# 1AC

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#### Contention 1 is Drug Prices

#### Evergreening keeps Drug Prices high.

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

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

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

* AT Medicare CP – won’t cover Drugs – CP can’t fiat coverage

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

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

#### That kills Millions.

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

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

#### Counterfeit Drugs cause Anti-Biotic Resistance.

Jahnke 19 Art Jahnke 1-14-2019 "How Bad Drugs Turn Treatable Diseases Deadly" <https://www.bu.edu/articles/2019/how-bad-drugs-turn-treatable-diseases-deadly/> (Senior editor Art Jahnke began his career at the Real Paper, a Boston area alternative weekly. He has worked as a writer and editor at Boston Magazine, web editorial director at CXO Media, and executive editor in Marketing & Communications at Boston University, where his work was honored with many awards. Art has served on the editorial board of the Boston Review and has taught at Harvard University summer school and Emerson College.)//Elmer

Four decades later as a Boston University professor of biomedical engineering and materials science and engineering, Zaman was reminded of the dangers of low-quality drugs in his native country when he learned that **more than 200 people in the city of Lahore died after being treated with an adulterated version of a hypertension drug.** That event, in 2012, altered the course of Zaman’s research. Now, he focuses on the global problem of “**substandard drugs**,” poorly made medicines containing ingredients that are either ineffective or toxic. His most recent discovery has startling implications for our understanding of drug resistance: a low-quality version of rifampin, a broad spectrum antibiotic typically used as the first line of defense to treat tuberculosis, **can** greatly **contribute to the development of drug-resistant infections**. The findings, published in Antimicrobial Agents and Chemotherapy, are particularly pressing because **drug-resistant TB** is **an increasing** **problem worldwide**. Of the **10 million new cases** of tuberculosis in 2016, about 600,000 were rifampin resistant, requiring second-line treatments which come with increased toxicity. “**There had not been a definitive study** showing that lack of [antibiotic] quality leads to resistance,” says Zaman, who is also a Howard Hughes Medical Institute Professor of Biomedical Engineering and International Health. “**Now we are sure that it does**, and it does with TB, **a** global **problem that has become stubbornly hard to resolve**.” “We had always thought of this a scientific issue, but now it is also an ethical issue.”Muhammad Zaman Zaman says substandard drugs, as well as drugs that are **deliberate counterfeits**, are all too common in developing nations. A recent survey by the World Health Organization found that in low- and middle-income countries, **one in ten medicines is substandard or falsified**. One contributing factor could be that government enforcement of safe manufacturing practices is feeble or nonexistent. In Pakistan, for example, a country of nearly 200 million people, only a handful of federal inspectors monitor the quality of drug manufacturing.

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

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

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

#### High Drug Prices pushes people into poverty – our internal is causal.

Hoban 10 Rose Hoban 9-13-2010 "High Cost of Medicine Pushes More People into Poverty" <https://www.voanews.com/science-health/high-cost-medicine-pushes-more-people-poverty> (spent more than six years as the health reporter for North Carolina Public Radio – WUNC, where she covered health care, state health policy, science and research with a focus on public health issues. She left to start North Carolina Health News after watching many of her professional peers leave or be laid off of their jobs, leaving NC with few people to cover this complicated and important topic. ALSO cites Laurens Niens who is a Health Researcher at Erasmus University Rotterdam)//Elmer

Health economist Laurens Niëns found that drugs needed to treat chronic diseases could be considered unaffordable **for many people in poor countries**. Medicines can be expensive and often make up a large portion of any family's health care budget. And the burden can be even greater for people in poor countries, where the **cost of vital medicines can push them into poverty**. The problem is growing as more people around the world are diagnosed with chronic diseases such as high blood pressure and diabetes. Being diagnosed with a chronic disease usually compells patients to seek treatment for a prolonged period of time. That increases the eventual price tag for health, says health economist Laurens Niëns at Erasmus University in the Netherlands. Niëns examined medication pricing data from the World Health Organization and also looked at data from the World Bank on household income in many countries. Using the data, he calculated how much people need to spend on necessities such as food, housing, education and medicines. "The medicines we looked at are medicines for patients who suffer from asthma, diabetes, hypertension and we looked at an adult respiratory infection," Niëns says. "Three conditions are for chronic diseases, which basically means that people need to procure those medicines each and every day." Niëns focused on the cost of medicine for those conditions. He found the essential drugs could be considered unaffordable for many people in poor countries - so much so that their cost often pushes people into abject poverty. "The proportion of the population that is living below the poverty line, plus the people that are being pushed below the poverty line, can **reach up to 80 percent** in some countries for some medicines," Niëns says. He points out that generic medicines - which are more affordable than brand-name medications - are often **not available in the marketplace**. And, according to Niëns, poor government policies can drive up the cost of medications. "For instance, a lot of governments actually tax medicines when they come into the country," he says. "[They] have no standard for the markups on medicines through the distribution chain. So often, governments think they pay a good price for the medicines when they procure them from the producer. However, before such a medicine reaches a patient, markups are sometimes up to 1,000 percent."

