysmal. The G20 145 nium Development Goals, with a focus on protecting the health of the worlds most economically vulnerable populations. The activities highlighted here clearly fall within WHO s UHC mandate. Research and Development for New Control Tools and Biotechnologies For many of the leading NTDs—including vector-borne diseases such as dengue, leishmaniasis, Chagas disease, African sleeping sickness, and malaria, and also some helminth infections such as hookworm, schistosomiasis, onchocerciasis, and foodborne trematodiases—there are equally urgent needs to develop new drugs, diagnostics, and vaccines. Each year, the Australian policy group known as Policy Cures publishes an annual G-FINDER Report that measures the global investment in new technologies for neglected diseases, defining them broadly to include both the NTDs and the “big three” diseases: HIV/ AIDS, ТВ, and malaria [6]. For the year 2014, G-FINDER determined that approximately $3.37 billion was invested globally in neglected disease R&D technology, with most of that support going toward the big three diseases [6]. A look at total government support for neglected disease R&D, almost all of it from G20 countries, is also interesting. The public sector provided 64% of the total funding, and the United States provided two-thirds of that funding, mostly from the US National Institutes of Health [6]. In all, 71% of the total government funding for neglected diseases comes from the United States, European Commission, and United Kingdom. However, as the G-FINDER Report points out, these absolute numbers do not consider the GDPs of these nations. In terms of public funding relative to GDP ratios, countries such as Ireland, Denmark, Norway, and Argentina do particularly well in this regard [6]. Shown in table 11.2 are selected estimates from G-FINDER of the percentage of their GDP that various governments have devoted to R&D on Of government funding for neglected diseases R&D, a whopping 71% comes from the United States, European Commission, and United Kingdom. We need greater involvement and support from the remainder of the G20 countries, including positive worm index G20 countries— Brazil, China, India, Indonesia, Mexico, and South Africa, in addition to Nigeria. 146 Blue Marble Health Although NTDs and other poverty-related diseases account for almost 14% of the global disease burden, they receive only a bit more than 1% of the global health-related R&D funds. neglected diseases. Using data from the G-FINDER Report combined with GDP information, I calculate that the world spends approximately 0.0028% of its GDP on neglected diseases R&D. Only three G20 countries—United States, United Kingdom, and Australia—match or exceed that percentage, ------------------- although India and France come close to it. The worstperforming countries were China and Japan. However, in 2013 the Japanese government, together with Japans major pharmaceutical companies and the Bill & Melinda Gates Foundation, formed a partnership known as the Global Health Innovative Technology (GHIT) Fund for supporting PDPs and other entities to develop and shape new biotechnologies for neglected diseases, with an emphasis on NTDs [7, 8]. China is a different matter. The New York Times has reported that China paid out $86.3 billion in foreign investments in the year 2013 [9], with much of that spent in fragile nations where health systems are broken and NTDs are widespread. Clearly, China needs to allocate some of those funds to neglected diseases, either for MDA or new technologies. In addition, the nation of Brazil could easily increase its global contribution to NTD technologies by ю -fold in order to match higher-performing nations in this regard. Germany is now looking at supporting NTD technologies as part of an overarching G7 initiative on NTDs. In 2011, the German government launched a policy roadmap for neglected and poverty-related diseases [10]. Indeed, a recent analysis conducted by German investigators has found although NTDs ------------------- and other poverty-related diseases account for almost 14% of the global disease burden, they receive only a bit more than 1% of the global health-related R&D funds [11]. As shown in figure 11.1, by presenting R&D expenditures for a particular disease divided by the disability adjusted life years (DALYs) it is possible to get a sense of ------------------- diseases that are especially underfunded—even compared with other NTDS—such as the intestinal helminth infections and other neglected enteric diseases, as well as rheumatic fever [11]. Such data argue for the great urgency needed in addressing these health disparities by increasing R&D funding and support. Recently, the Dutch and German governments and the European Union (EU) have established important initiatives to support NTD R&D. The Dutch Ministry of Foreign Affairs, for instance, has been a major partner in our human hookworm vaccine initiative, while the EU has an important Frameworks Program 7 (FP7) for supporting new technologies [12], including a HOOKVAC Consortium of partners organized through the Amster dam Institute of Global Health and Development [13]. Most recently, the EU has established an ambitious Horizon 2020 program for expanding R&D in Europe, including NTD R&D activities [14], on top of a European and Developing Countries Clinical Trials Partnership (EDCTP) for clinically evaluating new NTD technologies [15]. New German government funding for NTD R&D funding was just announced. These Dutch, German, and EU initiatives represent an important advance for shaping the next generation of products to treat and prevent NTDs. Yet another aspect of blue marble health is the rise in comorbid conditions between the NTDs, the big three diseases, and the noncommunicable diseases. Impoverished and neglected populations in the G20 countries and Nigeria are facing a double hit resulting from the convergence of NTDs and NCDs. For instance, in Texas, Mexico, and India (but presumably elsewhere) they include both ТВ and diabetes interactions and, lately, dengue and diabetes interactions. In South Africa, HIV/AIDS now flourishes amidst the high prevalence of female genital schistosomiasis. Studying the pathogenesis and epidemiology of these comorbid interactions will also be an important theme in the coming years. Shaping a Policy for the G20 The G20 began meeting in 2008 in response to that years global recession