## 1AC vs Kritik

### 1AC: Innovation

#### The Advantage is Innovation

#### 1] We are in an innovation crisis – up to 80% of all new patents are not new drugs but old ones.

Feldman 1 Robin Feldman 18, May your drug price be evergreen, Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, Pages 590–647, <https://doi.org/10.1093/jlb/lsy022> Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation (Study Notes: Presenting the first comprehensive study of evergreening, this article examines the extent to which evergreening behavior—which can be defined as artificially extending the protection cliff—may contribute to the problem. The author analyses all drugs on the market between 2005 and 2015, combing through 60,000 data points to examine every instance in which a company added a new patent or exclusivity.)//sid

The study results demonstrate definitively that the pharmaceutical industry has strayed far from the patent system's intended design. The patent system is not functioning as a time-limited opportunity to garner a return, followed by open competition. Rather, companies throughout the industry seek and obtain repeated extensions of their competition-free zones. Moreover, the incidence of such behavior has steadily increased between 2005 and 2015, especially on the patent front and for certain highly valuable exclusivities. Most troubling, the data suggest that the current state of affairs **is harming innovation** in tangible ways. Rather than creating new medicines—sallying forth into new frontiers for the benefit of society—drug companies are focusing their time and effort extending **the patent life of old products**. This, of course, is not the innovation one would hope for. The greatest creativity at pharmaceutical **companies should be in the lab, not in the legal department**.115 The following sections describe the results obtained through our analysis in detail, but below are the key takeaways from the study: Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. In fact, 78% of the drugs associated with new patents in the FDA’s records **were not new drugs** coming on the market, but existing drugs. In some years, the percentage reached as high as 80%. Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70% extended their protection at least once, with more than 50% extending the protection cliff more than once. Looking at the full group, almost 40% of all drugs available on the market created additional market barriers by **having patents or exclusivities added** to them.

#### 2] 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

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.

#### 2 impacts:

#### 1] 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.”

#### Evolving superbugs trigger extinction.

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

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

#### 2] Pharma spills-over – has cascading global impacts that are necessary for human survival.

NAS 8 National Academy of Sciences 12-3-2008 “The Role of the Life Sciences in Transforming America's Future Summary of a Workshop” //Re-cut by Elmer

Fostering Industries to Counter Global Problems The life sciences have applications in areas that range far beyond human health. Life-science based approaches could **contribute to advances in** many industries, from energy production and pollution remediation, to clean manufacturing and the production of new biologically inspired materials. In fact, biological systems could provide the basis for new products, services and industries that we cannot yet imagine. Microbes are already producing biofuels and could, through further research, provide a major component of future energy supplies. Marine and terrestrial organisms extract carbon dioxide from the atmosphere, which suggests that biological systems could be used to help manage climate change. Study of the complex systems encountered in biology is decade, it is really just the beginning.” Advances in the underlying science of plant and animal breeding have been just as dramatic as the advances in genetic can put down a band of fertilizer, come back six months later, and plant seeds exactly on that row, reducing the need for fertilizer, pesticides, and other agricultural inputs. Fraley said that the global agricultural system needs to adopt the goal of doubling the current yield of **crops while reducing key inputs like pesticides, fertilizers, and water** by one third. “It is more important than putting a man on the moon,” he said. Doubling agricultural yields would “change the world.” Another billion people will join the middle class over the next decade just in India and China as economies continue to grow. And all people need and deserve secure access to food supplies. Continued progress will require both basic and applied research, The evolution of life “put earth under new management,” Collins said. Understanding the future state of the planet will require understanding the biological systems that have shaped the planet. Many of these biological systems are found in the oceans, which cover 70 percent of the earth’s surface and have a crucial impact on weather, climate, and the composition of the atmosphere. In the past decade, new tools have become available to explore the microbial processes that drive the **chemistry of the oceans**, observed David Kingsbury, Chief Program Officer for Science at the Gordon and Betty Moore Foundation. These technologies have revealed that a large proportion of the planet’s genetic diversity resides in the oceans. In addition, many organisms in the oceans readily exchange genes, creating evolutionary forces that can have global effects. The oceans are currently under great stress, Kingsbury pointed out. Nutrient runoff from agriculture is helping to create huge and expanding “dead zones” where oxygen levels are too low to sustain life. Toxic algal blooms are occurring with higher frequency in areas where they have not been seen in the past. Exploitation of ocean resources is disrupting ecological balances that have formed over many millions of years. Human-induced changes in the chemistry of the atmosphere are changing the chemistry of the oceans, with potentially catastrophic consequences. “If we are not careful, we are not going to have a sustainable planet to live on,” said Kingsbury. Only by understanding the basic biological processes at work in the oceans can humans live sustainably on earth.