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

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

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

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

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

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

#### Evergreening restricts Generic Patents by artificially extending Patent Cliffs.

Moir and Gleeson 14 Hazel Moir and Deborah Gleeson 11-5-2014 "Explainer: evergreening and how big pharma keeps drug prices high" <https://theconversation.com/explainer-evergreening-and-how-big-pharma-keeps-drug-prices-high-33623> (Adjunct Associate Professor; economics of patents, copyright and other "IP", Australian National University AND Lecturer in Public Health, La Trobe University)//Elmer

Efforts by pharmaceutical companies to extend their patents cost taxpayers millions of dollars each year. In some cases they also mean people are subjected to unnecessary clinical trials. **Big pharma** makes big profits. Their useful new **drugs are patented**, **protecting them from competition** and allowing them to charge high prices. When the patent ends, other companies are allowed to supply the previously patented drug. These are **known as generics**. The prices of generic drugs are much lower than the prices of in-patent drugs – it has been suggested that for widely used drugs price falls can be as much as 95%. Pharmaceutical companies want to get their new products listed on the Pharmaceutical Benefits Scheme (PBS), because they will sell in much higher volumes. Taxpayers have an interest in ensuring that these drugs move from the high in-patent price to the much lower off-patent price as early as possible. On average, a patent provides effective protection from competition for about 14 years. But, of course, **companies** like monopolies and would like to **extend the patent period**. Over the past few decades they have **used** a process known as evergreening to keep generic companies out of the market for longer. How evergreening works **Evergreening** is achieved by seeking extra patents on variations of the original drug – new forms of release, new dosages, new combinations or variations, or new forms. Big pharma refers to this as “lifecycle management”. Even if the patent is dubious, the company can earn more from the higher prices than it pays in legal fees to keep the dubious patent alive. Evergreening is possible because in Australia the standard required to get a patent is very low. Different methods of delivering drugs (such as extended release, for example) have been known for decades. But when one of these known delivery methods is combined with a known drug, the patent office considers this sufficiently inventive to grant a new 20-year patent. Another favourite evergreening strategy is to patent a slight variation of the drug. Brand pharmaceutical companies argue that these “lifecycle management” patents provide improved health outcomes to the community. They meet the (very low) patentability thresholds of novelty and inventiveness. Critics argue that the claimed improved health outcomes are small or non-existent. An evergreening story: from Efexor to Efexor-XR to Pristiq An example is useful. In the case of the depression drug **venlafaxine** (marketed as Efexor), the original version had major side-effects. However, when provided in extended release form these side-effects were substantially reduced. Naturally the extended release form (Efexor-XR) became preferred. Although it might seem obvious to combine venlafaxine with an extended release form to overcome the side-effect problem, the patent office **granted two new patents** for extended release versions of venlafaxine. One of these was written in such a broad form that it **delayed generic entry by two and a half years**, while legal wrangling took place. Eventually the evergreening patent was declared invalid. But the cost to taxpayers of this delay is estimated at $209 million. Pfizer has a second evergreening strategy for venlafaxine. When venlafaxine is taken, the human body converts it to desvenlafaxine. In other words desvenlafaxine is a variant of the original active pharmaceutical ingredient venlafaxine. Clearly the two compounds are closely related. So it is astonishing that desvenlafaxine passed the tests for getting a patent. Desvenlafaxine is marketed as Pristiq. Pristiq entered the market early in the two-and-a-half-year period of legal wrangling over the extended release venlafaxine (Efexor-XR) patent. Pfizer’s marketing of Pristiq in February 2009 was so lavish that it attracted the attention of investigative journalists. Pristiq has no additional benefits for patients. Despite this, during the first six months of 2014 half of prescriptions were written for Pristiq rather than for the clinically identical Efexor-XR. But Pristiq costs between $A22.32 and $A26.50 more than Efexor-XR, depending on the dose. Based on reported prescription volumes in 2013-14, the cost to the taxpayer of doctors prescribing Pristiq rather than Efexor-XR exceeds $21 million a year. Unless generic companies challenge the desvenlafaxine patent, there will be **no generic versions of Pristiq until after August 2023**, when the patent expires.

#### That inhibits India’s Pharma Industry – exports of Generics is key to revitalize India Pharma Leadership.

Neelakantan 14 Murali Neelakantan 11-11-2014 “Indian Pharmaceutical Industry: Affordable Access to Healthcare for all” https://web.archive.org/web/20150315092713/https://abcmundial.com/en/news/brics/technology/3838-indian-pharmaceutical-industry-affordable-access-healthcare-all/ (consejero general global de Cipla Limited)//Elmer