and have since convened in a summit each year to discuss the major policy issues of the day [16]. At the 2015 G20 Summit held in Turkey, the major areas of broad emphasis included strengthening the global recovery and enhancing resilience, while ensuring sustainability [17]. Clearly, lifting the bottom segments of their populations out of poverty through NTD control and elimination could fall within the G20 remit. It is imperative that the six member nations with positive worm indices commit to providing total MDA coverage for their populations affected by the major helminth infections, and also that the four Western Hemispheric countries step up surveillance, diagnosis, and treatment for Chagas disease. Leishmaniasis, both kala-azar and the cutaneous form, also represent major NTDs affecting the G20, and these diseases need to be targeted for control and elimination. The US, Dutch, German, and Japanese governments, along with the EU, stand out for their contributions toward supporting product development to counter NTDs, 150 Blue Marble Health Equally important is the R&D agenda. There are some obvious underachievers among the G20 countries that must step up and contribute to R&D for new drug, diagnostic, and vaccine products to fight the neglected diseases [18]. Toward that aim, several investigators have proposed the establishment of R&D funds to support neglected disease research. They include a global vaccine development fund [19] and a general biomedical R&D fund focused on antimicrobial resistance, emerging infectious diseases, and neglected diseases [20]. Both proposals are thoughtful, have a lot of merit, and need to be considered, but I offer an alternative or complementary solution. In 2013, the World Health Assembly passed a resolution (66.22) that proposes a “strategic work plan” to achieve sustainable funding for health R&D that could emphasize NTDs. The plan commits the director-general of the World Health Organization to establish a global “observatory” in order to identify gaps and opportunities for health R&D related to neglected diseases [21]. Through a pooled fund managed by WHO-TDR (a special program on tropical disease research and training), several pilot projects are now being supported [22]. Given that todays neglected disease R&D support comes mostly from the United States—and indeed mostly from a single agency, the National Institutes of Health—it is difficult to envision how such a fund would be created without calling on the NIH yet again. Realistically, it is unlikely the NIH leadership or the well-established community of US scientists would be willing to cede control of NIH budgets to an international body. Instead, I think it is worth considering the possibility of having each of the G20 countries establish its own version of the Japanese GHIT Fund, which builds on indigenous scientists and academic institutions and their own pharmaceutical industries. A Chinese or South Korean version of GHIT for example could become a vital and important institution. Creating twenty separate innovation funds could achieve the same goals as a global fund, while simultaneously ensuring national ownership and capacity building for indigenous academic and industrial institutions. Many of them could develop and shape new biotechnologies in collaboration with the 16 international PDPs. This approach would be especially useful for the less developed G20 countries, including Brazil, Global funds for R&D are an option. An attractive alternative is to create national funds for product development R&D in each of the G20 countries and Nigeria—ones that resemble those put forward by the Dutch and Japanese governments. The G20 151 India, Indonesia, and Mexico. These nations have indigenous vaccine manufacturers, which are represented by the Developing Country Vaccine Manufacturers Network, and therefore have a level of sophistication for producing next-generation NTD vaccines. Still another option is for smaller groups of G20 countries to come together to support R&D investments. The EU’s programs for new NTD technologies highlighted above represent important examples. In addition, if institutions from China and India (both rivals and neighbors) collaborated in the area of neglected diseases [23], some important NTD problems affecting Asia could be solved in the coming years. The United States has potential to extend its outreach on NTDs by collaborating with other G20 nations in the Americas or other countries [24]. As a UN agency, WHO could certainly partner with one or more of these G20 NTD R&D investment funds, especially through its global health R&D observatory mechanism. Another key United Nations agency might include WIPO—the World Intellectual Property Organization. Through the Patent Cooperation Treaty mechanism, the Geneva-based WIPO represents one of the few revenue-generating UN agencies. In 2011, in collaboration with BIO Ventures for Global Health, it established WIPO Re:Search to facilitate the development of products to combat NTDs by bringing together major pharmaceutical companies and academic investigators working on these diseases [25]. As a revenue-generating UN agency under the charismatic leadership of Francis Gurry, WIPO has the potential to expand this remit to support NTD product R&D. Looking beyond the G20 The major NTDs linked to wealthy countries and blue marble health could also be addressed by nongovernmental organizations, including faith-based groups. For example, in 2011 the Pew Research Centers Forum on Religion and Public Life reported that the center of the worlds Christian-majority countries has shifted from Europe and North America to the Global South, meaning Africa, Asia, and Central and South America [26]. Thus, countries such as Brazil, Philippines, Angola, Democratic Republic of Congo, and Papua New Guinea now have some of the highest percentages of Christian populations. As shown in table 11.3, from an analysis published in PLOS NTDs I found that almost all of the world s Chagas disease cases and African trypanosomiasis (sleeping sickness) can be found in Christian-majority countries, in addition to almost one-half of the schistosomiasis cases [26]. These findings suggest the possibility of bringing in new actors to combat NTDs. They could include the Vatican and Pope Francis, especially given the new popes renewed commitment to impoverished populations [19]. The Orthodox Christian Church also has opportunities to highlight NTDs in countries such as Ethiopia or those in the Middle East, as do many Christian faith-based organizations and universities. The G20 153 Summary Points 1. The six G20 countries with positive worm indices—Brazil, China, India, Indonesia, Mexico, and South Africa, together with Nigeria, have the means and capacity to eliminate LF within their own borders, while greatly reducing the disease burdens of their intestinal helminth infections and schistosomiasis through MDA. 2. G20 countries without classical worm indices, including the United States, also need to find mechanisms for promoting surveillance and access to essential medicine options for the poor living with NTDs within their own borders. 