#### Climate change destroys the world.

Specktor 19 [Brandon writes about the science of everyday life for Live Science, and previously for Reader's Digest magazine, where he served as an editor for five years] 6-4-2019, "Human Civilization Will Crumble by 2050 If We Don't Stop Climate Change Now, New Paper Claims," livescience, <https://www.livescience.com/65633-climate-change-dooms-humans-by-2050.html> JW

\*\*Cites and talks about the Spratt and Dunlop study

What might an accurate worst-case picture of the planet's climate-addled future actually look like, then? The authors provide one particularly grim scenario that begins with world governments "politely ignoring" the advice of scientists and the will of the public to decarbonize the economy (finding alternative energy sources), resulting in a global temperature increase 5.4 F (3 C) by the year 2050. At this point, the world's ice sheets vanish; brutal droughts kill many of the trees in the [Amazon rainforest](https://www.livescience.com/57266-amazon-river.html) (removing one of the world's largest carbon offsets); and the planet plunges into a feedback loop of ever-hotter, ever-deadlier conditions.

"Thirty-five percent of the global land area, and 55 percent of the global population, are subject to more than 20 days a year of [lethal heat conditions](https://www.livescience.com/55129-how-heat-waves-kill-so-quickly.html), beyond the threshold of human survivability," the authors hypothesized.

Meanwhile, droughts, floods and wildfires regularly ravage the land. Nearly one-third of the world's land surface turns to desert. Entire ecosystems collapse, beginning with the planet's coral reefs, the rainforest and the Arctic ice sheets. The world's tropics are hit hardest by these new climate extremes, destroying the region's agriculture and turning more than 1 billion people into refugees.

This mass movement of refugees — coupled with [shrinking coastlines](https://www.livescience.com/51990-sea-level-rise-unknowns.html) and severe drops in food and water availability — begin to stress the fabric of the world's largest nations, including the United States. Armed conflicts over resources, perhaps culminating in nuclear war, are likely.

The result, according to the new paper, is "outright chaos" and perhaps "the end of human global civilization as we know it."

### 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 protection.

#### Contention 2 is Solvency

#### 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.

### Framework

#### The standard is maximizing expected wellbeing.

#### Prefer:

#### 1] Pleasure and pain are intrinsic value and disvalue-- robust neuroscience prove.

Blum et al. 18

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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] Extinction outweighs

#### **a] Forecloses improvement – we can never improve society because our impact is irreversible.**

#### **b] Turns suffering – mass death causes suffering because people can’t get access to resources and basic necessities.**

#### **c] Moral obligation – allowing people to die is unethical and should be prevented because it creates ethics towards other people.**

#### **d] Objectivity – body count is the most objective way to calculate impacts because comparing suffering is unethical.**

#### **e] Moral uncertainty – if we’re unsure about which interpretation of the world is true – we ought to preserve the world to keep debating about it.**

**3] Actor specificity: A] Governments must aggregate since every policy benefits some and harms others, which also means side constraints freeze action.**

#### 5] Util first – Death is the worst evil

Craig **Paterson** (20**03**, Department of Philosophy, Providence College, Rhode Island., “A Life Not Worth Living?”, Studies in Christian Ethics, https://pubmed.ncbi.nlm.nih.gov/15000090/)

Contrary to those accounts, I would argue that it is death per se that is really the objective evil for us, not because it deprives us of a prospective future of overall good judged better than the alter- native of non-being. It cannot be about harm to a former person who has ceased to exist, for no person actually suffers from the sub-sequent non-participation. Rather, death in itself is an evil to us because it ontologically destroys the current existent subject — it is the ultimate in metaphysical lightening strikes.80 The evil of death is truly an ontological evil borne by the person who already exists, independently of calculations about better or worse possible lives. Such an evil need not be consciously experienced in order to be an evil for the kind of being a human person is. Death is an evil because of the change in kind it brings about, a change that is destructive of the type of entity that we essentially are. Anything, whether caused naturally or caused by human intervention (intentional or unintentional) that drastically interferes in the process of maintaining the person in existence is an objective evil for the person. What is crucially at stake here, and is dialectically supportive of the self-evidency of the basic good of human life, is that death is a radical interference with the current life process of the kind of being that we are. In consequence, death itself can be credibly thought of as a ‘primitive evil’ for all persons, regardless of the extent to which they are currently or prospectively capable of participating in a full array of the goods of life.81 In conclusion, concerning willed human actions, it is justifiable to state that any intentional rejection of human life itself cannot therefore be warranted since it is an expression of an ultimate disvalue for the subject, namely, the destruction of the present person; a radical ontological good that we cannot begin to weigh objectively against the travails of life in a rational manner. To deal with the sources of disvalue (pain, suffering, etc.) we should not seek to irrationally destroy the person, the very source and condition of all human possibility.82

### Underview

#### 1] 1AR theory – or neg gets to be infinitely abusive which outweighs on magnitude. Its drop the debater – the 1ARs too short to have a fair shot at both theory and substance. Competing interps on aff theory – offense defense paradigm checks the neg dumping a slew of 2NR generic defense so winning a shell is impossible. No 2NR rvis – they can dump on it for 6 minutes and I can never answer the args in half the time, which destroys all check on neg abuse.