The story of the Indian pharma sector could well have been like the IT sector if only enough attention was paid to its achievements and the huge impact it has had on healthcare around the world. Unlike other manufacturing or heavy industries in **India**, the **pharma** sector is innovative, widely **acknowledged as making a global impact in** the **treatment** of diseases like HIV AIDS[1] and also able to support the healthcare needs of the world[2]. The fact that Indian factories are licensed to produce 3,685 drugs compared with 3,815 made within the UK suggests that Indian factories meet global quality standards and are able to produce complex drugs.[3] While news of regulators visiting Indian manufacturing facilities and finding fault with processes is widely reported, very little is said about how routine this is. Gerald Heddell, director of inspections, enforcement and standards at the MHRA, stressed that the number of problems identified by regulators in India was in proportion to the volume of medicines they produced. “When we look back over 110 inspections we conducted over the last two years in India, we had significant concerns with 9 or 10 companies,” he said. “That does not represent a statistically higher proportion than in other parts of the world. India stands out because it is just such a big supplier.”[4] The **Indian pharma Industry** **produces** about **20%** [5] **of** the **global generic drugs** **with the US accounting for** nearly **28 per cent of Indian pharmaceutical exports**[6], followed by the European Union at 18 per cent and Africa at over 17 per cent.[7] This should be a clear acknowledgement of the **global leadership that Indian pharma industry has** achieved which would have been impossible without following global quality standards. Another popular criticism of Indian pharma has been that there is insufficient investment in innovation and R&D. Despite over 500 new drugs being discovered by Indian pharma companies during 1985 – 2005, there seems a perception that India thrives on copying foreign products[8]. A recent study by Evaluate[9], a leading independent specialist pharma consultancy, reports that there is little difference in the investment by “innovators” and “generics” and it is just a myth that “innovators” invest heavily in research while “generics” don’t. Despite well publicised claims of the Western world, there seems to be a marked decrease in R&D investments[10] and this trend is expected to continue.[11] When one realises that almost 50% of the European pharma patents are either lying dormant or filed in order to block competitors[12] one wonders how innovation is being defined and encouraged. Is it innovation if the effect is stifling further innovation and competition and creating barriers for improvements? **Indian pharma** industry has clearly demonstrated that it **has** the **potential to be** a part of **the solution** for universal access to healthcare. India’s strength is **innovating** **to improve global access to medicines** as opposed to developing more and more “me too” drugs which have been traditionally defined by the West as innovation. There is now a growing acknowledgment that the existing IPR regime that is being touted by the West doesn’t foster innovation. As such, the current patent system is itself reeling from the ill effects of patent assertion entities (trolls) that do not produce anything of value but merely hold patents with a view to threatening businesses with infringement actions to obtain licensing revenue. Patents have other flaws that relate to monopoly power, both because it harms consumers who have to pay high prices and because it can hinder improvements and subsequent innovations.[13] Static distortions, too little incentive for original research, and wasteful duplication of research are some of the most serious problems of the patent system.[14]In addition to TRIPs - compliant patent regimes which ostensibly promote innovation and discourage copying, the next generation of barriers to competition seems to be set up as global standards. Just as IPR was addressed by the WTO in TRIPs, the more recent barriers are likely to be in the form of harmonised regulations. Patent linkage[15] (in Canada and the US for example) denies access to markets on a mere allegation of patent infringement. Despite the US Supreme Court[16] indicating that patent linkage needs to be reconsidered and access to medicines should not be denied on allegation of patent infringement and recent attempts by Italy to introduce a system of patent linkage resulted in a notice from the European Commission asking for the removal of these provisions from Italian law,[17] patent linkage is a real barrier to competition in healthcare which is beset with unaffordable drugs. Data exclusivity extends the term of monopoly enjoyed by patent holders and keeps out competition and innovation without any benefits to society. This concept does not exist in sectors other than pharma and there seems to be no real rationale for pharma to get special treatment. In fact, data exclusivity raises several ethical and moral issues. Countries have always been allowed to customise their IP policy and regulation based on their unique local conditions. Some countries are more technologically proficient than others, and this distinction may warrant separate norms in areas of technology that they are strong in.[18] Even where harmonisation has been accepted as a concept, like the EU for example, it has been implemented in a manner that is sympathetic to the local conditions of individual countries. India’s strength and expertise lies in developing drugs which are accessible for patients across the globe. India’s stand on IPR regime acknowledges that diverse countries cannot be forced to one uniform regulatory system. This principled stand was recently demonstrated during the Bali round of talks on the Trade Facilitation Agreement.[19] In the background of the Trans Pacific and Trans Atlantic Partnerships being negotiated, India has the opportunity to demonstrate leadership in the global market place by pioneering the opposition to using harmonisation as a proxy for barriers to competition. While the US and its allies may officially oppose India’s view of the IPR regime they have realised that the key to their sustainable development is the ability of government to ensure that healthcare is accessible to everyone, not just the rich. Cost of healthcare has increased significantly causing an alarming number of patients to go off treatment, risk importing counterfeits[20] or in many cases, declare bankruptcy[21]. The issue of access to healthcare in the developing world has, despite some efforts by the UN, The Global Fund, PEPFAR and other aid institutions, not had the impact that it should have. There is a realisation, albeit unarticulated, that Indian Pharma companies have the potential to be, like Indian technology companies averted the y2K crisis, a key element of the solution to world's healthcare crisis. **Now is** a great **opportunity for India to demonstrate leadership** in IPR regimes as more and more countries like South Africa and Brazil are following India’s example.

#### Indian pharma strength is key to their soft power

Jha 16 Prem Shankar Jha 11-5-2016 “Let India unleash its soft power” <https://www.thehindu.com/opinion/lead/Let-India-unleash-its-soft-power/article13292272.ece> (Writer at the Hindu)//Elmer

And why stop at food grains? In drought-struck regions, contaminated water kills much faster than hunger and takes the very young and the very old first. The **Indian pharmaceuticals** industry **is the envy of the world**, **because it produces and sells** **medicines at a tenth to a thirtieth** of the **retail prices abroad**. **Can Delhi not buttress its** **food aid with medicines** and vitamins? This will give **an entirely new meaning to** the concept of **Soft Power for**, **unlike the West** in its present incarnation, **it would be seeking to build influence by protecting** and preserving, **not destroying**; by expanding peoples' futures instead of ending them in darkness. We have been relatively **slow to realise** our **full potential** for the exercise of soft power. This could be because of our too-ready acceptance of a concept that was created by an American to address American foreign policy concerns. In Joseph Nye's original definition, soft power originated in the capacity to attract others to your country's culture, values and institutions. Indian policymakers have taken this to heart and relied mainly upon India's open society, democratic institutions, lack of aggressive intent and willingness to share the burden of U.N. peacekeeping and policing the global commons, to garner respect and support in the international community. It is only in the last half-decade, as the Westphalian international order crumbled and India's neighbourhood became increasingly unstable, that New Delhi has begun to explore the economic dimensions of ‘soft power' seriously. Afghanistan has been the focus of its initial efforts, and its success is attested to by the threat (irrational though it is) that Pakistan feels from it.