3. The G20 countries also have important biotechnology capabilities, which have yet to be adequately tapped for producing new NTD diagnostics, drugs, and vaccines. Beyond the United States, European nations, Australia, and Japan, they also include Brazil, China, India, Indonesia, Mexico, Russian Federation, Saudi Arabia, South Africa, and South Korea. 4. Yet another aspect of blue marble health is the rise in comorbid conditions between the NTDs, the big three diseases, and the NCDs. 5. The EU and the Dutch and German governments have launched important NTD technology initiatives, as has the Japanese government and its partners through a new GHIT Fund. These activities support PDPs committed to NTDs as well as indigenous academic institutions and industrial organizations. 6. Large G20 economies such as Brazil and China must increase their global commitment to support new NTD technologies and R&D. 7. There are opportunities to link these new investments with parallel activities ongoing at two UN agencies, namely, WHO and WIPO. 8. These topics should be highlighted at future G20 summits. 9. Faith-based organizations could have a future role. For instance, the Vatican and related entities have opportunities to expand commitments to control those NTDs that are found to be prevalent among Christian-majority countries. Central to the blue marble health concept is that each of the G20 nations and Nigeria need to take greater responsibility for their own neglected diseases and neglected populations. Doing so could result in the control or elimination of one-half or more of the planets NTDs, with substantial gains made against HIV/AIDS, ТВ, and malaria. Thus, while programs of overseas development assistance devoted to health, such as PEPFAR, GFATM, PMI, and USAID’s NTD Program, in which the worlds richest countries provide support to the poorest nations for their neglected diseases, must continue and should even expand, we need increasingly to recognize the hidden burden of neglected diseases among the poor living in wealthy countries. As a first step, we must expand initiatives that raise awareness about the problem of NTDs within each of the G20 countries and Nigeria. The Global Network for NTDs linked to the Sabin Vaccine Institute has been working closely with the governments of India and Nigeria, respectively, in order to explain the opportunity for mass drug administration and its potential impact on health and economic development. MDA coverage rates are disappointingly low in these nations, especially for intestinal helminth infections and LF, as well as for schistosomiasis in the case of Nigeria. An extraordinary finding is that at least three nations with positive worm indices—India, Pakistan, and China—also maintain nuclear stockpiles [1]. Could the scientific horsepower of these nuclear states be partly redirected toward reducing endemic NTDs at home? 154 A Framework for Science and Vaccine Diplomacy 155 Outside of India and Nigeria, there is a need to promote NTD awareness in each of the G20 countries. For example, in the United States, our National School of Tropical Medicine has been highlighting the plight of some 12 million Americans living with NTDs. We have now worked with the Texas Legislature to enact a bill for NTD surveillance in suspected high-prevalence areas. However, similar initiatives need to be enacted across the G20 nations, including the European Union. In addition, international cooperation between the different G20 nations and Nigeria could be critical in achieving higher population coverage for MDA. For instance, China, despite its billions of dollars of business investments in sub-Saharan Africa, has not yet promoted NTD control efforts there. Yet China has tre- mendous expertise in MDA for NTDs and could provide Africa with valuable advice in this area. China was the first country to eliminate LF and has achieved successes in re- ducing its burden of schistosomiasis more than ю -fold since the 1949 revolution. China could also share its best practices with neighboring India, where NTDs remain practically ubiquitous [ 2]. Similarly, Japan and South Korea have made great gains toward eliminating intestinal helminth infections, while the former has also successfully eliminated LF and schistosomiasis. International cooperation between these three East Asian nations and Nigeria, or with the G20 countries with positive worm indices, especially India, Indonesia, and Brazil (where they are the highest), could result in important, positive health and economic gains. Each of these activities represents examples of what some refer to as global health diplomacy. Global Health Diplomacy My former colleague at Yale University, Ilona Kickbusch, currently the director of the Global Health Programme at the Graduate Institute of International and Development Studies in Geneva, has provided several working definitions of global health diplomacy, including efforts to “position health in foreign policy negotiations,” together with the establishment of global health governance initiatives [3]. Indeed, the creation of the GAVI Alliance, GFATM, UN AIDS, and other Geneva-based organizations might be considered vital examples of organizations created under the auspices of global health diplomacy, with the first two created following the 2000 Millennial Development Goals. The MDGs themselves represent an important framework for global health diplomacy, and arguably the most successful. Since 2005, several global health diplomacy initiatives have been enacted that could facilitate NTD activities among the G20 and Nigeria, although most of these actions are more focused on emerging viral infections of pandemic potential rather