#### 4] Interpretation: the neg must not contest the aff framework or read an alternative framework provided that: the aff standard is act utilitarianism and it’s open sourced

#### a] Clash – AFC is key to force substantive engagement – util doesn’t exclude impacts and forces debaters to do advocacy comparison and engage in meaningful rebuttal clash. The disclosure plank means no prep skew and that you should be ready to debate the aff which is key to topic clash

#### b] Strat skew – neg is reactive and can up-layer the aff on moral frameworks, procedurals, and discursive arguments – AFC levels the playing field by forcing the neg to commit to the aff on substance, which ensures the AC matters

#### Ci and DTD no rvi on 1ac theory - the sole purpose of 1ac theory is to deter arguments and anything else lets the 1nc read it regardless No RVIs on 1ac theory - otherwise they can spend 7 minutes on the shell and the debate ends right there

Fairness above ervything 1] key to test and evaluate their grtuth claims 2] intrinsic -- args that answer fairness need toe be evaluated fairly 3] clash - unfair gmae means we can't clash it's intrinsic to debate 4] engagement - cretes ebtter debates over how to guide action under your top

### 1AC: Method [Generic vs Kritik]

#### Contention 3 is our Method –

#### Disparities within health are not ontological but formed and maintained by social norms upheld by legal indifference – solving the discriminatory practices of public health is uniquely key as a starting point

Matthew 18, Dayna Bowen. Just medicine: A cure for racial inequality in American health care. NYU Press, 2018. (Resident senior fellow in the Center for Health Policy, who works at the University of Colorado School of Law, the Colorado School of Public Health, and the Center for Bioethics and Humanities at the University of Colorado Health Sciences Center specializes in health and behavioral sciences and her research interests include public health law, poverty, and ethics in health professions)//Elmer