#### Successful India Soft Power solves Extinction

Kamdar 7, Mira. Planet India: How the fastest growing democracy is transforming America and the world. Simon and Schuster, 2007. (Bernard Schwartz Fellow at the Asia Society in 2008)//Elmer

**No other country matters more to the future of our planet than India**. There is no challenge we face, no opportunity we covet where India does not have critical relevance. **From combating global terror to finding cures for dangerous pandemics, from dealing with the energy crisis to averting the worst scenarios of global warming**, from rebalancing stark global inequalities to spurring the vital innovation needed to create jobs and improve lives—**India is now a pivotal player**. The world is undergoing a process of profound recalibration in which the rise of Asia is the most important factor. India holds the key to this new world. India is at once an ancient Asian civilization, a modern nation grounded in Enlightenment values and democratic institutions, and a rising twenty-first-century power. With a population of 1.2 billion, India is the world’s largest democracy. It is an open, vibrant society. India’s diverse population includes Hindus, Muslims, Sikhs, Christians, Buddhists, Jains, Zoroastrians, Jews, and animists. There are twenty-two official languages in India. Three hundred fifty million Indians speak English. India is the world in microcosm. Its geography encompasses every climate, from snowcapped Himalayas to palm-fringed beaches to deserts where nomads and camels roam. A developing country, India is divided among a tiny affluent minority, a rising middle class, and 800 million people who live on less than $2 per day. India faces all the critical problems of our time—extreme social inequality, employment insecurity, a growing energy crisis, severe water shortages, a degraded environment, global warming, a galloping HIV/AIDS epidemic, terrorist attacks—on a scale that defies the imagination. India’s goal is breathtaking in scope: transform a developing country of more than 1 billion people into a developed nation and global leader by 2020, and do this as a democracy in an era of resource scarcity and environmental degradation. The world has to cheer India on. If India fails, there is a real risk that **our world will become hostage to political chaos, war over dwindling resources, a poisoned environment, and galloping disease**. Wealthy enclaves will employ private companies to supply their needs and private militias to protect them from the poor massing at their gates. But, if India succeeds, it will demonstrate that it is possible to lift hundreds of millions of people out of poverty. It will prove that multiethnic, multireligious democracy is not a luxury for rich societies. It will **show us how to save our environment, and how to manage in a fractious, multipolar world**. India’s gambit is truly the venture of the century.

### 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.

### 1AC---Method

#### 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.

#### Debates surrounding health policies are good.

Shelton 17, Rachel C., Derek M. Griffith, and Michelle C. Kegler. "The promise of qualitative research to inform theory to address health equity." Health Education & Behavior 44.5 (2017): 815-819. (Assistant Professor, Sociomedical Sciences, Columbia University)//Elmer

