### 1AC: Innovation

#### Advantage 1 is Innovation:

#### Most recent evidence concludes Aff – 78% of New Drugs aren’t innovative but rather repurposed.

PFAD 21 Patients for Affordable Drugs 2-3-2021 “BIG PHARMA’S BIG LIE: THE TRUTH ABOUT INNOVATION & DRUG PRICES” <https://patientsforaffordabledrugs.org/2021/02/03/innovation-report/> (a patient advocacy and lobbying organisation based in Washington, D.C. founded by David Mitchell who suffers from multiple myeloma. Ben Wakana is the executive director. It focuses on policies to lower drug prices.)//Elmer

The drug industry talks a lot about how reforms to lower prices threaten cutting-edge breakthroughs, but in reality, **only a fraction of new medications are truly innovative**. **Since 1975**, **only 10** to 15 **percent** of drugs entering the market **represented** **therapeutic advances**; **instead**, **drug companies prioritized the development of existing drugs with minor variations that lack clinical significance**.21 Drug patents offer a stark illustration of this point. Between 2005 and 2015, **78 percent of drug patents were related to drugs already on the market.**22 **Instead of investing in R&D that could lead to new** breakthrough **therapies**, **drug companies spend resources obtaining patents on old drugs** — not to improve user experience — but **to extend patent protection**, prolong monopoly pricing periods, and keep generic competitors off the market. So if we understand that new drugs are not the same as new cures, a small reduction in new drugs doesn’t pose a threat to innovation. Harvard economist Richard Frank summed it up this way: “If drug companies claim lowering drug prices means somewhat fewer new drug launches, remember that there are **numerous new products sold every year whose elimination would have little to no impact on the health of Americans**.”23 If our current system of drug development does not result primarily in truly innovative drugs, we can’t let the pharmaceutical industry use the threat of R&D cuts as a scapegoat to thwart reforms. We can create a system that incentivizes valuable innovation that delivers meaningful clinical benefit to patients — instead of repurposing old drugs.

#### The only major study confirms our Internal Link – Evergreening decimates competition by resulting in functional monopolies

Arnold Ventures 20 9-24-2020 "'Evergreening' Stunts Competition, Costs Consumers and Taxpayers" <https://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/> (Arnold Ventures is focused on evidence-based giving in a wide range of categories including: criminal justice, education, health care, and public finance)//Elmer

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.” Competition is the backbone of the U.S. economy. But it’s not what we’re **seeing in the drug industry**. Professor Robin Feldman Director of the UC Hastings Center for Innovation 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."