than the widespread chronic and debilitating NTDs. The International Health Regulations (IHR) were enacted in 2005 as a binding legal mechanism for all member states of WHO and focused on responses to acute public health emergencies [4]. IHR demands that countries report outbreaks and other public health events, while WHO responds with measures to uphold and enforce global health security [4]. IHR also establishes an emergency committee that advises the WHO director-general on whether an unexpected event should be considered a public health emergency. It also provides recommendations on initial steps for travel restrictions, surveillance, and infection control. With the possible exception of dengue fever, it is not clear how IHR will substantively address the NTDs or other blue marble health conditions. Moreover, even with IHR in place, the global response to the 2014 emergence of Ebola in West Africa was slow and inadequate and led to a catastrophic outbreak in the fall of that year [5]. This failure may require future revisions in the IHR, as recently recommended in a 2015 Lancet article by Lawrence Gostin and his colleagues at Georgetown University [6]. The Global Health Security Agenda (GHSA) is an interagency initiative of the US government conducted in partnership with other nations and international organizations, including WHO [7]. GHSA is also focused on preventing or reducing the impact of epidemics and outbreaks of pandemic potential, such as H7N9 influenza virus or MERS coronavirus, as well as detecting emerging threats and implementing rapid and effective responses. In some respects, GHSA represents the US component or response to IHR. It also covers intentional or accidental releases of dangerous infectious disease pathogens. Global Health 203s and The Lancet Commission were launched in 2013, coinciding with the twentieth anniversary of a landmark 1993 World Development Report that helped to ignite international efforts to link investments in health with economic development [8]. The Lancet Commission identifies four key messages and actions: (1) the substantial economic return on investing in health, which can be as much as 24% in low- and middle-income countries; (2) implementation of a “grand convergence” in global health through scale-up of health technologies and strengthening health systems by the year 2035; (3) fiscal policies such as taxation of tobacco and reduction of subsidies for fossil fuels, which represent powerful forces or “levers” for elected leaders; and (4) universal health coverage as an efficient mechanism to improve health as well as to provide “financial protection” [8]. The Addis Ababa Action Agenda (AAAA) is the product of the first of three international meetings for implementing the UN s 2015 Sustainable Development Goals. However, health is at present only a minor component of the AAAA. Indeed, the SDGs have been criticized because health is now only 1 of the 17 goals, whereas it was front and center among the 2000 MDGs. So far, the AAAAs recommendations have included the promotion of the health systems strengthening component of the GFATM and GAVI Alliance and the establishment of a Global Financing Facility (GFF) for womens and childrens health that would go hand-inhand with the UN secretary generals new Global Strategy for Every Woman Every Child [9]. The emphasis of these initiatives is to reduce preventable maternal, child, and adolescent deaths by 2030. Despite the evidence that hookworm infection and Chagas disease rank among the leading complications of pregnancy among women living in poverty in low- and middle-income countries, while female genital schistosomiasis is among sub-Saharan Africa’s most common gynecologic condition, there is not yet a specific mention of NTDs in the AAAA or GFF. Ultimately, the G20 nations can identify ways to address blue marble health disparities under the auspices of the SDGs or the global health diplomacy initiatives highlighted above. However, at present there is no specific mandate for them to do so. Vaccine Science Diplomacy Concurrently, the G20 nations have opportunities to collaborate in scientific activities leading to the development of new drugs, diagnostics, and vaccines. I have used the term “vaccine science diplomacy” to refer to inter- national scientific codevelopment of lifesaving vaccines between scientists of different nations, but particularly from nations with strained or evenly openly contentious international relations. The best historical example of vaccine science diplomacy is the codevelopment of the oral polio vaccine, led on the American side by Dr. Albert B. Sabin, and his Soviet virologist counterparts, including Dr. Mikhail Petrovich Chumakov [3]. In modern times there is potential interest in explor ing vaccine science diplomacy opportunities between the United States and some of the worlds Muslim-majority nations belonging to the Organisation of Islamic Cooperation [10,11]. OIC countries include most of the Middle East and North Africa, as well as some highly populated Southeast Asian nations, including Bangladesh, Indonesia, and Malaysia, as well as most of central Asia. New estimates that we published in PLOS NTDs in 2015 indicate that the 30 most-populated OIC countries account for 35% of the worlds helminth infections comprising the global Worm Index, including 50% of the worlds children who require MDA for schistosomiasis [11]. Given that approximately 1.5 billion people live in OIC countries, or about 20% of the global population, helminth infections appear to disproportionately affect the health and economic development of Muslim-majority countries, as does leishmaniasis, trachoma, and possibly other NTDs [11]. As shown in figure 12.1, there is also tight inverse association between the worm index and human development index in the Muslim world [11]. OIC nations with strong infrastructures in science and biotechnology are potentially attractive candidates to pursue joint vaccine science diplomacy initiatives with the United States. Here the idea would be to promote scientific collaborations between US scientists and scientists from selected OIC countries in order to create new NTD technologies for some of the worst-off Muslim-majority countries. The “worst-off” might include OIC countries at the high end of the worm index, including Mali, Cote d’Ivoire, Mozambique, Cameroon, Burkina Faso, and Niger, as well as Nigeria [11].