For the past thirty years, medical doctors, social scientists, psychologists, policy analysts, jurists, and a wide spectrum of health care providers have been studying and discussing health inequality in America. Meanwhile, by one estimate, 83,570 minority patients die annually due to health care disparities. Black and brown patients consistently receive inferior medical treatment—fewer angiographies, bypass surgeries, organ transplants, cancer tests, and resections, less access to pain treatment, rehabilitative services, asthma remedies, and nearly every other form of medical care—than their white counterparts. Yet minority patients are sicker and more likely to die than whites from a wide range of diseases and illnesses for which we have data. Certainly, this picture is complicated. For example, health and illness for all racial and ethnic groups follow a social gradient so that minority populations, which disproportionately occupy low socioeconomic strata, also predictably suffer relatively worse health outcomes than whites do. Although it is popular to blame the poor for the their poor healthy by pointing to risky health behaviors, careful studies of nationally representative populations conclude that the significantly higher prevalence of cigarette smoking, alcohol consumption, obesity, and physical inactivity are only one aspect of the relationship between lower socioeconomic status and poor health. Moreover, behavioral disparities must not be taken out of their societal context where unequal exposure to the stress of discrimination, inequitable access to healthy food and built environments, and inferior access to resources generally are integrally associated with many racial and ethnic differences in health behavior. In fact, racial and ethnic differences in health treatment and outcomes persist in multiple studies even after controlling for differences in insurance status, income, education, geography, and socioeconomic status. Researchers have identified numerous structural and individual determinants of these disparities at all levels. These include socioeconomic circumstances such as poverty, inferior education, and segregated housing conditions along with lack of access to healthy food choices or recreational facilities; systemic and organizational contributors such as medical practice settings and sources of insurance; and geographic proximity to care. The economic and social conditions called “social determinants of health” often drive patient-specific contributors to poor health such as poor family health history, diet, and low physical activity. All have been shown to contribute to the disparity of health outcomes experience by ethnic and racial minority patients in the United States. However, this book is about the single most important determinant of health disparities that is not being widely discussed in straightforward terms: this determinant is racial and ethnic discrimination against minority patient populations, an uncontrovertibly significant contributor to health inequality. The evidence that the majority of Americans involuntarily harbor anti-minority prejudices makes it impossible, even immoral, not to examine the impact of unconscious racism on health and health care. Therefore, this book makes a thorough examination of the scientific evidence that does exist to confirm that providers discriminate against patients and patients discriminate against providers. This cycle of discrimination produces inequality throughout the health care system. The inequality itself is not news. But the fact that it is avoidable challenges the complacency that allows the racial and ethnic discrimination that produces them to persist. This book calls for providers, patients, scientists, and jurists to face the uncomfortable truth that although overt racism, prejudice, and bigotry may have subsided in America, racial and ethnic injustice, unfairness, and even segregation in American health care have not. The most tragic proof that racial and ethnic injustice is alive and well is the phenomenon we politely call “health disparities.” The message of this book is that a significant cause of these health disparities is the unconscious racial and ethnic bias that infects our delivery system. Implicit racial and ethnic biases in health care are harmful, avoidable, and unjust. This book charts a way to deal with health and health care disparities as injustices, not merely as inevitable byproducts of human nature or a phenomenon subordinate to biological and social differences. Instead, the argument made here is that health inequality due to unconscious discrimination is a structural malady in need of a system cure. This book lays bare a disturbing contradiction. On one hand, injustice and inequality are anathema to our professed national identity. Yet on the other hand, unconscious bias has become an entrenched and acceptable social norm, empirically demonstrated to control decision-makers not only in health care, but in civil and criminal justice proceedings, law enforcement, employment, media, and education. Unconscious racism has become the new normal. Thus, to defeat inequality due to unconscious racism in health care, individuals as well as institutions must realign themselves away from this social norm that is incongruous with the core underlying values to which our nation’s doctors, patients, and health care professionals expressly aspire. The solutions this book proposes are comprehensive; they have their origin in law, and to some this may seem radical. But they are solutions grounded in a historical and empirical record. The solutions are further supported by original, qualitative interviews reported here. These narratives allow doctors, nurses, and