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

* AT Advantage CPs to solve Drug Prices

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

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

#### Patents incentivize Negative Innovation.

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

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

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

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

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

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

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

It is by now no secret that the human species is locked in a race of its own making with “**superbugs**.” Indeed, if popular science fiction is a measure of awareness, the theme has pervaded English-language literature from Michael Crichton’s 1969 Andromeda Strain all the way to Emily St. John Mandel’s 2014 Station Eleven and beyond. By a combination of massive inadvertence and what can only be called stupidity, we must now invent new and effective antibiotics faster than deadly bacteria evolve—and regrettably, they are rapidly doing so with our help. I do not exclude the possibility that bad actors might deliberately engineer deadly superbugs.1 But even if that does not happen, humanity faces an existential threat largely of its own making in the absence of malign intentions. As threats go, this one is entirely predictable. The concept of a “black swan,” Nassim Nicholas Taleb’s term for low-probability but high-impact events, has become widely known in recent years. Taleb did not invent the concept; he only gave it a catchy name to help mainly business executives who know little of statistics or probability. Many have embraced the “black swan” label the way children embrace holiday gifts, which are often bobbles of little value, except to them. But the threat of inadvertent pandemics is not a “black swan” because its probability is not low. If one likes catchy labels, it better fits the term “gray rhino,” which, explains Michele Wucker, is a high-probability, high-impact event that people manage to ignore anyway for a raft of social-psychological reasons.2 A pandemic is a quintessential gray rhino, for it is no longer a matter of if but of when it will challenge us—and of how prepared we are to deal with it when it happens. We have certainly been warned. The curse we have created was understood as a possibility from the very outset, when seventy years ago Sir Alexander Fleming, the discoverer of penicillin, predicted antibiotic resistance. When interviewed for a 2015 article, “The Most Predictable Disaster in the History of the Human Race, ” Bill Gates pointed out that one of the costliest disasters of the 20th century, worse even than World War I, was the Spanish Flu pandemic of 1918-19. As the author of the article, Ezra Klein, put it: “No one can say we weren’t warned. And warned. And warned. A pandemic disease is the most predictable catastrophe in the history of the human race, if only because it has happened to the human race so many, many times before.”3 Even with effective new medicines, if we can devise them, we must contain outbreaks of bacterial disease fast, lest they get out of control. In other words, we have a social-organizational challenge before us as well as a strictly medical one. That means getting sufficient amounts of medicine into the right hands and in the right places, but it also means educating people and enabling them to communicate with each other to prevent any outbreak from spreading widely. Responsible governments and cooperative organizations have options in that regard, but even individuals can contribute something. To that end, as a medical doctor I have created a computer app that promises to be useful in that regard—of which more in a moment. But first let us review the situation, for while it has become well known to many people, there is a general resistance to acknowledging the severity and imminence of the danger. What Are the Problems? Bacteria are among the oldest living things on the planet. They are masters of survival and can be found everywhere. Billions of them live on and in every one of us, many of them helping our bodies to run smoothly and stay healthy. Most bacteria that are not helpful to us are at least harmless, but some are not. They invade our cells, spread quickly, and cause havoc that we refer to generically as disease. Millions of people used to die every year as a result of bacterial infections, until we developed antibiotics. These wonder drugs revolutionized medicine, but one can have too much of a good thing. Doctors have used antibiotics recklessly, prescribing them for just about everything, and in the process helped to create strains of bacteria that are resistant to the medicines we have. We even give antibiotics to cattle that are not sick and use them to fatten chickens. Companies large and small still mindlessly market antimicrobial products for hands and home, claiming that they kill bacteria and viruses. They do more harm than good because the low concentrations of antimicrobials that these products contain tend to kill friendly bacteria (not viruses at all), and so clear the way for the mass multiplication of surviving unfriendly bacteria. Perhaps even worse, hospitals have deployed antimicrobial products on an industrial scale for a long time now, the result being a sharp rise in iatrogenic bacterial illnesses. Overuse of antibiotics and commercial products containing them has helped superbugs to evolve. We now increasingly face microorganisms that cannot be killed by antibiotics, antifungals, antivirals, or any other chemical weapon we throw at them. Pandemics are the major risk we run as a result, but it is not the only one. Overuse of antibiotics by doctors, homemakers, and hospital managers could mean that, in the not-too-distant future, something as simple as a minor cut could again become life-threatening if it becomes infected. Few non-medical professionals are aware that antibiotics are the foundation on which nearly all of modern medicine rests. Cancer therapy, organ transplants, surgeries minor and major, and even childbirth all rely on antibiotics to prevent infections. If infections become untreatable we stand to lose most of the medical advances we have made over the past fifty years. And the problem is already here. In the summer of 2011, a 43-year-old woman with complications from a lung transplant was transferred from a New York City hospital to the Clinical Center at the National Institutes of Health (NIH), in Bethesda, Maryland. She had a highly resistant superbug known as Klebsiella pneumoniae carbapenemase (KPC). The patient was treated and eventually discharged after doctors concluded that they had contained the infection. A few weeks later, a 34-year-old man with a tumor and no known link to the woman contracted KPC while at the hospital. During the course of the next few months, several more NIH patients presented with KPC. Doctors attacked the outbreak with combinations of antibiotics, including a supposedly powerful experimental drug. A separate intensive care unit for KPC patients was set up and robots disinfected empty rooms, but the infection still spread beyond the intensive care area. Several patients died and then suddenly all was silent on the KPC front, with doctors convinced they had seen the last of the dangerous bacterium. They couldn’t have been more mistaken. A year later, a young man with complications from a bone marrow transplant arrived at NIH. He became infected with KPC and died. This superbug is now present in hospitals in most, if not all U.S. states. This is not good. This past year an outbreak of CRE (carbapenem-resistant enterobacteriaceae) linked to contaminated medical equipment infected 11 patients and killed two in Los Angeles area hospitals. This family of bacteria has evolved resistance to all antibiotics, including the powerful carbapenem antibiotics that are often used as a last resort against serious infections. They are now so resilient that it is virtually impossible to remove them from medical tools such as catheters and breathing tubes placed into the body, even after cleaning. Then we have gonorrhea, chlamydia, and other sexually transmitted diseases that we cannot treat and that are spreading all over the world. Anyone who has sex can catch these infections, and because most people may not exhibit any symptoms they spread infections without anyone knowing about it. Sexually transmitted diseases used to be treatable with antibiotics, but in recent years we have witnessed the rise of multi-drug resistant STDs. Untreated gonorrhea can lead to infertility in men and women and blindness and other congenital defect in babies. As is well known, too, we have witnessed many cases of drug-resistant pneumonia. These problems have arisen in part because of simple mistakes healthcare professionals repeatedly make. Let me explain. Neither superbugs nor common bacterial infections produce any special symptoms indicative of their cause. Rashes, fevers, sneezing, runny noses, ear pain, diarrhea, vomiting, coughing, fatigue, and weakness are signs of common and minor illnesses as well as uncommonly deadly ones. Therefore, the major problem for clinicians is to identify a common symptom that may potentially be an early sign of a major infection that could result in an epidemic. We know that dangerous infections in any given geographical area do not start at the same time. They start with one victim and gradually spread. But that victim is only one among hundreds of patients a doctor will typically see, so many doctors will miss patients presenting with infections that are serious. They will probably identify diseases that kill fast, but slow-spreading infections such as skin infections that can lead to septicemia are rarely diagnosed early. In addition, I have seen doctors treating eczema with antibiotic cream, even though they know that bacteria are resistant to the majority of these drugs. This sort of action encourages simple infections to spread locally, because patients are therefore not instructed to take other, more useful precautions. On top of that, some people are frivolous about infections and assume doctors are exaggerating the threat. And some people are selfish. Once I was called to see a passenger during a flight who had symptoms consistent with infection. He boarded the plane with these symptoms, but began to feel much worse during the flight. I was scared, knowing how infections such as Ebola can spread. This made me think about a way to screen passengers before they board a flight. Airlines could refund a traveler’s ticket, or issue a replacement, in case of sickness—which is not the policy now. We currently have no method to block infectious travelers from boarding flights, and there are no changes in the incentive system to enable conscientious passengers to avoid losing their money if they responsibly miss a flight because of illness. Speaking of selfishness, I once saw a mother drop her daughter off at school with a serious bout of impetigo on her face. When I asked her why she had brought her daughter to school with a contagious infection, she said she could not spare the time to keep her at home or take her to the doctor. By allowing this child to contact other children, a simple infection can become a major threat. Fortunately, I could see the rash on the girl’s face, but other kids in schools may have rashes we cannot see. Incorrect diagnosis of skin problems and mistaken use of antibiotics to treat them is common all over the world, and so we are continually creating superbugs in our communities. Similarly, chest infections, sore throats, and illnesses diagnosed as colds that unnecessarily treated with antibiotics are also a major threat. By prescribing antibiotics for viral infections, we are not only helping bacteria develop resistance, but we are also polluting the environment when these drugs are passed in urine and feces. All of this helps resistant bacteria to spread in the community and become an epidemic. Ebola is very difficult to transmit because people who are contagious have visible and unusual symptoms. However, the emerging infections and pandemics of the future may not have visible symptoms, and they could break out in highly populous countries such as India and China that send thousands of travelers all over the world every day. When a person is infected with a contagious disease, he or she can expect to pass the illness on to an average of two people. This is called the “reproduction number.” Two is not that high a number as these things go; some diseases have far greater rates of infection. The SARS virus had a reproduction number of four. Measles has a reproduction number of 18. One person traveling as an airplane passenger and carrying an infection similar to Ebola can infect three to five people sitting nearby, ten if he or she walks to the toilet. The study that highlighted this was published in a medical journal a few years ago, but the airline industry has not implemented any changes or introduced screening to prevent the spread of infections by air travel passengers, a major vehicle for the rapid spread of disease. It is scary to think that nobody knows what will happen when the world faces a lethal disease we’re not used to, perhaps with a reproduction number of five or eight or even ten. What if it starts in a megacity? What if, unlike Ebola, it’s contagious before patients show obvious symptoms? Past experience isn’t comforting. In 2009, H1N1 flu spread around the world before we even knew it existed. The Questions Remains Why do seemingly intelligent people repeatedly do such collectively stupid things? How did we allow this to happen? The answer is disarmingly simple. It is because people are incentivized to prioritize short-term benefits over long-term considerations. It is what social scientists have called a “logic of collective action” problem. Everyone has his or her specialized niche interest: doctors their patients’ approval, business and airline executives their shareholders’ earnings, hospitals their reputations for best-practice hygienics, homemakers their obligation to keep their own families from illness. But no one owns the longer-term consequences for hundreds of millions of people who are irrelevant to satisfying these short-term concerns. Here is an example. At a recent Superbug Super Drug conference in London that I attended, scientists, health agencies, and pharmaceutical companies were vastly more concerned with investing millions of dollars in efforts to invent another antibiotic, claiming that this has to be the way forward. Money was the most pressing issue because, as everyone at the conference knew, for many years pharmaceutical companies have been pulling back from antibiotics research because they can’t see a profit in it. Development costs run into billions of dollars, yet there is no guarantee that any new drug will successfully fight infections. At the same conference Dr. Lloyd Czaplewski spoke about alternatives to antibiotics, in case we cannot come up with new ones fast enough to outrun superbug evolution. But he omitted mention of preventive strategies that use the internet or communication software to help reduce the spread of infections among families, communities, and countries. It is madness that we don’t have a concrete second-best alternative to new antibiotics, because we need them and we need them quickly. Of course, this is why we have governments, which have been known occasionally in the past as commonwealths. Governments are supposed to look out for the wider, common interests of society that niche-interested professionals take no responsibility for, and that includes public health. It is why nearly every nation’s government has an official who is analogous to the U.S. Surgeon General, and nearly every one has a public health service of some kind. Alas, national governments do not always function as they should. Several years ago physician and former Republican Senator Bill Frist submitted a proposal to the Senate for a U.S. Medical Expeditionary Corps. This would have been a specialized organization that could coordinate and execute rapid responses to global health emergencies such as Ebola. Nothing came of it, because Dr. Frist’s fellow politicians were either too shortsighted or too dimwitted to understand why it was a good idea. Or perhaps they simply realized that they could not benefit politically from supporting it. Plenty of mistakes continue to be made. In 2015, a particularly infectious form of bird flu ripped through 14 U.S. states, leading farmers to preventively slaughter nearly 40 million birds. The result of such callous and unnecessary acts is that, instead of exhausting themselves in the host population of birds, the viruses quickly find alternative hosts in which to survive, and could therefore easily mutate into a form that can infect humans. Earlier, during the 1980s, AIDS garnered more public attention because a handful of rich and famous people were infected, and because the campaign to eradicate it dovetailed with and boosted the political campaign on behalf of homosexual rights. Methicillin resistant Staphylococcus aureus (MRSA) in hospitals, by far the bigger threat at the time, was virtually ignored. Some doctors knew that MRSA would bring us to our knees and kill millions of people worldwide, but pharmaceutical companies and device and equipment manufacturers ignored these doctors and the thousands of patients dying in hospitals as a result of MRSA. They prioritized the wrong thing, and government did not correct the error. And that is partly how antibiotic-resistant infection went from an obscure hospital problem to an incipient global pandemic. Politics well outside the United States plays several other roles in the budding problem that we are confronting. Countries often will not admit they have a problem and request help because of the possible financial implications in terms of investment and travel. Guinea did not declare the Ebola epidemic early on and Chinese leaders, worried about trade and tourism, lied for months in 2002 about the presence of the SARS virus. In 2004, when avian influenza first surfaced in Thailand, officials there displayed a similar reluctance to release information. Hospitals in some countries, including India, are managed and often owned by doctors. They refuse to share information about existing infections and often categorically deny they have a problem. Reporting infections to public health authorities is not mandatory, and so hospitals that fail to say anything are not penalized. Even now, the WHO and the CDC do not have accurate and up-to-date information about the spread of E. coli or other infections, and part of the reason is that for-profit hospitals are reluctant to do anything to diminish their bottom line. Syria and Yemen are among those countries that are so weak and fragmented that they cannot effectively coordinate public healthcare. But their governments are also hostile to external organizations that offer relief. Part of the reason is xenophobia, but part is that this makes the government look bad. Relatedly, most poor-nation governments do not trust the efficacy of international institutions, and think that cooperating with them amounts to a re-importation of imperialism. They would rather their own people suffer and die than ask for needed help. That brings us to the level of international public health governance. Alas, sometimes poor-country governments estimate the efficacy of international institutions accurately. The WHO’s Ebola response in 2014-15 was a disaster. The organization was slow to declare a public health emergency even after public warnings from Médecins Sans Frontières, some of whose doctors had already died on the front line. The outbreak killed more than 28,000 people, far more than would have been the case had it been quickly identified. This isn’t just an issue of bureaucratic incompetence. The **WHO is under-resourced for the problems it is meant to solve. Funding comes from voluntary donations, and there is no mechanism by which it can quickly scale up its efforts during an emergency. The result is that its response to the next major disease outbreak is likely to be as inadequate as were its responses to Ebola, H1N1, and SARS**. Stakeholders admit that we need another mechanism, and most experts agree that the world needs some kind of emergency response team for dangerous diseases. But no one knows how to set one up amid the dysfunctional global governance structures that presently exist. Maybe they should turn to Bill Frist, whose basic concept was sound; if the U.S. government will not act, perhaps some other governments will, and use the UN system to do so. But as things stand, we lack a health equivalent of the military reserve. Neither government leaders nor doctors can mobilize a team of experts to contain infections. People who want to volunteer, whether for government or NGO efforts, are not paid and the rules, if any, are sketchy about what we do with them when they return from a mission. Are employers going to take them back? What are the quarantine rules? It is all completely ad hoc, meaning that humanity lacks the tools it needs to protect itself. And note, by the way, the contrast between how governments prepare for facing pandemics and how they prepare for making war. War is not more deadly to the human race than pandemics, but national defense against armed aggression is much better planned for than defense against threats to public health. There is a wealth of rules regarding it, too. Human beings study and plan for war, which kills people both deliberately and accidentally, but they do not invest comparable effort planning for pandemics, which are liable to kill orders of magnitude more people. To the mind of a medical doctor, this is strange. Creating Conditions for Infections to Spread Superbug infections spread for several interlocking reasons. Some are medical-epidemiological. Most of the infections of the past thirty years have started in one place and in one family. As already noted, they spread because many infectious diseases are highly contagious before the onset of symptoms, and because it is difficult to prevent patients who know they are sick from going to hospitals, work, and school, or from traveling further afield. But again, one reason for the problem is political, not medical. Many governments have no strategies in place to prevent pandemics because they are unwilling to tell their people how infections spread. They don’t want to worry people with such talk; it will make them, they fear, unpopular. So governments may have mountains of bureaucracy with great heaps of rules and regulations concerning public health, but they are generally unwilling to trust their own citizens to use common sense on their own behalf. This, too, seems very strange. Until now, no one has come forward to help us develop strategies to educate people how to identify and prevent the spread of infection to their families and communities. The majority of stakeholders have also been oblivious to the use of new technologies to help reduce the spread of these infections. There are some exceptions. In a fun blog post called Preparedness 101: Zombie Apocalypse, the CDC uses the threat of a zombie outbreak as a metaphor to encourage people to prepare for emergencies, including pandemics. It is well meaning and insightful, yet when my colleagues and I try to discuss ways of scaling up the CDC’s example with doctors and nurses, they shut down. Nobody plans for an actual crisis partly because it is too scary and hence paralyzing to think about. But it is also because it is not most health professionals’ job; it is not what they are trained and paid to do. It is always someone else’s job, except that it has turned out to be nobody’s job. Worse, the situation is not static. While we sit paralyzed, superbugs are evolving. Epidemiological models now predict how an algorithmic process of disease spread will move through the modern world. All urban centers around the entire globe can become infected within sixty days because we move around and cross borders much more than our ancestors did, thanks to air travel. A new pandemic could start crossing borders before we even know it exists. A flu-like disease could kill more than 33 million people in 250 days.3