In the 30 years since the 1985 Secretary’s Task Force Report on Black and Minority Health was released (Heckler, 1985), the 20 years since Society of Public Health Education (SOPHE) published its first research agenda (Clark & McLeroy, 1995), and the decade since the Inaugural SOPHE Summit on Eliminating Racial and Ethnic Health Disparities (Airhihenbuwa, 2006), the patterns of health and illness in the United States continue to tell a story of societal inequity. Whether implicit or explicit, theory is critical in that it serves as a lens through which we can view the contours of health issues and inequities. Given our modest progress in reducing health disparities over the past 20 years, it is possible that our current theories are not directing us to the priority determinants, which, if modified, could enable us make significant progress in achieving health equity. It is also plausible that the theory-based change strategies and interventions that researchers and practitioners typically implement fall short of what is needed to create significant changes to redress structural, social, and historical injustices that have contributed to health disparities. Qualitative methods are uniquely poised to offer insight into not just the theory of the problem but insight into the principles and theories that may be the best candidates on which to build an intervention (McLeroy et al., 1993). Yet qualitative methods (used on their own or in the context of mixed-methods research) tend to be perceived within the scientific community as less valuable and important than quantitative methods in the context of health disparities research. To understand the perspectives, context, and daily lives and experiences that shape health, qualitative research is essential. Particularly in the context of health education and health promotion, qualitative research has provided critical insights into the factors that shape modifiable determinants of health across all levels of the ecological model (McLeroy, Bibeau, Steckler, & Glanz, 1988). Previously, there has been little critical or systematic consideration of how qualitative research could be used to advance research on health disparities or health equity in our field. In this commentary, we reflect on some of the theoretical and conceptual challenges facing health disparities and health equity research and highlight how qualitative methods provide important and unique insights that inform future research and practice. Role of Theory In health education and health promotion, we discuss the theory of the problem and change theories or theories of action (Glanz, Rimer, & Viswanath, 2015). Theories of the problem are explanatory and help identify and describe determinants of a problem and identify modifiable factors that can be prioritized for change (Glanz et al., 2015). Theories of change inform how to design intervention strategies that will influence priority determinants and also help pinpoint logical short-term and intermediate outcomes for logic models and evaluation efforts (Bartholomew, Parcel, Kok, Gottlieb, & Fernandez, 2011; Crosby, Kegler, & DiClemente, 2009; Eldredge, Markham, Ruiter, Kok, & Parcel, 2016; Glanz et al., 2015). Thus, theories provide an organizing framework for our research and practice by systematically guiding us toward constructs to target with our interventions and organize our evaluation and research results. Despite growing recognition of the importance of broader organizational, community, and policy-related factors in shaping health and health disparities, our field’s tendency to use theories at the individual and interpersonal levels is well documented (Golden & Earp, 2012; Painter, Borba, Hynes, Mays, & Glanz, 2008). Even our program and intervention planning models, which allow for selection of constructs from a range of theories depending on the identified determinants (Airhihenbuwa, 1995; Bartholomew et al., 2011; Green & Kreuter, 2005; Iwelunmor, Newsome, & Airhihenbuwa, 2014), largely rely on our existing theories to shape the questions we ask and how we go about addressing the identified determinants. In the context of informing efforts to pursue health equity, however, the challenge is that few of our theories specify how constructs intersect and interact across levels, and which of these are most powerful in explaining behavior and the environmental conditions that create, maintain, or exacerbate disparities. Moreover, our theories **generally** **do not provide guidance** as to which causal pathways are most likely to specifically reduce disparities and in which populations (Diez Roux, 2012). Additionally, theories at the higher levels of the social ecology are less likely to be operationalized and measured in a manner consistent with our quantitative research methods, which may present barriers to more widespread application. Furthermore, with some rare exceptions (e.g., critical race theory/public health critical race praxis; Ford & Airhihenbuwa, 2010a, 2010b), our existing theories in health behavior and health education neither critically examine nor address the important fundamental causes of health, including the social and political determinants that may be at the root of health inequities. Given the nature of short-term grant and budget cycles (and prohibitions on lobbying with federal funds), it is not surprising that the theories most typically pursued in our field focus on proximal or short-term outcomes and what is perceived as more easily addressable determinants of health. Therefore, as a field, we do not typically recognize or attempt to address historical and ongoing societal factors that have implications for health disparities like racism and power. The Promise of Qualitative Methods In considering how qualitative research might advance theory pertinent to health equity, it is first important to recognize that experts approach the application of theory in research from a variety of perspectives. Hennink, Hutter, and Bailey (2011) describe an interplay between deductive and inductive reasoning in their approach and describe how theory is central in the design phase with a clear role in framing research questions and informing conceptual models and frameworks (Hennink et al., 2011). Depending on the goal and context of the research, the analytic process can involve developing inductive theory or applying deductive codes from the research questions, existing theory, or conceptual frameworks. Hennink et al. (2011) argue there is always a theory underlying research and making it explicit is essential, typically in the form of a conceptual framework to guide the research (e.g., categories of questions asked, coding, organization of data, and results; Hennink et al., 2011). Patton (2015) describes theory primarily within the context of sampling and analysis. For example, he describes deductive theoretical sampling for deepening or verifying theory-derived constructs, giving examples such as resilience, trauma, and respect. He also describes inductive grounded theory sampling in which the sample is constructed as the emerging theory begins to take shape and evolves from exploratory to verification. These examples highlight that there is a vast array of opportunities for theory to inform disparities-oriented research. To date, however, there has been relatively little attention paid to the use of qualitative research to advance theory in the area of health disparities and health equity. The volume of literature describing health disparities and discussing strategies to eliminate health disparities has not made strong conceptual or empirical distinctions between minority health promotion and health disparities elimination (Srinivasan & Williams, 2014). While both outcomes are important and deserve attention, it is likely that each has different determinants and intervention strategies that matter most; as such, the theoretical and conceptual frameworks used to study them may also be different. Furthermore, there are some limitations to relying predominately on a comparative approach that has become the cornerstone of health disparities research in recent years (Bediako & Griffith, 2007). In this context, qualitative methods can play an important role in how we understand and describe the problem