patients to bring their voices and real-life experiences to bear on a worthy cause: achieving justice and equity in American health care. Chapter 1 recounts the historical origins of legally enforced discrimination that have laid the structural foundations for African, Asian, Hispanic, and Native Americans to suffer inferior health outcomes in the United States since this country’s inception. I argue that law has directly influenced the differences in health and health care experiences between minorities and whites throughout our nation’s history. When laws enforced slavery, segregations, and nationalism, minority health fared poorly. During the periods of our history when civil rights laws were effectively used to desegregate health care and promote equal access, health care disparities improved. Today, however, traditional civil rights laws have become irrelevant in the effort to bring justice to health care. Those antidiscrimination laws punish only outright bigotry and the most virulent forms of racism. Now that these forms of overt racism are out of vogue and mostly absent from the health care system, the rule of law has been neutralized and no longer controls racial discrimination. Therefore, the great American traditional of running two separate and unequal medical systems for white and non-white patients is back. Chapter 2 explains the nature and evidence of discrimination in contemporary health care. The quantitative and qualitative data gathered in this chapter explain that health care providers unintentionally discriminate against racial and ethnic minority patients—and that their unintentional discrimination directly and substantially contributes to ethnic and racial health care disparities. Moreover, the evidence also shows that patients hold implicit biases and thus react to providers discrimination through the lens of their own experiences with race bias and inequity. The result is a viciously reciprocal cycle of miscommunication between doctors and patients that ultimately harms patients’ health. When patients perceive or experience discrimination arising from implicit biases, they often respond rationally by seeking to minimize the reoccurrence of the offense. Thus, minority patients are more likely to switch providers, less likely to follow up on or adhere to their doctors’ advice, and more likely to generally distrust their providers. Decreased patient satisfaction and decreased continuity of care follow, to the detriment of minority health outcomes. Much of the current discourse on health disparities “blames the victim,” charging patients with non-adherence and with poor diet and living choices or alleging the existence of biologically based justifications for inequality. My analysis of patient bias does not belong to this genre. Instead, I employ the evidence that patients unconsciously react negatively to unconscious racism to explain how implicit bias is a culprit on both sides of the clinical encounter, which occurs within a structurally unsound environment that in turn reinforces bias. Chapter 3 presents a preponderance of evidence showing that providers’ disparate treatment of their minority patients is closely associated with their implicit racial and ethnic biases. This chapter identifies physicians’ unconscious racism as a primary contributor to health disparities. Chapters 4, 5, and 6 present the Biased Care Model, one of this book’s core contributions to advance our understanding of health and health care disparities. The Biased Care Model organizes the best social science literature on implicit bias into a conceptual framework to answer important, but hitherto unresolved questions raised by the Institute of Medicine in its landmark 2003 report on American health disparities. Specifically, the Biased Care Model identifies the mechanisms by which implicit biases affect disparate health outcomes. The model explains how health providers continue to discriminate against minority patients even as polls and surveys tell us that most Americans, especially doctors, are decidedly not racists. The model’s mechanisms are grounded in empirical literature and are supported by the voices of doctors and patients whose interviews confirm the presence and influences of implicit biases in their clinical experiences. Thus, the rich qualitative and quantitative data that supports the Biased Care Model spans three chapters. Chapter 4 describes the impact implicit biases have before a physician and patient meet, chapter 5 discusses the role of implicit biases during the clinical encounter, and chapter 6 examines the mechanisms that permit implicit biases to continue contributing to health disparities even after the clinical encounter ends. The questions these chapters confront are tough, and the facts are uncomfortable. The answers the Biased Care Model provides fill an important void in our understanding of the way health inequalities evolve, and thus they lay the foundation for fashioning evidence-based policy solutions. Chapter 7 introduces an evidentiary “game changer” in the discourse about addressing implicit bias in health care. This chapter explains the social science evidence that implicit racial and ethnic biases are malleable. Contrary to popular fiction, unconscious racism is neither inevitable nor unalterable. This chapter is full of evidence that confirms that the habit of acting out of one’s implicit racial biases can be changed. Therefore, the chapter concludes, health care providers and the institutions that employ them can be held morally responsible for addressing the inequities these biases cause. This chapter opens the way for structural responses to the health disparity crisis. The next chapter explains why responding to this