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

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

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

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

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

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

### 1AC: Drug Prices

#### Advantage 2 is Drug Prices:

#### Evergreening is the root cause of high drug prices by delaying generics – that’s a critical internal link to healthcare costs.

Vanni 21 Amaka Vanni 3-23-2021 “On Intellectual Property Rights, Access to Medicines and Vaccine Imperialism” <https://twailr.com/on-intellectual-property-rights-access-to-medicines-and-vaccine-imperialism/> (PhD and LLM degrees in International Economic Law from the University of Warwick)//re-cut by Elmer

Third, **patent practices** in recent decades have **seen** **pharmaceutical companies engaging in trivial** and cosmetic **tweaking of a drug** **whilst** still **reaping the benefit of 20 years of patent protection**. This tweaking sometimes involves making minor changes to patented drugs, such as changes in mode of administration, new dosages, extended release, or change in color of the drug. These changes normally **do not offer** **any** significant **therapeutic advantage** even though pharmaceutical companies argue they provide improved health outcomes to patients. These additional patents on small changes to existing drugs, known as **evergreening** or patent thickets, **block** the early **entry of** competitive, **generic medicines** **that drive medicine prices down**. For example, while not mandated by TRIPS, many US led TRIPS-plus free trade agreements have expanded the scope for evergreening. These include the US-Jordan FTA (2000), US-Australia FTA (2004) as well as the US-Korea FTA (2007), which allow for the patenting of new forms, uses, or methods of using existing products. The cancer drug Gleevec®, owned by Novartis, is another example of how pharmaceutical companies often secure patents on new, more convenient versions with marginal therapeutic benefit to patients whilst blocking the entry of generic medicines. In 2013, Novartis’ patent application for Gleevec®– the β crystalline form of the salt imatinib mesylate – was rejected by the Indian Supreme Court because it lacked novelty. However, the company has secured patents for this product in other jurisdictions such as the US and has maintained a high price of Gleevec there. But in India the price of Gleevec® was reduced from approximately USD 2,200 to USD 88 for one month’s treatment in the generic drugs market as a result of the 2013 Indian Supreme Court judgement. Novartis is not the only culprit. The depression drug Effexor® by Pfizer was granted an evergreen patent when the company introduced an extended-release version, Efexor-XR®, even though there was no additional benefit to patients. Eventually, the patent was declared invalid, but by then it had already cost an estimated USD 209 million to Australian taxpayers and kept generic competition off the market for two and a half years. In another instance, Pfizer went on to secure an additional patent for the Pristiq®, which contained identical chemical compound as Efexor-XR®,and again with no added therapeutic benefit. These evergreening practices, of course, have material effects. Apart from delaying the entry of generic versions, they give brand-name pharmaceutical companies **free reign in the market**, which allows them to set the market price. Recent years have seen **monopoly prices rise** exorbitantly **causing** significant **financial strain to patients**, domestic **healthcare services and** even **insurance companies** in developed countries. A notorious example is Martin Shkreli, who in 2015 bought the rights to an anti-malarial drug, then raised the price by 5,000 per cent from a cost of USD 13.50 to USD 750. Similarly, a white paper by I-MAK shows how excessive patenting and related strategies are driving families to overspend on lifesaving medicines. Celgene, the makers of Revlimid® raised the price of the drug by more than 50 per cent since 2012 to over USD 125,000 per year of treatment. Using the example of Solvadi® by Gilead, which costs USD 84,000 per treatment, Feldman notes the drug would cost the US Department of Defense more than USD 12 billion to treat all hepatitis-infected patients in US Veterans Affairs. But the US is not alone. In Europe, expensive drugs have prompted a growing backlash against pharmaceutical corporations. Reacting to these price hikes, Dutch pharmacies are bypassing these exorbitant prices by preparing medicines in-house for individual patients. The broken IP system ranging from an extraordinarily low standard for granting patents to permissions of patent thickets around a single molecule has not only severely distorted the system of innovation, but they have also skewed access to life-saving drugs. As a result, prices for new and existing medicines are constantly rising, making essential medicines inaccessible for millions of people around the world.

#### Pharma’s the largest drive of healthcare costs.

Brennan 16, Hannah, et al. "A prescription for excessive drug pricing: leveraging government patent use for health." Yale JL & Tech. 18 (2016): 275. (Law Clerk to the Honorable Theodore McKee, Chief Judge, Third Circuit)//re-cut by Elmer

The **soaring cost of pharmaceuticals is one of the most pressing domestic policy issues** in the United States today. Nearly **one-fifth of** the U.S. Gross Domestic Product (**GDP) is spent on healthcare**, and **pharmaceuticals are a key expenditure**.1 In 2014, the **U**nited **S**tates **spent a record $297.7 billion** on pharmaceuticals, over 12% more than the previous 2 year. The 2014 increase in prescription drug spending can be attributed almost entirely to recently approved drugs that treat the Hepatitis C virus (HCV). 3 With list prices that approach $100,000 for a twelve-week regimen, 4 these new medicines have brought the issue of drug pricing roaring to the fore in policy debates. **High drug prices are of enormous concern** to voters, 5 policymakers, and politicians across the political 6 spectrum. High drug prices also have a significant impact on health. The new HCV drugs offer an excellent example. Potentially deadly if untreated, HCV is one of the most pressing health problems facing the United States. 7 The new drugs are far superior to previous treatments and could potentially enable elimination of the disease.8 But treating all of the approximately 5.2 million people who currently have HCV in the United States at the best reported prices offered by Gilead, the sole supplier of the most important new drugs, would cost at least $234 billion.9 Given the budget impact of these new medicines, most payors have sharply restricted their availability-covering them only for the very sickest, or refusing to cover them at all 0-instead of rapidly rolling them out. Medicaid, for example, treated only 2.4% of enrollees estimated to have HCV in 2014, despite spending more than a billion dollars on the new medicines1.1 Even with the small number treated, Gilead's earnings have been stratospheric: the company earned $36 billion from its new HCV medicines in their first twenty-seven months on the market. 12

#### That hurts the Economy

Sood et Al 7, Neeraj, Arkadipta Ghosh, and J. Escarse. "The effect of health care cost growth on the US economy." Office of the Assistant Secretary for Planning and Evaluation, US Department of Health and Human Services (September). Available at (http://aspe. hhs. gov/health/reports/08/healthcarecost/report. html (HHS) (2007). (PhD, is professor and vice dean for research at the USC Price School of Public Policy and a founding member the USC Schaeffer Center)//Elmer