#### Solves hotspot escalation

Nang and Martin 17, Roberto N., and Keith Martin. "Global health diplomacy: A new strategic defense pillar." Military medicine 182.1-2 (2017): 1456-1460. (MC, Global Health Division, Uniformed Services University of the Health Sciences)//Elmer

INTRODUCTION: FORCE IF NECESSARY BUT NOT NECESSARILY FORCE The world appears unhinged. Instability from the Middle East, Caucasus, Africa, and Central America to Asia abound. The Study of Terrorism and Response to Terrorism database identified fewer than 300 major terrorist incidents between 1998 and 2004 in the Middle East and North Africa. In 2013, they listed 4,650 such incidents.1 Quieter cracks tear at the fabric of South America and parts of Asia. Although geographically distinct, many of these areas of instability share underlying causes that give rise to threats to the United States and the global community. Human-generated causes include corruption, poor governance, absence of the rule of law, violence, gross human rights abuses, climate change, environmental degradation, a weak civil society, and a lack of professional capabilities across skill sets within the government departments needed to effectively manage the operations of a well-run state.2 Natural causes include disasters, disease, demographic changes, and limited access to the resources essential for life. When these human or natural causes create conditions that result in poor provision of, or unequal access to essential services, such as water, food, shelter, health services, education, and economic opportunity, people lose confidence in government and hope for their children and their future. They become restless, demonstrate, can become violent and overthrow their governments (such as the self-immolation of Mohamed Bouazizi, the Tunisian cart vendor, which sparked 35 more selfimmolations by extralegal businessmen and started the Arab Spring), or can result in mass migrations.3 Desperate human security, conditions create desperate people undermining stability and creating even more demands from host nation governments and governments in neighboring states. Although force and counter terrorism programs are sometimes needed to address security threats, enormous opportunities are available to use nonkinetic capabilities within the Department of Defense (DoD), Department of State, U.S. Agency for International Development, other U.S. Government agencies, and civilian organizations to address the underlying causes of instability. Global health diplomacy is an underutilized strategic asset to do this. At a far lower cost, it will save lives, decrease economic losses, reduce the need for kinetic military operations, increase security cooperation, improve diplomatic relations, encourage trade, and create the foundations for longterm stability. HEALTH IS A NATIONAL SECURITY IMPERATIVE—DISTANT HEALTH THREATS ARE GLOBAL THREATS Health is a national security imperative. The second- and thirdorder effects of a strategic health or global health issue that severely impacts and overwhelms the stability of a far-distant nation can have broad and multiplying effects that transcend boundaries and can become regional and global security threats. When human immunodeficiency virus/acquired immunodeficiency syndrome first started to be seen in the United States, there were U.S. leaders that were not too concerned about its impact on the general public, alluding to the fact that it was a disease that mostly affected the four H’s: homosexuals, heroin addicts, hemophiliacs, and Haitians.4 From its first known cases in 1981 up to 2013, human immunodeficiency virus has infected almost 78 million people and killed about 39 million.5 The Chernobyl power plant accident that occurred on October 26, 1986, was a catastrophic nuclear accident. Several studies have been done to estimate the increase in health effects and cancer-related morbidity and mortality in Europe.6 Communicable diseases can be easily carried from a distant area of the world to a teeming metropolis within 24 hours because of the ease and affordability of plane travel. The interconnectedness of countries as a result of trade has its drawbacks— biological or chemical contamination of food or products commonly occur across oceans and continents.7 Noncommunicable diseases are also affecting not just high income countries but also low-to-middle income countries. Ubiquitous exports of fast-food meals, high-fructose drinks, and salty, fried foods have contributed to a tremendous increase in obesity and hypertension.8 Obese and sedentary populations negatively impact the workforce of a nation and its productivity. The offices of military personnel and readiness cite obesity as the number one disqualifying reason for new recruits.9 Twenty seven percent of the U.S. young adults are not fit to serve in the military.10 Addiction to illegal drugs is an important global health threat. The problems created by the manufacture of opium in Afghanistan, methamphetamine in Mexico, and cocaine in Peru and Columbia create tremendous and devastating health effects, loss of productivity, social disruptions, breed corruption in a nation’s military and police forces, and create turbulent violence all along its wake, both in the countries manufacturing the drugs and the countries importing them. Weather forecasters often discuss the multiplying effects that the fluttering of a butterfly’s wings in one country may have on the regional weather of another distant country. Global health professionals and more and more of our military and political leaders are now concerned that the disease that we see in a child in Africa or a pig in Asia may have tremendous impacts on the public health, economic productivity, military readiness, and strategic security interests of their nation. In addition, a weak health and political system anywhere can be a threat everywhere. LINKAGES: GLOBAL HEALTH, SECURITY, AND STRATEGIC CHALLENGES Global health encompasses the basic needs required for human security: respect for people’s universal rights, personal protection, the rule of law, access to food, water, health care, education, basic infrastructure, and shelter.11 Their absence