of health inequities and their determinants. Not only can these approaches help illuminate social, cultural, and political factors that may underlie health disparities, but qualitative approaches are also uniquely positioned to document and contextualize how these factors affect health across levels of the social–ecological framework in a more nuanced and in-depth way. Qualitative methods also have the potential to illuminate new theories of change, particularly those that operate at higher levels of the social ecological framework, as well as interactions between constructs at varying levels of the framework. Providing insight into how well-accepted theoretical constructs should be operationalized or adapted for specific subpopulations (e.g., social norms, social capital, intention, or attitudes; Burke, Bird, et al., 2009; Pasick, Barker, et al., 2009; Pasick, Burke, et al., 2009) is another potential strength of a qualitative approach. By acknowledging the complex interplay of factors that influence and underlie health disparities, social ecologic approaches that have been informed by qualitative methodologies may provide a good blueprint for moving toward health equity. While qualitative methods offer these possibilities, according to Hennink et al. (2011), without theory development of some kind, qualitative research ends purely in description, which does not explain a phenomenon and neglects to answer “how” and “why” questions (Hennink et al., 2011). Similarly, Patton (2015) states that “much qualitative inquiry stops at reporting the explanations of the people studied” (p. 583) without attempting further qualitative causal analysis. He further acknowledges that asserting that qualitative analysis can yield causal explanations remains controversial, and this is undoubtedly true in health education and health promotion as well. This may relate in part to the tendency by qualitative researchers to downplay or minimize the generalizability of findings, often due to relatively small sample sizes, which is in sharp contrast to quantitative research that seeks to highlight the generalizability and reproducibility of its findings. However, we encourage our fellow qualitative researchers to go further with our studies and make a concerted (and well-documented) effort to develop, extend, or refine theory within the context of trying to figure out how to reduce health disparities, and when appropriate, to highlight any insights that are consistent with prior work and could be scaled up and tested on a broader scale. Moving Forward To make real progress in addressing health disparities and moving toward health equity will require a renewed commitment to and deeper understanding of qualitative research on the part of health disparities researchers in our field. In particular, we encourage researchers to move beyond only descriptive documentation of disparities toward thinking about mechanisms and theory building and refining, with an eye toward informing interventions, strategies, and health promotion messaging in public health and clinical contexts. Through this process, it will be important that researchers refrain from relying only on individual and interpersonal theories, and begin explicitly incorporating behavior change theories with theories at the social, organizational, community, and policy levels, and consider how factors interact synergistically across levels. While we agree that the field should be selective and parsimonious with respect to the development of new theories (Glanz et al., 2015), we also assert that with respect to promoting health equity, there is room for the development of new theories and refinement of theoretical constructs, particularly for those pertaining to the social, organizational, community, and policy levels. Building theoretical and conceptual frameworks and models that can be applied across multiple levels is highly pertinent to disparities research in several ways. First, these theories are more likely to address the larger societal and social factors that shape disparities and can help researchers identify which factors matter most across levels (e.g., what is most relevant and meaningful for a population), and should therefore be prioritized as intervention or policy targets. While most research to date has focused on using qualitative research to provide insight into the populations experiencing inequities, we recommend researchers use qualitative research to advance understanding of “behaviors in context,” and the settings and social context in which disparities arise (Burke, Joseph, Pasick, & Barker, 2009; Okechukwu, Davison, & Emmons, 2014). This includes investigating the contexts in which interventions to address disparities are implemented, with an eye toward theory building and theory refinement. Second, we encourage researchers to move beyond approaching health disparities largely as a single dimension toward considering the possible intersectionality of social dimensions that have implications for health equity (Bauer, 2014; Bowleg, 2008). Using qualitative research that is grounded in the daily experiences of people’s lives may help address the methodological challenges of thinking about social categories as additive and instead frame them as related and intersecting social structures that create and recreate social disadvantage and health inequity. There are also many opportunities for researchers to use more community-engaged, participatory, and action-oriented theories and frameworks that not only focus narrowly on health disparities but also encourage an assets-based approach that focuses on promoting health equity (Grieb, Smith, Calhoun, & Tandon, 2015; Wallerstein & Duran, 2006). This Commen-tary is consistent with Bowleg’s (2017) Perspective in Health Education & Behavior, which advocates for the wider use of critical theoretical frameworks in health equity research. In making advances in this area, it is also clear that we have much to learn from other disciplines that have rich histories in both theory and qualitative research, including anthropology, history, and sociology (Chowkwanyun, 2011; Hirsch, Wardlow, & Smith, 2009; Livingood et al., 2011; Livingood, Allegrante, & Green, 2016; Nathanson, 2007; Pasick & Burke, 2008). Of note, these fields have also incorporated a much broader range of qualitative approaches in their research (e.g., textual analysis, comparative ethnography) that we encourage researchers to explore and embrace. Finally, we recommend that in examining health disparity issues, researchers in this area be thoughtful and detailed in the social dimension and lenses through which they are grouping “disparity” populations, as there is tremendous diversity and heterogeneity within groups (e.g., documented differences among Latinos in health disparities and determinants of health by country of origin; Shelton, Jandorf, Thelemaque, King, & Erwin, 2012). This will help increase the likelihood that interventions will be developed or adapted with cultural specificity when needed (e.g., when the determinants are unique to that population) or will help identify when there are commonalities across social groups that can be addressed across disparity populations (Emmons, Barbeau, Gutheil, Stryker, & Stoddard, 2007; Goldman et al., 2003). In addition, qualitative research can be used to inform the operationalization and measurement of constructs that may be newly identified within a social context and/or are culturally specific (Airhihenbuwa, 2006; Airhihenbuwa & Liburd, 2006). In conclusion, we believe there is much work to do to make progress in both eliminating health disparities and promoting health equity. In fact, in examining qualitative research focused on promoting health equity, the majority of research, including the rich scholarship featured in this special issue, focuses on the methodological and intervention implications of their research findings. However, we also believe that there are tremendous opportunities for qualitative and health equity scholars to advance research and practice in this area through the expansion and application of rigorous, theoretically informed qualitative research. We hope researchers will recognize and seize this challenging, but critically important opportunity.