2. CONCEPTUAL OVERVEIW OF POTENTIAL MECHNISMS THROUGH WHICH HEALTH CARE INFLATION COULD AFFECT THE US ECONOMY Not surprisingly, the dramatic increases in health care spending and the share of GDP devoted to health care have raised concerns about the **negative impact of health care cost inflation on the U.S. economy**. In an era of global economic markets, these concerns are reinforced by the status of the U.S. as a spending outlier among competing nations. The major concern is that **rapid increases in health care spending** **can affect** **major economic indicators such** per capita **GDP, employment and inflation**. The effects are likely to occur **across all sectors** of the economy – governments, businesses and households – as all these interrelated sectors play an important role in the provision, financing and consumption of health care in the US. For example, Federal, state and local governments collect taxes from businesses and households to finance public health insurance programs and to directly provide health care to households. Businesses provide employment to US households and also provide health insurance to their employees. Households are the final consumers of health care and also bear some incidence of health care costs. In this report we separately identify the effects of health care costs on the aggregate economy and on each one of these interrelated sectors. However, it is important to note that the **effects** of health care costs **on one sector** are **likely to affect** outcomes in **other sectors**. For example, **faced with rising health care costs** **governments** might **attempt to reduce health spending by reducing eligibility for public health insurance**, consequently **increasing** **uninsurance rates** among households. The increase in health care costs might also prompt governments **to raise taxes**, increase borrowing or **reduce investments in** other **critical sectors such as education and infrastructure,** **suppressing economic growth** and affecting both businesses and households. Similarly, **US companies** faced with rapidly growing health care costs **might reduce employment** and investments in the US economy. Rising health care costs could also **fuel inflation** in the U.S. and make U.S. goods and services less competitive in international markets over time, because increasing health care costs might eventually be reflected in higher product prices. Since most other nations do not have employer-sponsored health insurance, companies in thosenations may be better able to keep prices low.2 Finally, high health care costs could reduce access to health care, bankrupt consumers and deplete retirement savings.

#### Economic decline results in multilateral breakdown that causes state collapse, conflict, climate change, and Arctic and Space War.

McLennan 21 – Strategic Partners Marsh McLennan SK Group Zurich Insurance Group, Academic Advisers National University of Singapore Oxford Martin School, University of Oxford Wharton Risk Management and Decision Processes Center, University of Pennsylvania, “The Global Risks Report 2021 16th Edition” “http://www3.weforum.org/docs/WEF\_The\_Global\_Risks\_Report\_2021.pdf //Re-cut by Elmer

Forced to choose sides, governments may face **economic** or diplomatic **consequences**, as proxy disputes play out in control over economic or geographic resources. The deepening of geopolitical fault lines and the lack of viable middle power alternatives make it harder for countries to cultivate connective tissue with a diverse set of partner countries based on mutual values and maximizing efficiencies. Instead, networks will become thick in some directions and non-existent in others. The COVID-19 crisis has amplified this dynamic, as digital interactions represent a “huge loss in efficiency for diplomacy” compared with face-to-face discussions.23 With some **alliances weakening**, diplomatic relationships will become more unstable at points where superpower tectonic plates meet or withdraw. At the same time, without superpower referees or middle power enforcement, global **norms** may **no longer govern** state **behaviour**. Some governments will thus see the solidification of rival blocs as an opportunity to engage in regional posturing, which will have destabilizing effects.24 Across societies, domestic discord and **economic crises will** **increase** the risk of **autocracy**, **with corresponding** **censorship, surveillance**, restriction of movement and abrogation of rights.25 Economic crises will also amplify the **challenges for middle power**s as they navigate geopolitical competition. **ASEAN countries, for example, had offered a potential new manufacturing base as the United States and China decouple, but the pandemic has left these countries strapped for cash to invest in the necessary infrastructure and productive capacity.26** Economic fallout is pushing many countries to debt distress (see Chapter 1, Global Risks 2021). While G20 countries are supporting debt restructure for poorer nations,27 larger economies too may be at **risk of default** in the longer term;28 this would **leave them further stranded**—**and unable to exercise leadership—on the global stage**. Multilateral meltdown **Middle power weaknesses** will be **reinforced** in weakened institutions, which may translate to **more uncertainty and lagging progress on shared global challenges such as climate change**, **health, poverty reduction and technology governance**. In the absence of strong regulating institutions, **the Arctic and space represent new realms for** potential **conflict** as the superpowers and middle powers alike compete to extract resources and secure strategic advantage.29 If the global superpowers continue to accumulate economic, military and technological power in a zero-sum playing field, some middle powers could increasingly fall behind. Without cooperation nor access to important innovations, middle powers will struggle to define solutions to the world’s problems. In the long term, GRPS **respondents forecasted “w**eapons of **m**ass **d**estruction” **and “state collapse**” as the two top critical threats: in the absence of strong institutions or clear rules, clashes— such as those in **Nagorno-Karabakh or the Galwan Valley**—**may more frequently flare into** full-fledged **interstate conflicts**,30 which is particularly worrisome where unresolved tensions among nuclear powers are concerned. These conflicts may lead to state collapse, with weakened middle powers less willing or less able to step in to find a peaceful solution.

#### COVID creates an economic brink---recovery is strong now because of effective monetary policy, but we’ve hit the zero-lower bound.

Christopher Rugaber 21. Associated Press. “Federal Reserve keeps key interest rate near zero, signals COVID-19 economic risks receding.” https://www.chicagotribune.com/business/ct-biz-fed-interest-rates-economy-20210428-bumyc3ynpza6ri4ygsntmdsmya-story.html.

WASHINGTON — The Federal Reserve is keeping its ultra-low interest rate policies in place, a sign that it wants to see more evidence of a strengthening economic recovery before it would consider easing its support.

In a statement Wednesday, the Fed expressed a brighter outlook, saying the economy has improved along with the job market. And while the policymakers noted that inflation has risen, they ascribed the increase to temporary factors.

The Fed also signaled its belief that the pandemic’s threat to the economy has diminished, a significant point given Chair Jerome Powell’s long-stated view that the recovery depends on the virus being brought under control. Last month, the Fed had cautioned that the virus posed “considerable risks to the economic outlook.” On Wednesday, it said only that “risks to the economic outlook remain” because of the pandemic.

The central bank left its benchmark short-term rate near zero, where it’s been since the pandemic erupted nearly a year ago, to help keep loan rates down to encourage borrowing and spending. It also said in a statement after its latest policy meeting that it would keep buying $120 billion in bonds each month to try to keep longer-term borrowing rates low.

The U.S. economy has been posting unexpectedly strong gains in recent weeks, with barometers of hiring, spending and manufacturing all surging. Most economists say they detect the early stages of what could be a robust and sustained recovery, with coronavirus case counts declining, vaccinations rising and Americans spending their stimulus-boosted savings.

#### Growth is sustainable, physical limits aren’t absolute, AND resource use is declining now---degrowth unleashes global disaster

Bailey 18 [Ronald; February 16; B.A. in Economics from the University of Virginia, member of the Society of Environmental Journalists and the American Society for Bioethics and Humanities, citing a compilation of interdisciplinary research; Reason, “Is Degrowth the Only Way to Save the World?” https://reason.com/2018/02/16/is-degrowth-the-only-way-to-save-the-wor; RP]

Unless us folks in rich countries drastically reduce our material living standards and distribute most of what we have to people living in poor countries, the world will come to an end. Or at least that's the stark conclusion of a study published earlier this month in the journal Nature Sustainability. The researchers who wrote it, led by the Leeds University ecological economist Dan O'Neill, think the way to prevent the apocalypse is "degrowth."

Vice, pestilence, war, and "gigantic inevitable famine" were the planetary boundaries set on human population by the 18th-century economist Robert Thomas Malthus. The new study gussies up old-fashioned Malthusianism by devising a set of seven biophysical indicators of national environmental pressure, which they then link to 11 indicators of social outcomes. The aim of the exercise is to concoct a "safe and just space" for humanity.

Using data from 2011, the researchers calculate that the annual per capita boundaries for the world's 7 billion people consist of the emission of 1.6 tons of carbon dioxide per year and the annual consumption of 0.9 kilograms of phosphorus, 8.9 kilograms of nitrogen, 574 cubic meters of water, 2.6 tons of biomass (crops and wood), plus the ecological services of 1.7 hectares of land and 7.2 tons of material per person.

On the social side, meanwhile, the researchers say that life satisfaction in each country should exceed 6.5 on the 10-point Cantril scale, that healthy life expectancy should average at least 65 years, and that nutrition should be over 2,700 calories per day. At least 95 percent of each country's citizens must have access to good sanitation, earn more than $1.90 per day, and pass through secondary school. Ninety percent of citizens must have friends and family they can depend on. The threshold for democratic quality must exceed 0.8 on an index scale stretching from -1 to +1, while the threshold for equality is set at no higher than 70 on a Gini Index where 0 represents perfect equality and 100 implies perfect inequality. They set the threshold for percent of labor force employed at 94 percent.