crisis is not only a moral responsibility, but also appropriately a legal one. Chapter 8 answers the question that will plague many health care providers who read this book, especially those who are sympathetic to the cause of justice and equality in health care: Why do we need a law to deal with implicit bias? The short answer is that other avenues will simply not work. Political efforts at universalizing access, regulatory efforts at enforcing cultural competency, and private efforts at “doing the right thing” have all failed. At best, these well-intentioned efforts have only reinforced the culture in which it is assumed that explicit racial motives have little remaining influence on health disparities today. Implicit biases are not entirely impervious to these programs and policies, but the public health policy literature helps to explain why they are insufficient solutions. The more complete answer is that health care disparities are rooted in structural inequities and therefore require a structural solution. Consequently, the legal reforms I propose will change the context in which health care is delivered and shift the social norm that has tolerated health inequality for far too long. The policy problem presented by health care disparities has both the good and bad fortune to be a late-comer to the list of complex practical conundrums that fundamentally challenge broad constitutionally protected American values such as racial equality and justice, but require interventions at the intersection of law and science to solve. For example, law has joined with scientific expertise to help regulate the evolving challenges presented by climate change, genetically modified foods. and pharmacogenomics just to name a few examples. Accordingly, chapter 8 makes the case for strengthening legal interventions to promote health equality. Chapter 9 proposes concrete reforms founded on legal and scientific solutions to the problem of racial and ethnic health disparities. This chapter challenges current antidiscrimination law’s “naive” assumption that humans act solely in accordance with their explicit and conscious intentions. In fact, the scientific evidence indicates that we all act much more consistently with our unconscious and implicit intentions. I compare the assumptions about human behavior that underlie the current law to what we know about real human behavior as it impacts health and health care, and I argue that antidiscrimination law should better match reality. I conclude with an appeal for action directed towards the four stakeholder groups I hope to impact most: social scientists, health care providers, law and policy-makers, and patients. I ask each group to consider its role in eradicating health inequality and to consider this book’s broader implications for the fight for racial and ethnic equality beyond health care. While my focus here is on unconscious racism, I do not overlook other determinants of health disparities that will not succumb to legal remedies. Changing only the law will not solve the socioeconomic disparities that lie at the foundation of our society and produce the poor health experienced by many poor people. Yet neither do I use the complexity of the problem and its causes as an excuse to avoid forthrightly addressing the pervasiveness of discriminatory health care. I also cannot shrink from confronting implicit racial bias due to a seemingly paralyzing fear that doing so is the equivalent of charging health care providers with outright racism and bigotry. The cure for this paralysis is an accurate understanding that implicit and unconscious biases are facts of American life that contradict and work against most Americans’ true intentions. Physicians are no exception; they need not be racist to discriminate against racial minorities. Nevertheless, discrimination due to implicit bias must be addressed because it unnecessarily decreases the quality and length of life of people in this country who are not white. Distinguishing overt from unconscious racism frees us to honestly and candidly address the problem of providers’ implicit bias. In the process. we will see that the scientific evidence is legally sufficient to warrant or even mandate reform of antidiscrimination law. I reach one primary conclusion in this book. It is that the presently available social science evidence associating implicit racial and ethnic bias with health disparities provides a morally compelling and legally sufficient basis for legal action. A sufficient stack of “further research” –the social scientist’s beloved refrain—could not be generated fast enough to slow the devastating effects of implicit bias on the lives of tens of thousands of minority patients each year. Ignoring health disparities due to discrimination is costly. In addition to the nearly 84,000 people of color who needlessly lose their lives annually due to health disparities, there are significant economic burdens imposed by health care discrimination. A 2009 report by the Joint Center for Political and Economic Studies estimated that eliminating health disparities would have reduced direct medical care expenditures by $229.4 billion and indirect costs due to illness and premature death by approximately $1 trillion during 2003-2006. Therefore, the pages that follow unite the medical, neuroscientific, psychological, and sociological expertise on the issue of implicit bias and health disparities with the powerful influence of explicit and enforceable rules of law to devise an effective and innovative plan to reduce implicit biases in health care and eliminate the inequity they cause so that all in America can enjoy a just, humane health care system, regardless of color, race, or national origin.