leaves populations vulnerable to the depredations of insurgent groups and corrupt, venal cabals that can hijack a region or state for the benefit of themselves and a select group of people. This creates an environment of the privileged and abused, the included and excluded, and an environment ripe for insecurity and conflict.12 For a nation to provide the environment where people’s basic needs can be met requires capabilities within their governing infrastructure and communities. This includes management, finance, education, social sciences, law,medicine, public health, engineering, veterinary medicine, agronomy, and more. Their absence [undermines] ~~cripples~~ a nation’s ability to support a foundation for human security and stability, inhibits its ability to thrive in good times, and respond effectively to natural and man-made threats in bad times. It breeds corruption, poverty, poor health outcomes, spread of lethal diseases, gross human rights abuses and conflict. This we have seen played out with grim efficiency in Afghanistan, Pakistan, Iraq, Syria, Sudan, Democratic Republic of the Congo, Central African Republic, Libya, Yemen, Somalia, Nigeria, Honduras, and beyond. All have had disastrous regional effects, many have created direct threats to U.S. interests. Islamic State in Iraq and Syria was borne out of the brutal kleptocracy of Assad’s Syria and a destructive government in Iraq. Al-Shabaab was created in the failed state of Somalia. Boko Haram grew in the destitute and neglected regions of northern Nigeria. Al Qaeda and the Taliban secured a haven in the lawless western regions of Pakistan. Weak governments in Central America created a fertile ground for organized criminal gangs to terrorize the populace and profiteer off the illegal drug trade that destroys lives, and drives people to desperately flee northward into the United States. Insurgencies, terrorist organizations, and other nonstate actors thrive in the presence of an incompetent or abusive state government that violates segments of its citizenry and fails to provide an environment where peoples’ rights are protected and their basic needs met. These groups divine counter narratives that take advantage of people’s lack of hope and fears. They create a refuge and an outlet for people’s rage. Such messages and place of belonging can be a powerfulmagnet for youths, the poor, and the disenfranchised,who see little hope in the future. Security threats are not only manmade but also can come from nature. The international community’s failure to dramatically reduce our carbon footprint leaves us vulnerable to an increasing number of extreme weather events that threaten everything from coastal communities to food and water security. This will amplify existing tensions over natural resources and could result in the forced migrations of massive numbers of vulnerable people. The world’s population is expected to reach 9 billion by 2030. The growth will primarily occur in cities in the developing world most of which already have fractured or nonexistent infrastructure. Climate change will have a dramatic effect on densely populated poor urban areas, especially those in arid zones and in littoral areas. This is a recipe for disaster. Environmental degradation is also increasing the spread of infectious diseases and facilitating zoonoses to jump the species barrier and infect humans. The Ebola outbreak, like severe acute respiratory syndrome and H1N1 before it, is part of a long list of diseases that have infected humans from an animal reservoir with devastating impact. Many zoonoses exist and more will come. Using history’s guide, the next pandemic will likely be a zoonotic agent. Recognizing this, the United States last year led the creation of the Global Health Security Agenda to prevent, detect, and respond to deadly disease outbreaks.13 Though accepted by many countries, it has been implemented by few. No amount of force can resolve these challenges. However, global health diplomacy, exercised through civil-military and military-military programs, is a promising strategic tool that should be employed to address these wicked strategic or global health problems and improve domestic and international security. AN OPPORTUNITY TO ACT Despite a growing level of interest in academia and government agencies, there is little agreement on how to define “global health diplomacy.”14 Michaud defined it as “international diplomatic activities that (directly or indirectly) address issues of global health importance, and is concerned with how and why global health issues play out in a foreign policy context.”14 The World Health Organization (WHO) states that it “brings together the disciplines of public health, international affairs, management, law, and economics, and focuses on negotiations that shape and manage the global policy environment for health.”15 We summarize global health diplomacy as the application of a broad range of skill sets to cooperatively improve human security throughout the world. A vital area of focus must be to strengthen public service, governance capabilities, and civil society in unstable regions. Doing so will enable nations to create an environment where their citizens’ basic needs can be met, universal rights respected, and the ability to hold a government to account, secure. This includes building and retaining capabilities to manage effective, noncorrupt, justice, finance, health, education, defense, public works, and environmental departments. The absence of these structures cripples a country’s ability to govern itself and leaves it vulnerable to the causes of instability, both human and natural. The United States, by virtue of its strengths across diplomacy, defense, development, trade, and its inherent domestic civilian capabilities, has an opportunity to exercise its leadership and mobilize these assets. Using global health diplomacy to comprehensively strengthen public service and governance capabilities has been chronically neglected by the international development community. It needs a leader to start this process and the United States has the ability and authority to do so in the national and international interest.