So how does the U.S. do with regard to their biophysical boundaries and social outcomes measures? We Americans transgress all seven of the biophysical boundaries. Carbon dioxide emissions stand at 21.2 tons per person; we each use an average of 7 kilograms of phosphorus, 59.1 kilograms of nitrogen, 611 cubic meters of water, and 3.7 tons of biomass; we rely on the ecological services of 6.8 hectares of land and 27.2 tons of material. Although the researchers urge us to move "beyond the pursuit of GDP growth to embrace new measures of progress," it is worth noting that U.S. GDP is $59,609 per capita.

On the other hand, those transgressions have provided a pretty good life for Americans. For example, life satisfaction is 7.1; healthy life expectancy is 69.7 years; and democratic quality stands at 0.8 points. The only two social indicators we just missed on were employment (91 percent) and secondary education (94.7 percent).

On the other hand, our hemisphere is home to one paragon of sustainability—Haiti. Haitians breach none of the researchers' biophysical boundaries. But the Caribbean country performs abysmally on all 11 social indicators. Life satisfaction scores at 4.8; healthy life expectancy is 52.3 years; and Haitians average 2,105 calories per day. The country tallies -0.9 on the democratic quality index. Haiti's GDP is $719 per capita.

Other near-sustainability champions include Malawi, Nepal, Myanmar, and Nicaragua. All of them score dismally on the social indicators, and their GDPs per capita are $322, $799, $1,375, and $2,208, respectively.

The country that currently comes closest to the researchers' ideal of remaining within its biophysical boundaries while sufficient social indicators is…Vietnam. For the record, Vietnam's per capita GDP is $2,306.

"Countries with higher levels of life satisfaction and healthy life expectancy also tend to transgress more biophysical boundaries," the researchers note. A better way to put this relationship is that more wealth and technology tend to make people happier, healthier, and freer.

O'Neill and his unhappy team fail drastically to understand how human ingenuity unleashed in markets is already well on the way toward making their supposed planetary boundaries irrelevant. Take carbon dioxide emissions: Supporters of renewable energy technologies say that their costs are already or will soon be lower than those of fossil fuels. Boosters of advanced nuclear reactors similarly argue that they can supply all of the carbon-free energy the world will need. There's a good chance that fleets of battery-powered self-driving vehicles will largely replace private cars and mass transit later in this century.

Are we about to run out of phosphorous to fertilize our crops? Peak phosphorus is not at hand. The U.S. Geological Survey (USGS) reports that at current rates of mining, the world's known reserves will last 266 years. The estimated total resources of phosphate rock would last over 1,140 years. "There are no imminent shortages of phosphate rock," notes the USGS. With respect to the deleterious effects that using phosphorus to fertilize crops might have outside of farm fields, researchers are working on ways to endow crops with traits that enable them to use less while maintaining yields.

O'Neill and his colleagues are also concerned that farmers are using too much nitrogen fertilizer, which runs off fields into the natural environment and contributes to deoxygenated dead zones in the oceans, among other ill effects. This is a problem, but one that plant breeders are already working to solve. For example, researchers at Arcadia Biosciences have used biotechnology to create nitrogen-efficient varieties of staples like rice and wheat that enable farmers to increase yields while significantly reducing fertilizer use. Meanwhile, other researchers are moving on projects to engineer the nitrogen fixation trait from legumes into cereal crops. In other words, the crops would make their own fertilizer from air.

Water? Most water is devoted to the irrigation of crops; the ongoing development of drought-resistant and saline-tolerant crops will help with that. Hectares per capita? Humanity has probably already reached peak farmland, and nearly 400 million hectares will be restored to nature by 2060—an area almost double the size of the United States east of the Mississippi River. In fact, it is entirely possible that most animal farming will be replaced by resource-sparing lab-grown steaks, chops, and milk. Such developments in food production undermine the researchers' worries about overconsumption of biomass.

And humanity's material footprint is likely to get smaller too as trends toward further dematerialization take hold. The price system is a superb mechanism for encouraging innovators to find ways to wring ever more value out less and less stuff. Rockefeller University researcher Jesse Ausubel has shown that this process of absolute dematerialization has already taken off for many commodities.

After cranking their way through their models of doom, O'Neill and his colleagues lugubriously conclude: "If all people are to lead a good life within planetary boundaries, then the level of resource use associated with meeting basic needs must be dramatically reduced." They are right, but they are entirely backward with regard to how to achieve those goals. Economic growth provides the wealth and technologies needed to lift people from poverty while simultaneously lightening humanity's footprint on the natural world. Rather than degrowth, the planet—and especially its poor people—need more and faster economic growth.

#### The Alternative to the Aff isn’t no medicine but exploitive medicine – the Plan’s orientation is a sequencing strategy to resistance.

Ahmed 20 A Kavum Ahmed 6-24-2020 "Decolonizing the vaccine" <https://africasacountry.com/2020/06/decolonizing-the-vaccine> (A. Kayum Ahmed is Division Director for Access and Accountability at the Open Society Public Health Program in New York and teaches at Columbia University Law School.)//Duong+Elmer

Reflecting on a potential COVID-19 vaccine trial during a television interview in April, a French doctor stated, “If I can be provocative, shouldn’t we be doing this study in Africa, where there are no masks, no treatments, no resuscitation?” These remarks reflect a colonial view of Africa, reinforcing the idea that Africans are non-humans whose black bodies can be experimented on. This colonial perspective is also clearly articulated in the alliance between France, The Netherlands, Germany and Italy to negotiate priority access to the COVID-19 vaccine for themselves and the rest of Europe. In the Dutch government’s announcement of the European vaccine coalition, they indicate that, “… the alliance is also working to make a portion of vaccines available to low-income countries, including in Africa.” In the collective imagination of these European nations, Africa is portrayed as a site of redemption—a place where you can absolve yourself from the sins of “vaccine sovereignty,” by offering a “portion of the vaccines” to the continent. Vaccine sovereignty reflects how European and American governments use public funding, supported by the pharmaceutical industry and research universities, to obtain priority access to potential COVID-19 vaccines. The concept symbolizes the COVID-19 **vaccine** (when it eventually becomes available) as **an instrument of power deployed to exercise control** **over who will live and who must die**. In order to counter vaccine sovereignty, we must decolonize the vaccine. Africans have a particular role to play in leading this decolonization process as subjects of colonialism and as objects of domination through coloniality. Colonialism, as an expansion of territorial dominance, and coloniality, as the continued expression of Western imperialism after colonization, play out in the vaccine development space, most notably on the African continent. So what does decolonizing the vaccine look like? And how do we decolonize something that does not yet exist? For Frantz Fanon, “**Decolonization**, which sets out to change the order of the world, **is**, obviously, a program of **complete disorder**.” **Acknowledging** **that the** COVID-19 **vaccine has been weaponized** **as an instrument of power** by wealthy nations, **decolonization** **requires** a Fanonian program of **radical re-ordering.** In the context of vaccine sovereignty, this re-ordering **necessitates** the **dismantling** of the **profit-driven biomedical system**. This program starts with **de-linking from** **Euro-American constructions of knowledge and power** that reinforce vaccine sovereignty through the profit-driven biomedical system. Advocacy campaigns such as the “People’s Vaccine”, which calls for guaranteed free access to COVID-19 vaccines, diagnostics and treatments to everyone, everywhere, are a good start. Other mechanisms, such as the World Health Organization’s COVID-19 Technology Access Pool, similarly supports universal access to COVID-19 health technologies as global public goods. Since less than 1% of vaccines consumed in Africa are manufactured on the continent, regional efforts to develop vaccine manufacturing capacity such as those led by the Africa Center for Disease Control and Prevention, as well as the Alliance of African Research Universities, must be supported. These efforts collectively advance delinking and move us closer toward the re-ordering of systems of power. The opportunity for disorder is paradoxically enabled by the COVID-19 pandemic, which has permitted moments of existential reflection in the midst of the crisis. A few months ago, a press release announcing the distribution of “a portion of the vaccines” to Africans, may have been lauded as European benevolence. But in the context of a pandemic that is more likely to kill black people, Africa’s reliance on Europe for vaccine handouts is untenable, necessitating a re-examination of the systems of power that hold this colonial relationship in place. The Black African body appears to be good enough to be experimented on, but not worthy of receiving simultaneous access to the COVID-19 vaccine as Europeans. Consequently, Africans continue to feel the effects of colonialism and white supremacy, and understand the pernicious nature of European altruism. By reinforcing the current system of vaccine research, development and manufacturing, it has become apparent that European governments want to retain their colonial power over life and death in Africa through the COVID-19 vaccine. Resistance to this colonial power requires the decolonization of the vaccine.