#### 1] Antiblackness is contingent – closed conceptions of humanity solidifies racism

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The first thing to bear in mind you may wonder why in the beginning of the talk I talked about philosophical anthropology. And many people when they are trying to talk about social change they never think about *what a human being is* and this is something Fanon pays attention to. **Many people want to have closed conceptions of human beings because then human beings can be predicable**. In fact, in fanons writing he gave an example. One of the problems is that when he would walk in reason seems to walk out. One problem we have to bear in mind when we try to look at the question of human beings **in terms of rigid closed systems** is that we often are trying to get as a model of how we work as theorists on issues of social change that are actually based on what we can call **law like generalizations**. Now what is a law like generalization? It is when you make sure that whatever you say has no contradiction down the line. So if you are to say this much [gestures with hand] the next stage must be consistent with that, and the next stage until you are maximally consistent. Do you get that? But here is the problem – and I can just put it in a nut shell- nobody, nobody in this room would like to date, be married to, or be a best friend with a maximally consistent person. You know what that is. Its hell. And this tells you something, because if somebody where maximally consistent, you know what you would say that person is not reasonable. And we have a person here who does work on Hegel that can point out this insight, that a human being has the ability to evaluate rationality. Now why is that important? Because you see the mistake many of us make is **many of us want to push the human being into that maximized law like generalization model**. So when we think about our philosophical anthropology, some people, our question about intersectionality for instance, what some people don’t understand is nowhere is there ever a human being who is one identity. People talk about race – do you ever really see a race walking? You see a racialized man or woman, or transman or transwoman. Do you ever see a class walking? Class is embodied in flesh and blood people. And we can go on and on. So if we enrich our philosophical anthropology we begin to notice certain other things. And one of the other things we begin to realize is that **we commit a serious problem when we do political work.** And the problem is this. The question about **Wilderson** for instance. There is this discussion going on (and allot of people build it out of my earlier books). I have a category I call, as a metaphor, an antiblack world. You notice **an indefinite article** – **an anti-black world**. The reason I say that is because **the world is different from an anti-black world**. The project of racism is to create a world that would be **completely anti-black or anti-woman.** **Although that is a project, it is not a fait accompli**. People don’t seem to understand how recent this phenomenon we are talking about is. A lot of people talk about race they don’t even know the history of how race is connected into theonaturalism. How, for instance, Andalucia and the pushing out of the Moors. The history of how race connected to Christianity was formed. A lot of people don’t understand – from the standpoint of a species whose history is 220,000 years old, what the hell is 500 years? **But the one thing that we don’t understand to is we create a false model for how we study those last 500 years**. We study the 500 years as if the people who have been dominated **have not been fighting and resisting.** Had they not been fighting and resisting we wouldn’t be here. And then we come into this next point because you see the problem in the formulation of **pessimism** and **optimism** is they are both based on forecasted knowledge, a prior knowledge. **But human beings don’t have prior knowledge.** And in fact – what in the world are we if we need to have guarantees for us to act. You know what you call such people? Cowards. The fact of the matter is our ancestors – let’s start with enslaved ancestors. The enslaved ancestors who were burning down those plantations, who were finding clever ways to poison their masters, who were organizing meetings for rebellions, none of them had any clue what the future would be 100 years later. Some had good reason to believe that it may take 1000 years. But you know why they fought? Because they knew it wasn’t for them. One of the problems we have in the way we think about political issues is we commit what Fanon and others in the existential tradition would call a form of political immaturity. Political immaturity is saying it is not worth it unless I, me, individually get the payoff. When you are thinking what it is to relate to other generations – remember Fanon said the problem with people in the transition, the pseudo postcolonial bourgeois – is that they miss the point, you fight for liberation for other generations. And that is why Fanon said other generations they must have their mission. But you see some people fought and said no I want my piece of the pie. And that means the biggest enemy becomes the other generations. And that is why the postcolonial pseudo-bourgeoisie they are not a bourgeoisie proper because they do not link to the infrastructural development of the future, it is about themselves. And that’s why, for instance, as they live higher up the hog, as they get their mediating, service oriented, racial mediated wealth, the rest of the populations are in misery. The very fact that in many African countries there are people whose futures have been mortgaged, the fact that in this country the very example of mortgaging the future of all of you is there. What happens to people when they have no future? It now collapses the concept of maturation and places people into perpetual childhood. So one of the political things – and this is where a psychiatrist philosopher is crucial – is to ask ourselves what does it mean to take on adult responsibility. And that means to understand that **in all political action it’s not about you**. **It is what you are doing for a world you may not even be able to understand**. Now that becomes tricky, because how do we know this? **People have done it before**. There were people, for instance, who fought anti-colonial struggles, there are people (and now I am not talking about like thirty or forty years ago, I am talking about the people from day one 17th 18th century all the way through) and we have no idea what we are doing for the 22nd century. And **this is where developing political insight comes in.** Because **we commit the error of forgetting the systems we are talking about are human systems**. They are not systems in the way we talk about the laws of physics. A human system can only exist by human actions maintaining them. **Which means every human system is incomplete.** **Every human being is by definition incomplete**. Which means you can go this way or you can go another way. The system isn’t actually closed.