#### Root cause explanations of international politics don’t exist – methodological pluralism is necessary to reclaim IR as emancipatory praxis and avoid endless political violence.

Bleiker 14, Roland. "International Theory Between Reification and Self-Reflective Critique." (2014): 325-327. (Professor of International Relations at the University of Queensland)//Elmer

This book is part of an increasing trend of scholarly works that have embraced poststructural critique but want to ground it in more positive political foundations, while retaining a reluctance to return to the positivist tendencies that implicitly underpin much of constructivist research. The path that Daniel Levine has carved out is innovative, sophisticated, and convincing. A superb scholarly achievement. For Levine, **the key challenge in** international relations (**IR**) scholarship **is** what he calls “**unchecked reification**”: the widespread and **dangerous** process of **forgetting** “the distinction between theoretical concepts and the real-world things they mean to describe or to which they refer” (p. 15). The dangers are real, Levine stresses, because **IR deals with** some of the most **difficult issues**, from genocides to war. **Upholding one subjective position** **without critical scrutiny can** thus **have far-reaching consequences**. Following Theodor Adorno—who is the key theoretical influence on this book—Levine takes a post-positive position and assumes that the world cannot be known outside of our human perceptions and the values that are inevitably intertwined with them. His ultimate goal is to overcome reification, or, to be more precise, to recognize it as an inevitable aspect of thought so that its dangerous consequences can be mitigated. Levine proceeds in three stages: First he reviews several decades of IR theories to resurrect critical moments when scholars displayed an acute awareness of the dangers of reification. He refreshingly breaks down distinctions between conventional and progressive scholarship, for he detects self-reflective and critical moments in scholars that are usually associated with straightforward positivist positions (such as E.H. Carr, Hans Morgenthau, or Graham Allison). But Levine also shows how these moments of self-reflexivity never lasted long and were driven out by the compulsion to offer systematic and scientific knowledge. The second stage of Levine's inquiry outlines why IR scholars regularly closed down critique. Here, he points to a range of factors and phenomena, from peer review processes to the speed at which academics are meant to publish. And here too, he eschews conventional wisdom, showing that work conducted in the wake of the third debate, while explicitly post-positivist and critiquing the reifying tendencies of existing IR scholarship, often lacked critical self-awareness. As a result, Levine believes that many of the respective authors failed to appreciate sufficiently that “reification is a consequence of all thinking—including itself” (p. 68). The third objective of Levine's book is also the most interesting one. Here, he outlines the path toward what he calls “sustainable critique”: a form of self-reflection that can counter the dangers of reification. Critique, for him, is not just something that is directed outwards, against particular theories or theorists. It is also inward-oriented, ongoing, and sensitive to the “limitations of thought itself” (p. 12). The challenges that such a sustainable critique faces are formidable. Two stand out: First, if the natural tendency to forget the origins and values of our concepts are as strong as Levine and other Adorno-inspired theorists believe they are, then how can we actually recognize our own reifying tendencies? Are we not all inevitably and subconsciously caught in a web of meanings from which we cannot escape? Second, if one constantly questions one's own perspective, does one not fall into a relativism that loses the ability to establish the kind of stable foundations that are necessary for political action? Adorno has, of course, been critiqued as relentlessly negative, even by his second-generation Frankfurt School successors (from Jürgen Habermas to his IR interpreters, such as Andrew Linklater and Ken Booth). The response that Levine has to these two sets of legitimate criticisms are, in my view, both convincing and useful at a practical level. He starts off with depicting reification not as a flaw that is meant to be expunged, but as an a priori condition for scholarship. The challenge then is not to let it go unchecked. **Methodological pluralism** lies at the heart of Levine's sustainable critique. He borrows from what Adorno calls a “constellation”: an attempt to juxtapose, rather than integrate, different perspectives. It is in this spirit that Levine advocates **multiple methods to understand the same event or phenomena.** He writes of the need to validate “multiple and mutually incompatible ways of seeing” (p. 63, see also pp. 101–102). In this model, a scholar oscillates back and forth between different methods and paradigms, trying to understand the event in question from multiple perspectives. **No single method can ever adequately** **represent the event or should gain the upper hand.** But **each should**, in a way, **recognize and capture** details or **perspectives** that the **others cannot** (p. 102). In practical terms, this **means** **combining** a range of **methods** even when—or, rather, precisely **when**—**they are deemed incompatible**. They can range from poststructual deconstruction to the tools pioneered and championed by positivist social sciences. The benefit of such a methodological polyphony is not just the opportunity to bring out nuances and new perspectives. Once the false hope of a smooth synthesis has been abandoned, the very incompatibility of the respective perspectives can then be used to identify the reifying tendencies in each of them. For Levine, this is how **reification may be “checked at the source**” and this is how a “critically reflexive moment might thus be rendered sustainable” (p. 103). It is in this sense that Levine's approach is not really post-foundational but, rather, an attempt to “balance foundationalisms against one another” (p. 14). There are strong parallels here with arguments advanced by assemblage thinking and complexity theory—links that could have been explored in more detail.

#### Refuse to categorize biomedicine as completely bad – medicine and disease are not stable categories.

Parens 13, Erik. "On good and bad forms of medicalization." Bioethics 27.1 (2013): 28-35. (Senior Research Scholar at The Hastings Center)//Elmer