#### This is a form of pharmaceutical capitalism – exploiting marginalized groups in the third world.

Lift Mode 17 3-10-2017 "Pharmaceutical Colonialism” <https://medium.com/@liftmode/pharmaceutical-colonialism-3-ways-that-western-medicine-takes-from-indigenous-communities-3a9339b4f24f> (We at Liftmode.com are a team of professionals from a variety of backgrounds, dedicated to the mission of providing the highest quality and highest purity nutritional health supplements on the market. We look specifically for the latest and most promising research in the fields of cognition enhancement, neuroscience and alternative health supplements, and develop commercial strategies to bring these technologies to the marketplace.)//Elmer

3. **Cost of medicine as a form of debt** **One of the biggest methods of extracting money from rural and indigenous communities is through increased costs of medication**. Pharmaceutical colonialism often uses the premise of providing cheap medication for the world’s neediest to acquire local knowledge and natural resources. This premise is pushed into society through advertising campaigns and processes like lobbying. However, those who benefit most are often the shareholders, and not the people who need help. An example was the 2009 Reuters report which found that nearly **a million people** were **dying from malaria** dying every year **due to overly expensive medication**. According to the report, Artemisinin combination therapies (ACTs) can cost up to 65 times the daily minimum wage in countries that are most affected by malaria. These high prices **come after the government subsidies** which push them down as low as possible.[19] Another famous and recent example was the businessman Martin Shkreli, who pushed the cost of an AIDS drug up from $13.50 to over $700 per pill. This created an outrage on social media and it highlighted the underlying mindset behind most pharmaceutical companies — profit above all. An interesting and disturbing source of information about this is the film Fire in the Blood, which documents how **western pharmaceutical companies** **blocked the sale of cheap antiretroviral drugs to AIDS patients** **in Sub-Saharan Africa**.[20] “There is indeed a sense in which all modern **medicine** is **engaged in a colonizing process**… It can be seen in **the** increasing **professionalization of medicine and the exclusion of ‘folk’ practitioners**, in the close and often symbiotic relationship between medicine and the modern state, in the far-reaching claims made by medical science for its ability to prevent, control, and even eradicate human diseases.”[21] — D Arnold, Colonizing the Body, 1993 Pharmaceutical companies have been responsible for saving millions of lives due to their advances in medicine. However, the number of lives that have been lost due to the lack of affordability of medicine and the lack of equity and sharing of profits is estimated to be extremely high. **Western capitalism** has the **potential to act as a new form of colonialism**, and the modern medical method is one great way to extend the branches of capitalism into developing countries. The slums in Brazil highlight the blatant inequality between nations and people.

#### The analytic of traumatic racial identification with pessimistic strategies, results in the mythologization of whiteness, this trades-off with material gains—externally, their alternative sustains white supremacy.

**Mbembe 15** [Achille, philosopher, political scientist, and public intellectual, Ph.D. in History from the University of Sorbonne in Paris, France, D.E.A. in Political Science at the Institut d’Etudes Politiques, has held appointments at Columbia University in New York, Brookings Institution in Washington, D.C., University of Pennsylvania, University of California, Berkeley, Yale University, Duke University and Council for the Development of Social Science Research in Africa (CODESRIA) in Dakar, Senegal, currently at the Wits Institute for Social and Economic Research (WISER) at the University of the Witwatersrand in Johannesburg, South Africa, “Achille Mbembe on The State of South African Political Life,” September 19, 2015, <http://africasacountry.com/2015/09/achille-mbembe-on-the-state-of-south-african-politics>]

In these times of urgency, when weak and lazy minds would like us to oppose “thought” to “direct action”; and when, precisely because of this propensity for “thoughtless action”, everything is framed in the nihilistic terms of power for the sake of power – in such times what follows might mistakenly be construed as contemptuous. And yet, as new struggles unfold, hard questions have to be asked. They have to be asked if, in an infernal cycle of repetition but no difference, one form of damaged life is not simply to be replaced by another. The force of affect Indeed the ground is fast shifting and a huge storm seems to be building up on the horizon. May 68? Soweto 76? Or something entirely different? The winds blowing from our campuses can be felt afar, in a different idiom, in those territories of abandonment where the violence of poverty and demoralization having become the norm, many have nothing to lose and are now more than ever willing to risk a fight. They simply can no longer wait, having waited for too long now. Out there, from almost every corner of this vast land seems to stretch a chain of young men and women rigid with tension. As tension slowly swells up, it becomes ever more important to hold on to the things that truly matter. A new cultural temperament is gradually engulfing post-apartheid urban South Africa. For the time being, it goes by the name “decolonization” – in truth a psychic state more than a political project in the strict sense of the term. Whatever the case, everything seems to indicate that ours is a crucial moment in the redefinition of what counts as “social protagonism” in this country. Mobilizations over crucial matters such as access to health care, sanitation, housing, clean water or electricity might still be conducted in the name of the implicit promise inherent to the struggle years – that life after freedom will be “better” for all. But fewer and fewer actually believe it. And as the belief in that promise fast recedes, raw affect, raw emotions and raw feelings are harnessed and recycled back into the political itself. In the process, new voices increasingly render old ones inaudible, while anger, rage and eventually muted grief seem to be the new markers of identity and agency. Psychic bonds – in particular bonds of pain and bonds of suffering – more than lived material contradictions are becoming the real stuff of political inter-subjectivity. “I am my pain” – how many times have I heard this statement in the months since #RhodesMustFall emerged? “I am my suffering” and this subjective experience is so incommensurable that “unless you have gone through the same trial, you will never understand my condition” – the fusion of self and suffering in this astonishing age of solipsism and narcissism. So it is that the relative cultural hegemony the African National Congress (ANC) exercised on black South African imagination during the years of the struggle is fast waning. In the bloody miasma of the Zuma years, these years of stagnation, rent-seeking and mediocrity parading as leadership, there is hardly any center left standing as institutions after institutions crumble under the weight of corruption, a predatory new black élite and the cynicism of former oppressors. In the bloody miasma of the Zuma years, the discourse of black power, self-affirmation and worldliness of the early 1990s is in danger of being replaced by the discourse of fracture, injury and victimization – identity politics and the resentment that always is its corollary. Rainbowism and its most important articles of faith – truth, reconciliation and forgiveness – is fading. Reduced to a totemic commodity figure mostly destined to assuage whites’ fears, Nelson Mandela himself is on trial. Some of the key pillars of the 1994 dispensation – a constitutional democracy, a market society, non-racialism – are also under scrutiny. They are now perceived as disabling devices with no animating potency, at least in the eyes of those who are determined to no longer wait. We are past the time of promises. Now is the time to settle accounts. But how do we make sure that one noise machine is not simply replacing another? Settling Accounts The fact is this – nobody is saying nothing has changed. To say nothing has changed would be akin to indulging in willful blindness. Hyperboles notwithstanding, South Africa today is not the “colony” Frantz Fanon is writing about in his Wretched of the Earth. If we cannot find a proper name for what we are actually facing, then rather than simply borrowing one from a different time, we should keep searching. What we are hearing is that there have not been enough meaningful, decisive, radical change, not only in terms of the life chances of the black poor, but – and this is the novelty – in terms of the future prospects of the black middle class. What is being said is that twenty years after freedom, we have not disrupted enough the structures that maintain and reproduce “white power and supremacy”; that this is the reason why too many amongst us are trapped in a “bad life” that keeps wearing them out and down; that this wearing out and down of black life has been going on for too long and must now be brought to an end by all means necessary (the right to violence?). We are being told that we have not radically overturned the particular sets of interests that are produced and reproduced through white privilege in institutions of public and private life – in law firms, in financial institutions such as banking and insurance, in advertising and industry, in terms of land redistribution, in media, universities, languages and culture in general. “Whiteness”, “white power”, “white supremacy”, “white monopoly capital” is firmly back on the political and cultural agenda and to be white in South Africa now is to face a new-old kind of trial although with new judges – the so-called “born-free”. Politics of impatience But behind whites trial looms a broader indictment of South African social and political order. South Africa is fast approaching its Fanonian moment. A mass of structurally disenfranchised people have the feeling of being treated as “foreigners” on their own land. Convinced that the doors of opportunity are closing, they are asking for firmer demarcations between “citizens” (those who belong) and “foreigners” (those who must be excluded). They are convinced that as the doors of opportunity keep closing, those who won’t be able to “get in” right now might be left out for generations to come – thus the social stampede, the rush to “get in” before it gets too late, the willingness to risk a fight because waiting is no longer a viable option. The old politics of waiting is therefore gradually replaced by a new politics of impatience and, if necessary, of disruption. Brashness, disruption and a new anti-decorum ethos are meant to bring down the pretence of normality and the logics of normalization in this most “abnormal” society. Steve Biko, Frantz Fanon and a plethora of black feminist, queer, postcolonial, decolonial and critical race theorists are being reloaded in the service of a new form of militancy less accommodationist and more trenchant both in form and content. The age of impatience is an age when a lot is said – all sorts of things we had hardly heard about during the last twenty years; some ugly, outrageous, toxic things, including calls for murder, atrocious things that speak to everything except to the project of freedom, in this age of fantasy and hysteria, when the gap between psychic realities and actual material realities has never been so wide, and the digital world only serves as an amplifier of every single moment, event and accident. The age of urgency is also an age when new wounded bodies erupt and undertake to actually occupy spaces they used to simply haunt. They are now piling up, swearing and cursing, speaking with excrements, asking to be heard. They speak in allegories and analogies – the “colony”, the “plantation”, the “house Negro”, the “field Negro”, blurring all boundaries, embracing confusion, mixing times and spaces, at the risk of anachronism. They are claiming all kinds of rights – the right to violence; the right to disrupt and jam that which is parading as normal; the right to insult, intimidate and bully those who do not agree with them; the right to be angry, enraged; the right to go to war in the hope of recovering what was lost through conquest; the right to hate, to wreak vengeance, to smash something, it doesn’t matter what, as long as it looks “white”. All these new “rights” are supposed to achieve one thing we are told the 1994 “peaceful settlement” did not achieve – decolonization and retributive justice, the only way to restore a modicum of dignity to victims of the injuries of yesterday and today. Demythologizing whiteness And yet, some hard questions must be asked. Why are we invested in turning whiteness, pain and suffering into such erotogenic objects? Could it be that the concentration of our libido on whiteness, pain and suffering is after all typical of the narcissistic investments so privileged by this neoliberal age? To frame the issues in these terms does not mean embracing a position of moral relativism. How could it be? After all, in relation to our history, too many lives were destroyed in the name of whiteness. Furthermore, the structural repetition of past sufferings in the present is beyond any reasonable doubt. Whiteness as a necrophiliac power structure and a primary shaper of a global system of unequal redistribution of life chances will not die a natural death. But to properly engineer its death – and thus the end of the nightmare it has been for a large portion of the humanity – we urgently need to demythologize it. If we fail to properly demythologize whiteness, whiteness – as the machine in which a huge portion of the humanity has become entangled in spite of itself – will end up claiming us. As a result of whiteness having claimed us; as a result of having let ourselves be possessed by it in the manner of an evil spirit, we will inflict upon ourselves injuries of which whiteness, at its most ferocious, would scarcely have been capable. Indeed for whiteness to properly operate as the destructive force it is in the material sphere, it needs to capture its victim’s imagination and turn it into a poison well of hatred. For victims of white racism to hold on to the things that truly matter, they must incessantly fight against the kind of hatred which never fails to destroy, in the first instance, the man or woman who hates while leaving the structure of whiteness itself intact. As a poisonous fiction that passes for a fact, whiteness seeks to institutionalize itself as an event by any means necessary. This it does by colonizing the entire realms of desire and of the imagination. To demythologize whiteness, it will not be enough to force “bad whites” into silence or into confessing guilt and/or complicity. This is too cheap. To puncture and deflate the fictions of whiteness will require an entirely different regime of desire, new approaches in the constitution of material, aesthetic and symbolic capital, another discourse on value, on what matters and why.