#### 2] Afropessimism is ahistorical.

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Allen and Ignatiev turned to this question in their further research, inspired by the insights of Du Bois. In the process they presented an exemplary model of a materialist investigation into the ideology of race, one that went from the abstract to the concrete. This work emerged alongside that of Barbara Fields and Karen Fields, David Roediger, and many others as a body of thought devoted to exposing race as a social construct. All of this research, in varying ways, has examined the history of the “white race” in its specificity. The guiding insight that must be drawn from it is that this racial phenomenon is not simply a biological or even cultural attribute of certain “white people”: it was produced by white supremacy in a concrete and objective historical process. As Allen put it on the back cover of his extraordinary vernacular history The Invention of the White Race: “When the first Africans arrived in Virginia in 1619, there were no white people there.” At the most immediate level, Allen was pointing to the fact that the word white didn’t appear in Virginia colonial law until 1691. Of course, this doesn’t mean that there was no racism before 1691. Allen’s argument was to show that racism was not attached to a concept of the white race. There were ideas of the superiority of European civilization, but this did not correspond to differences in skin color. The clearest example is that of the Irish, whose racial oppression by the English precedes their racial oppression of Africans by several centuries. Today white nationalists distort this history, attempting to use the racial oppression of the Irish to try to dismiss the history of white supremacy. Yet this example actually demolishes their entire framework. What the example of the Irish illustrates is a form of racial oppression that is not based on skin color and that in fact precedes the very category of whiteness. Indeed, the early forms of English racial ideology represented the Irish as inferior and subhuman, and this ideology was later repeated word for word to justify both the genocide of Indigenous people in the Americas and the enslavement of Africans. Nor was it only a matter of words: the very practices of settler colonialism, land seizures, and plantation production were established in Ireland. Allen demonstrates this with reference to specific laws: If under Anglo-American slavery, “the rape of a female slave was not a crime, but a mere trespass on the master’s property,” so, in 1278, two Anglo-Normans, brought into court and charged with raping Margaret O’Rorke were found not guilty because “the said Margaret is an Irishwoman.” If a law enacted in Virginia in 1723, provided that, “manslaughter of a slave is not punishable,” so under Anglo-Norman law it sufficed for acquittal to show that the victim in a slaying was Irish. Anglo-Norman priests granted absolution on the grounds that it was “no more sin to kill an Irishman than a dog or any other brute.”9 So racial oppression arises in the Irish case without skin color as its basis. We are forced to ask how we end up with a racial ideology revolving around skin color that represents African people as subhuman and that considers both Irish and English to be part of a unitary “white race.” The historical record quite clearly demonstrates that white supremacy and thus the white race are formed within the American transition to capitalism, specifically because of the centrality of racial slavery. However, we have to resist the temptation, imposed on us by racial ideology, to explain slavery through race. Slavery is not always racial. It existed in ancient Greece and Rome and also in Africa, and was not attached specifically to a racial ideology. Slavery is a form of forced labor characterized by the market exchange of the laborer. But there are various forms of forced labor, and its first form in Virginia was indentured labor, in which a laborer is forced to work for a limited period of time to work off a debt, often with some incentive like land ownership after the end of the term. The first Africans to arrive in Virginia 1619 were put to work as indentured servants, within the same legal category as European indentured servants. In fact, until 1660 all African American laborers, like their European American counterparts, were indentured servants who had limited terms of servitude. There was no legal differentiation based on racial ideology: free African Americans owned property, land, and sometimes indentured servants of their own. There were examples of intermarriage between Europeans and Africans. It was only in the late seventeenth century that the labor force of the American colonies shifted decisively to African slaves who did not have limits on their terms of servitude. As Painter points out in The History of White People, these forms of labor and their transformations are fundamental in understanding how racial ideology comes about: Work plays a central part in race talk, because the people who do the work are likely to be figured as inherently deserving the toil and poverty of laboring status. It is still assumed, wrongly, that slavery anywhere in the world must rest on a foundation of racial difference. Time and again, the better classes have concluded that those people deserve their lot; it must be something within them that puts them at the bottom. In modern times, we recognize this kind of reasoning as it relates to black race, but in other times the same logic was applied to people who were white, especially when they were impoverished immigrants seeking work.10 “In sum,” Painter writes, “before an eighteenth-century boom in the African slave trade, between one-half and two-thirds of all early white immigrants to the British colonies in the Western Hemisphere came as unfree laborers, some 300,000 to 400,000 people.”11 The definitions of whiteness as freedom and blackness as slavery did not yet exist. It turns out that defining race involves answering some unexpected historical questions: How did some indentured servants come to be forced into bondage for their entire lives rather than a limited term? How did this category of forced labor come to be represented in terms of race? Why did the colonial ruling class come to rely on racial slavery when various other regimes of labor were available? The first economic boom of the American colonies was in Virginia tobacco production in the 1620s, and it was based on the labor of primarily European indentured servants. African Americans were only about a fifth of the labor force: most forced labor was initially European, and the colonial planter class relied on this forced labor for its economic growth. But they couldn’t just rely on European indentured labor because it was based on voluntary migration, and the incentive to participate in a life of brutal labor and die early was not sufficient to generate a consistently growing workforce. As Barbara Fields puts it, “Neither white skin nor English nationality protected servants from the grossest forms of brutality and exploitation. The only degradation they were spared was perpetual enslavement along with their issue in perpetuity, the fate that eventually befell the descendants of Africans.”12 African Americans, on the other hand, had been forcibly removed from their homelands. So the ruling class began to alter its laws to be able to deny some laborers an end to their terms of servitude, which they were only able to accomplish in the case of African laborers. What really changed everything was Bacon’s Rebellion in 1676. This began as a conflict within the elite planter class, directed toward a brutal attack on the Indigenous population. But it also gave rise to a rebellious mob of European and African laborers, who burned down the capital city of Jamestown and forced the governor to flee. The insurrectionary alliance of European and African laborers was a fundamental existential threat to the colonial ruling class, and the possibility of such an alliance among exploited peoples had to be prevented forever. Here we see a watershed moment in the long and complex process of the invention of the white race as a form of social control. The ruling class shifted its labor force decisively toward African slaves, and thus avoided dealing with the demand of indentured servants for eventual freedom and landownership. It fortified whiteness as a legal category, the basis for denying an end to the term of servitude for African forced labor. By the eighteenth century the Euro-American planter class had entered into a bargain with the Euro-American laboring classes, who were mostly independent subsistence farmers: it exchanged certain social privileges for a cross-class alliance of Euro-Americans to preserve a superexploited African labor force. This Euro-American racial alliance was the best defense of the ruling class against the possibility of a Euro-American and African American working-class alliance. It is at this point, Nell Painter concludes, that we see the “now familiar equation that converts race to black and black to slave.”13 The invention of the white race further accelerated when the Euro-American ruling class encountered a new problem in the eighteenth century. As the colonial ruling class began to demand its independence from the divinely ordained executives and landed wealth of the English nobility, they made claims for the intrinsic equality of all people and the idea of natural rights. As Barbara Fields puts it: Racial ideology supplied the means of explaining slavery to people whose terrain was a republic founded on radical doctrines of liberty and natural rights, and, more important, a republic in which those doctrines seemed to represent accurately the world in which all but a minority lived. Only when the denial of liberty became an anomaly apparent even to the least observant and reflective members of Euro-American society did ideology systematically explain the anomaly.14 In other words, the Euro-American ruling class had to advance an ideology of the inferiority of Africans in order to rationalize forced labor, and they had to incorporate European populations into the category of the white race, despite the fact that many of these populations had previously been considered inferior.