#### 3] Disease and bioweapons cause extinction – mathematically outweighs, even if they win mitigation.

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

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

## Advocacy

#### Thus, the plan: the member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by limiting drug innovators to one market exclusivity of their choice for their drug.

#### Solves better than any counterplan – only the aff tackles incentives

Feldman 19 (Feldman, Robin. “Drug Patent Protection: It's Time for a 'One-and-Done' Approach.” STAT, 11 Feb. 2019, [www.statnews.com/2019/02/11/drug-patent-protection-one-done/. [Robin Feldman is professor of law and director of the Institute for Innovation Law at UC Hastings College of the Law in San Francisco and author of “Drugs, Money, and Secret Handshakes” (Cambridge University Press, March 2019).])//LK](http://www.statnews.com/2019/02/11/drug-patent-protection-one-done/.%20%5b%5d)//LK) [Accessed 8/25/2021]

In a perfect world, the system for conveying medications from their makers to patients should be designed to deliver the lowest-cost drugs. The system in the U.S. doesn’t even come close. Insurers should provide the lowest-cost and highest-quality drug benefit for each plan, public or private. But they don’t. Pharmacy benefit managers should use their volume buying power to obtain rebates that individuals could never obtain on their own and pass those rebates along to patients. But they don’t. Pharmacists, who know the prices of the drugs in their stock and who see patients’ cost-sharing amounts at the cash register, should be motivated to provide their customers with information on how to find the best deal so they can afford their medicines. But they aren’t. Doctors should make medication decisions that are in the best interests of their patients. But they often don’t. All of this occurs against the backdrop of a national conversation to lower drug costs and a policy to expedite and encourage vigorous competition in the pharmaceutical industry through the rapid entry of generic drugs as soon as patents expire. But even though the vast majority of prescriptions are filled with generic drugs, rising prices on existing brand-name drugs and sky-high prices for new drugs are swamping the savings from generics. Why isn’t the system working as it should? Related: Behind the patent thicket: tactics AbbVie allegedly used to thwart biosimilar versions of Humira Some experts believe the U.S. can rein in drug process with value-based pricing, which aims to tie the prices we pay for drugs to the benefits they provide, either in terms of longer life or better quality of life. Others call for dismantling pharmacy benefit managers. Still others want large groups like Medicare to negotiate with drug companies for better drug prices. While each of these might help, they cannot solve the problem alone. Why? Because they do not reach the heart of the problem. As I explain in my new book, “Drugs, Money, and Secret Handshakes,” the government itself is giving pharmaceutical companies the power they are wielding through overly generous drug patent protection. Effective solutions must address that problem. Drug companies have brought great innovations to market. Society rewards innovation with patents, or with non-patent exclusivities that can be obtained for activities such as testing drugs in children, undertaking new clinical studies, or developing orphan drugs. The rights provided by patents or non-patent exclusivities provide a defined time period of protection so companies can recoup their investments by charging monopoly prices. When patents end, lower-priced competitors should be able to jump into the market and drive down the price. But that’s not happening. Instead, drug companies build massive patent walls around their products, extending the protection over and over again. Some modern drugs have an avalanche of U.S. patents, with expiration dates staggered across time. For example, the rheumatoid arthritis drug Humira is protected by more than 100 patents. Walls like that are insurmountable. Rather than rewarding innovation, our patent system is now largely repurposing drugs. Between 2005 and 2015, more than three-quarters of the drugs associated with new patents were not new ones coming on the market but existing ones. In other words, we are mostly churning and recycling. Particularly troubling, new patents can be obtained on minor tweaks such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit. Related: WATCH: What is a biosimilar, exactly? I believe that one period of protection should be enough. We should make the legal changes necessary to prevent companies from building patent walls and piling up mountains of rights. This could be accomplished by a “one-and-done” approach for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug. Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. The result, however, is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of data exclusivity (in which no generic is allowed to use the original drug’s safety and effectiveness data), or something else — but not all of the above and more. Consider Suboxone, a combination of buprenorphine and naloxone for treating opioid addiction. The drug’s maker has extended its protection cliff eight times, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That makes almost two additional decades in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained. Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals, not for all types of technologies. That way, one-and-done could be implemented through legislative changes to the FDA’s drug approval system, and would apply to patents granted going forward. Related: Extraordinary tactics, perverse incentives: Makers of top-selling drugs hike prices in lockstep, and patients bear the cost One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing patent obviousness doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented. Either by congressional clarification or judicial interpretation, many pile-on patents could be eliminated with a ruling that the core concept of the additional patent is nothing more than the original formulation. Anything else is merely an obvious adaptation of the core invention, modified with existing technology. As such, the patent would fail for being perfectly obvious. Even without congressional action, a more vigorous and robust application of the existing obviousness doctrine could significantly improve the problem of piled-up patents and patent walls. Pharmaceutical companies have become adept at maneuvering through the system of patent and non-patent rights to create mountains of rights that can be applied, one after another. This behavior lets drug companies keep competitors out of the market and beat them back when they get there. We shouldn’t be surprised at this. Pharmaceutical companies are profit-making entities, after all, that face pressure from their shareholders to produce ever-better results. If we want to change the system, we must change the incentives driving the system. And right now, the incentives for creating patent walls are just too great.

## Framing --- Util

#### The standard is maximizing expecting well being.

#### 1] Actor specificity

#### ---A] Aggregation – every policy benefits some and harms others, which also means side constraints freeze action.

#### ---B] No act-omission distinction – choosing to omit is an act itself – governments actively decide not to act so there is no omission

#### 2] Util is a lexical pre-requisite to any other framework: Threats to life preclude the ability for moral actors to effectively utilize and act upon other moral theories since they are in a constant state of crisis – that inhibits the ideal moral conditions which other theories presuppose.

#### 3] Extinction matters under any framework:

#### ---A] It precludes the possibility of any kind of moral value – we can’t confer value onto anything if we’re not alive.

#### ---B] Future generations means infinite magnitude – we have to look towards future lives too

## Underview

#### 1AR theory –

#### ---A] AFF gets it because otherwise the neg can engage in infinite abuse, making debate impossible. No 2n theory – kills resolvability because judge has to intervene in weighing interp and 2ar counterinterp.

#### ---B] drop the debater – the short 1AR irreparably skewed from abuse on substance and time investment on theory.

#### C] no RVIs – the 6-minute 2nr can collapse to a short shell and get away with infinite 1nc abuse via sheer brute force and time spent on theory.

#### ---D] Use competing interps – 1AR interps aren’t bidirectional and the neg should have to defend their norm since they have more time.

#### ] Yes Aff RVIs

#### ---A] I have a 4 minute 1AR to answer T or Theory which skews my time from other arguments. T bites out of a higher percentage of my rebuttal time.

#### B] No risk issue for the negative, you can go for it in the 2nr if I undercover but if I overallocate you can just kick it.

#### ] Fairness is a voter – debate is a competitive activity and needs both debaters to be on an equal playing field argumentatively.