### 1AC: Plan

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

#### The Plan solves Evergreening.

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

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

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

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

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

### 1AC: Framing

#### The standard is maximizing expected wellbeing.

#### Prefer:

#### 1] Pleasure and pain *are* intrinsic value and disvalue – everything else *regresses* – robust neuroscience.

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**Pleasure** is not only one of the three primary reward functions but it also **defines reward.** As homeostasis explains the functions of only a limited number of rewards, the principal reason why particular stimuli, objects, events, situations, and activities are rewarding may be due to pleasure. This applies first of all to sex and to the primary homeostatic rewards of food and liquid and extends to money, taste, beauty, social encounters and nonmaterial, internally set, and intrinsic rewards. Pleasure, as the primary effect of rewards, drives the prime reward functions of learning, approach behavior, and decision making and provides the **basis for hedonic theories** of reward function. We are attracted by most rewards and exert intense efforts to obtain them, just because they are enjoyable [10].

Pleasure is a passive reaction that derives from the experience or prediction of reward and may lead to a long-lasting state of happiness. The word happiness is difficult to define. In fact, just obtaining physical pleasure may not be enough. One key to happiness involves a network of good friends. However, it is not obvious how the higher forms of satisfaction and pleasure are related to an ice cream cone, or to your team winning a sporting event. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure [14].

Pleasure as a hallmark of reward is sufficient for defining a reward, but it may not be necessary. A reward may generate positive learning and approach behavior simply because it contains substances that are essential for body function. When we are hungry, we may eat bad and unpleasant meals. A monkey who receives hundreds of small drops of water every morning in the laboratory is unlikely to feel a rush of pleasure every time it gets the 0.1 ml. Nevertheless, with these precautions in mind, we may define any stimulus, object, event, activity, or situation that has the potential to produce pleasure as a reward. In the context of reward deficiency or for disorders of addiction, homeostasis pursues pharmacological treatments: drugs to treat drug addiction, obesity, and other compulsive behaviors. The theory of allostasis suggests broader approaches - such as re-expanding the range of possible pleasures and providing opportunities to expend effort in their pursuit. [15]. It is noteworthy, the first animal studies eliciting approach behavior by electrical brain stimulation interpreted their findings as a discovery of the brain’s pleasure centers [16] which were later partly associated with midbrain dopamine neurons [17–19] despite the notorious difficulties of identifying emotions in animals.

Evolutionary theories of pleasure: The love connection BO:D

Charles Darwin and other biological scientists that have examined the biological evolution and its basic principles found various mechanisms that steer behavior and biological development. Besides their theory on natural selection, it was particularly the sexual selection process that gained significance in the latter context over the last century, especially when it comes to the question of what makes us “what we are,” i.e., human. However, the capacity to sexually select and evolve is not at all a human accomplishment alone or a sign of our uniqueness; yet, we humans, as it seems, are ingenious in fooling ourselves and others–when we are in love or desperately search for it.

It is well established that modern biological theory conjectures that **organisms are** the **result of evolutionary competition.** In fact, Richard Dawkins stresses gene survival and propagation as the basic mechanism of life [20]. Only genes that lead to the fittest phenotype will make it. It is noteworthy that the phenotype is selected based on behavior that maximizes gene propagation. To do so, the phenotype must survive and generate offspring, and be better at it than its competitors. Thus, the ultimate, distal function of rewards is to increase evolutionary fitness by ensuring the survival of the organism and reproduction. It is agreed that learning, approach, economic decisions, and positive emotions are the proximal functions through which phenotypes obtain other necessary nutrients for survival, mating, and care for offspring.

Behavioral reward functions have evolved to help individuals to survive and propagate their genes. Apparently, people need to live well and long enough to reproduce. Most would agree that homo-sapiens do so by ingesting the substances that make their bodies function properly. For this reason, foods and drinks are rewards. Additional rewards, including those used for economic exchanges, ensure sufficient palatable food and drink supply. Mating and gene propagation is supported by powerful sexual attraction. Additional properties, like body form, augment the chance to mate and nourish and defend offspring and are therefore also rewards. Care for offspring until they can reproduce themselves helps gene propagation and is rewarding; otherwise, many believe mating is useless. According to David E Comings, as any small edge will ultimately result in evolutionary advantage [21], additional reward mechanisms like novelty seeking and exploration widen the spectrum of available rewards and thus enhance the chance for survival, reproduction, and ultimate gene propagation. These functions may help us to obtain the benefits of distant rewards that are determined by our own interests and not immediately available in the environment. Thus the distal reward function in gene propagation and evolutionary fitness defines the proximal reward functions that we see in everyday behavior. That is why foods, drinks, mates, and offspring are rewarding.

There have been theories linking pleasure as a required component of health benefits salutogenesis, (salugenesis). In essence, under these terms, pleasure is described as a state or feeling of happiness and satisfaction resulting from an experience that one enjoys. Regarding pleasure, it is a double-edged sword, on the one hand, it promotes positive feelings (like mindfulness) and even better cognition, possibly through the release of dopamine [22]. But on the other hand, pleasure simultaneously encourages addiction and other negative behaviors, i.e., motivational toxicity. It is a complex neurobiological phenomenon, relying on reward circuitry or limbic activity. It is important to realize that through the “Brain Reward Cascade” (BRC) endorphin and endogenous morphinergic mechanisms may play a role [23]. While natural rewards are essential for survival and appetitive motivation leading to beneficial biological behaviors like eating, sex, and reproduction, crucial social interactions seem to further facilitate the positive effects exerted by pleasurable experiences. Indeed, experimentation with addictive drugs is capable of directly acting on reward pathways and causing deterioration of these systems promoting hypodopaminergia [24]. Most would agree that pleasurable activities can stimulate personal growth and may help to induce healthy behavioral changes, including stress management [25]. The work of Esch and Stefano [26] concerning the link between compassion and love implicate the brain reward system, and pleasure induction suggests that social contact in general, i.e., love, attachment, and compassion, can be highly effective in stress reduction, survival, and overall health.

Understanding the role of neurotransmission and pleasurable states both positive and negative have been adequately studied over many decades [26–37], but comparative anatomical and neurobiological function between animals and homo sapiens appear to be required and seem to be in an infancy stage.

Finding happiness is different between apes and humans

As stated earlier in this expert opinion one key to happiness involves a network of good friends [38]. However, it is not entirely clear exactly how the higher forms of satisfaction and pleasure are related to a sugar rush, winning a sports event or even sky diving, all of which augment dopamine release at the reward brain site. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure.

Remarkably, there are pathways for ordinary liking and pleasure, which are limited in scope as described above in this commentary. However, there are **many brain regions**, often termed hot and cold spots, that significantly **modulate** (increase or decrease) our **pleasure or** even produce **the opposite** of pleasure— that is disgust and fear [39]. One specific region of the nucleus accumbens is organized like a computer keyboard, with particular stimulus triggers in rows— producing an increase and decrease of pleasure and disgust. Moreover, the cortex has unique roles in the cognitive evaluation of our feelings of pleasure [40]. Importantly, the interplay of these multiple triggers and the higher brain centers in the prefrontal cortex are very intricate and are just being uncovered.

Desire and reward centers

It is surprising that many different sources of pleasure activate the same circuits between the mesocorticolimbic regions (Figure 1). Reward and desire are two aspects pleasure induction and have a very widespread, large circuit. Some part of this circuit distinguishes between desire and dread. The so-called pleasure circuitry called “REWARD” involves a well-known dopamine pathway in the mesolimbic system that can influence both pleasure and motivation.

In simplest terms, the well-established mesolimbic system is a dopamine circuit for reward. It starts in the ventral tegmental area (VTA) of the midbrain and travels to the nucleus accumbens (Figure 2). It is the cornerstone target to all addictions. The VTA is encompassed with neurons using glutamate, GABA, and dopamine. The nucleus accumbens (NAc) is located within the ventral striatum and is divided into two sub-regions—the motor and limbic regions associated with its core and shell, respectively. The NAc has spiny neurons that receive dopamine from the VTA and glutamate (a dopamine driver) from the hippocampus, amygdala and medial prefrontal cortex. Subsequently, the NAc projects GABA signals to an area termed the ventral pallidum (VP). The region is a relay station in the limbic loop of the basal ganglia, critical for motivation, behavior, emotions and the “Feel Good” response. This defined system of the brain is involved in all addictions –substance, and non –substance related. In 1995, our laboratory coined the term “Reward Deficiency Syndrome” (RDS) to describe genetic and epigenetic induced hypodopaminergia in the “Brain Reward Cascade” that contribute to addiction and compulsive behaviors [3,6,41].

Furthermore, ordinary “liking” of something, or pure pleasure, is represented by small regions mainly in the limbic system (old reptilian part of the brain). These may be part of larger neural circuits. In Latin, hedus is the term for “sweet”; and in Greek, hodone is the term for “pleasure.” Thus, the word Hedonic is now referring to various subcomponents of pleasure: some associated with purely sensory and others with more complex emotions involving morals, aesthetics, and social interactions. The capacity to have pleasure is part of being healthy and may even extend life, especially if linked to optimism as a dopaminergic response [42].

Psychiatric illness often includes symptoms of an abnormal inability to experience pleasure, referred to as anhedonia. A negative feeling state is called dysphoria, which can consist of many emotions such as pain, depression, anxiety, fear, and disgust. Previously many scientists used animal research to uncover the complex mechanisms of pleasure, liking, motivation and even emotions like panic and fear, as discussed above [43]. However, as a significant amount of related research about the specific brain regions of pleasure/reward circuitry has been derived from invasive studies of animals, these cannot be directly compared with subjective states experienced by humans.

In an attempt to resolve the controversy regarding the causal contributions of mesolimbic dopamine systems to reward, we have previously evaluated the three-main competing explanatory categories: “liking,” “learning,” and “wanting” [3]. That is, dopamine may mediate (a) liking: the hedonic impact of reward, (b) learning: learned predictions about rewarding effects, or (c) wanting: the pursuit of rewards by attributing incentive salience to reward-related stimuli [44]. We have evaluated these hypotheses, especially as they relate to the RDS, and we find that the incentive salience or “wanting” hypothesis of dopaminergic functioning is supported by a majority of the scientific evidence. Various neuroimaging studies have shown that anticipated behaviors such as sex and gaming, delicious foods and drugs of abuse all affect brain regions associated with reward networks, and may not be unidirectional. Drugs of abuse enhance dopamine signaling which sensitizes mesolimbic brain mechanisms that apparently evolved explicitly to attribute incentive salience to various rewards [45].

Addictive substances are voluntarily self-administered, and they enhance (directly or indirectly) dopaminergic synaptic function in the NAc. This activation of the brain reward networks (producing the ecstatic “high” that users seek). Although these circuits were initially thought to encode a set point of hedonic tone, it is now being considered to be far more complicated in function, also encoding attention, reward expectancy, disconfirmation of reward expectancy, and incentive motivation [46]. The argument about addiction as a disease may be confused with a predisposition to substance and nonsubstance rewards relative to the extreme effect of drugs of abuse on brain neurochemistry. The former sets up an individual to be at high risk through both genetic polymorphisms in reward genes as well as harmful epigenetic insult. Some Psychologists, even with all the data, still infer that addiction is not a disease [47]. Elevated stress levels, together with polymorphisms (genetic variations) of various dopaminergic genes and the genes related to other neurotransmitters (and their genetic variants), and may have an additive effect on vulnerability to various addictions [48]. In this regard, Vanyukov, et al. [48] suggested based on review that whereas the gateway hypothesis does not specify mechanistic connections between “stages,” and does not extend to the risks for addictions the concept of common liability to addictions may be more parsimonious. The latter theory is grounded in genetic theory and supported by data identifying common sources of variation in the risk for specific addictions (e.g., RDS). This commonality has identifiable neurobiological substrate and plausible evolutionary explanations.

Over many years the controversy of dopamine involvement in especially “pleasure” has led to confusion concerning separating motivation from actual pleasure (wanting versus liking) [49]. We take the position that animal studies cannot provide real clinical information as described by self-reports in humans. As mentioned earlier and in the abstract, on November 23rd, 2017, evidence for our concerns was discovered [50]

In essence, although nonhuman primate brains are similar to our own, the disparity between other primates and those of human cognitive abilities tells us that surface similarity is not the whole story. Sousa et al. [50] small case found various differentially expressed genes, to associate with pleasure related systems. Furthermore, the dopaminergic interneurons located in the human neocortex were absent from the neocortex of nonhuman African apes. Such differences in neuronal transcriptional programs may underlie a variety of neurodevelopmental disorders.

In simpler terms, the system controls the production of dopamine, a chemical messenger that plays a significant role in pleasure and rewards. The senior author, Dr. Nenad Sestan from Yale, stated: “Humans have evolved a dopamine system that is different than the one in chimpanzees.” This may explain why the behavior of humans is so unique from that of non-human primates, even though our brains are so surprisingly similar, Sestan said: “It might also shed light on why people are vulnerable to mental disorders such as autism (possibly even addiction).” Remarkably, this research finding emerged from an extensive, multicenter collaboration to compare the brains across several species. These researchers examined 247 specimens of neural tissue from six humans, five chimpanzees, and five macaque monkeys. Moreover, these investigators analyzed which genes were turned on or off in 16 regions of the brain. While the differences among species were subtle, **there was** a **remarkable contrast in** the **neocortices**, specifically in an area of the brain that is much more developed in humans than in chimpanzees. In fact, these researchers found that a gene called tyrosine hydroxylase (TH) for the enzyme, responsible for the production of dopamine, was expressed in the neocortex of humans, but not chimpanzees. As discussed earlier, dopamine is best known for its essential role within the brain’s reward system; the very system that responds to everything from sex, to gambling, to food, and to addictive drugs. However, dopamine also assists in regulating emotional responses, memory, and movement. Notably, abnormal dopamine levels have been linked to disorders including Parkinson’s, schizophrenia and spectrum disorders such as autism and addiction or RDS.

Nora Volkow, the director of NIDA, pointed out that one alluring possibility is that the neurotransmitter dopamine plays a substantial role in humans’ ability to pursue various rewards that are perhaps months or even years away in the future. This same idea has been suggested by Dr. Robert Sapolsky, a professor of biology and neurology at Stanford University. Dr. Sapolsky cited evidence that dopamine levels rise dramatically in humans when we anticipate potential rewards that are uncertain and even far off in our futures, such as retirement or even the possible alterlife. This may explain what often motivates people to work for things that have no apparent short-term benefit [51]. In similar work, Volkow and Bale [52] proposed a model in which dopamine can favor NOW processes through phasic signaling in reward circuits or LATER processes through tonic signaling in control circuits. Specifically, they suggest that through its modulation of the orbitofrontal cortex, which processes salience attribution, dopamine also enables shilting from NOW to LATER, while its modulation of the insula, which processes interoceptive information, influences the probability of selecting NOW versus LATER actions based on an individual’s physiological state. This hypothesis further supports the concept that disruptions along these circuits contribute to diverse pathologies, including obesity and addiction or RDS.

#### 2] Death is bad and outweighs – a) agents can’t act if they fear for their bodily security which constrains every ethical theory, b) it destroys the subject itself – kills any ability to achieve value in ethics since life is a prerequisite which means it’s a side constraint since we can’t reach the end goal of ethics without life