It can be appropriate to use medical means to prevent suffering and enhance well-being even if the source of the problem is not a disease. Laura Purdy2 For the last thirty or forty years, sociologists have used the term medicalization to refer to the process by which ‘non-medical’ (or ‘life’ or ‘human’) problems become understood and treated as ‘medical’ problems.3 Of course social scientists typically understand themselves to be describing – not evaluating – social processes. Indeed, one of the fathers of medicalization theory, the sociologist Peter Conrad, has stated more than once that the term medicalization is value neutral. In his recent book he writes: ‘While medicalization describes a social process, like globalization or secularization, it does not imply that a change is good or bad.’4 That assertion notwithstanding, when sociologists use the term medicalization, they have traditionally assumed that the process it names is bad. In this paper, I will suggest that we in **bioethics should not make** that **simplifying assumption**, but should instead do the complex work of attempting to **distinguish between good and bad** forms of **medicalization**. That suggestion might sound radical at first, but it isn’t. In fact, into both the sociological and bioethical literatures there has already begun to creep a distinction which does roughly the same work as the distinction I’m getting at with the difference between ‘bad’ and ‘good’ forms of medicalization. I am referring to the distinction between ‘over-medicalization’ (which is assumed to be bad) and ‘medicalization’ (which is assumed to be not bad). In an attempt to deflect the criticism that the term medicalization entails but does not acknowledge the assumption that the process is bad, Conrad writes: ‘While ‘medicalize’ literally means ‘to make medical,’ and the analytical emphasis has been on over-medicalization and its consequences, assumptions of over-medicalization are not a given in the perspective.’5 That is, in the course of attempting to deflect the charge that the sociological analysis takes the badness of medicalization to be ‘a given,’ Conrad tacitly distinguishes between overmedicalization, which is bad, and medicalization, which apparently is not. One can find the same tacit distinction in the bioethics literature. In their argument for distinguishing between using memory-attenuating drugs to respond to Post Traumatic Stress Disorder (which they approve of) and using the same drugs to achieve non-medical purposes (which they do not approve of), Michael Henry and colleagues write: ‘If memory-attenuating drugs prove effective, we argue that the most immediate social concern is the over-medicalization of bad memories and its subsequent exploitation by the pharmaceutical industry.’6 Like Conrad, Henry et al. tacitly distinguish between medicalization and over-medicalization. They approve of the sort of ‘medicalization’ that occurred when we applied the PTSD diagnosis to the once-familiar human problem of shell shock, but disapprove of the sort of ‘over-medicalization’ that a pharmaceutical company might initiate with the creation of a new diagnosis like Bad Memories Syndrome. I am merely suggesting that we should become explicit about what we’re already trying to do: get over **the traditional assumption that medicalization is bad per se**, and try to articulate the difference between good and bad forms of it. In preparation for explicating how such an attempt has actually begun in the context of the debates about using pharmaceuticals to shape our experience of love, I want first to rehearse what I take to be the great insights as well as the blind spots built into the term medicalization. I. THE MEDICALIZATION CHARGE HAS TRADITIONALLY ILLUMINATED AND OBFUSCATED What’s wrong with medicalization? First, construing non-medical (or life or human) problems as medical problems, construing normal human variations as pathological, commits a category mistake. Sadness is a problem that human beings experience when, for example, someone they love dies. Shyness can be an unpleasant state that many people experience upon meeting new people. Short stature can occasion unpleasant feelings in some short individuals. And so on. But, the critic of medicalization observes, neither sadness7 nor shyness8 nor short stature9 is a medical problem. Sadness is a normal, perhaps even essential part of a full human life. The feelings that can go with being sad or shy or short may be difficult, but they are not symptoms of disease; only disease-mongers suggest otherwise. To treat human problems as medical problems, according to the critique, is to make a mistake about the nature of the world. Seeing clearly and living well require us to avoid such a mistake. More specifically, living well requires that we learn to let some sorts of problems be. It requires that we learn to affirm, rather than try to erase, variations in our moods, behaviors, and appearances. In addition to entailing a category mistake, medicalization can have bad consequences. Perhaps the easiest to see is that, insofar as medicalization expands the category of what warrants medical treatment, the cost of medical treatment grows exponentially. While this may be to the advantage of gluttonous purveyors of medical products and services, it makes it ever harder for any government to pay for medical care for all.10 On top of the astronomical direct costs of such interventions are the indirect costs of their side-effects. A second bad consequence is that, insofar as the institution of medicine focuses on human beings as objects (i.e. as bodies), the medicalization process potentially undermines seeing ourselves as subjects; it potentially undermines our ‘subjectivity.’ When we argue, say, against the medicalization of badness – e.g., against treating criminal behavior as the symptom of a psychiatric disorder – we are arguing against the view of ourselves as objects at the mercy of forces beyond ourselves, and for the view of ourselves as subjects who can choose. Similarly, when, for example, we argue against using medical means such as drugs to treat sadness, we are often arguing against the view of ourselves as objects that can be fixed and for the view of ourselves as subjects who can be influenced by reasons.11 The critic of medicalization can accept that we need both ways of understanding ourselves, but worry that the medical way is crowding out the other. This is at least one thing critics are getting at when they suggest that we should use means like psychotherapy before or instead of using drugs. A third bad consequence of medicalization is that, insofar as medicine focuses on changing individuals’ bodies to reduce suffering, its increasing influence steals attention and resources away from changing the social structures and expectations that can produce such suffering in the first place. The idea is that, for example, rather than changing the bodies of shy people with drugs, we could change our expectations of how people behave in novel situations; again, doing so, would exemplify the virtue of learning to affirm natural variation. Further, changing social expectations would be fairer to individuals, who, instead of changing their bodies to better fit dominant norms, could, again, be affirmed in their normchallenging variation.12 Whether critics argue that we are making a category mistake, or are creating a putative need that no government can afford to fulfill, or are undermining understanding ourselves as subjects, or are obscuring understanding the social sources of suffering, the basic idea is that it is bad when the institution of medicine oversteps its proper limits. As someone who is by nature-nurture a critic of medicalization, I think that the preceding worries are insightful and important. But I also want to call attention to what the critique can obfuscate. Specifically, I want to call attention to some of the problematic assumptions that the critique inadvertently entails – where by ‘problematic’ I mean assumptions that contradict or at least are in tension with other assumptions that critics like me tend to embrace. Problematic assumptions built into the notion of medicalization First, the idea of medicalization **depends upon the notion that medicine has ‘proper’ goals,** which are visible to those with knowledge of the essence of medicine. More specifically, while it’s true that broad conceptions of the goals of medicine (such as the World Health Organization’s) 13 are indeed available, one needs a narrow conception of those goals to get traction for the medicalization critique. Without a narrow conception, one can’t restrict the range of the targets that medicine ‘properly’ aims at. **Those** of us **attuned to how** institutional **goals change** over time with the coming and going of more and less savory political interests, however, **will be wary of** an **analysis that assumes knowledge of** a given institution’s ‘proper’ or ‘essential’ or **‘real’ goals**. Peter Conrad fully anticipates such wariness. Indeed, he begins his recent summary of his thinking on medicalization by saying that he will ‘bracket’ the question of whether the conditions he says are medicalized are ‘real’ medical problems.14 To justify setting aside the question of how he knows what a real medical problem is or what the proper goals of medicine are, he makes a distinction. He says that ‘it is the viability of the designation rather than the validity of the diagnosis that is grist for the sociological mill’ (emphasis added).15 He is asserting that when he uses the term medicalization, he does not mean to assume that he knows the difference between valid (or real) medical diagnoses and invalid (or fake) ones; he means only to assume that the new, expanded conceptions of medical problems are ‘viable’. But that distinction does not so much resolve as reintroduce the original concern about essentialism. How does the sociologist know which ‘viable’ diagnoses to investigate as examples of medicalization? To pick them she has to assume that she knows the difference between viable diagnoses that are valid and viable diagnoses that are not; otherwise she would have to investigate all viable medical diagnoses as instances of medicalization – and that is clearly not what is happening. All of which is to say that, the valid/viable distinction seems to depend on the same assumption – about knowing the difference between real and fake medical conditions – that Conrad recognizes is problematic. The specter of inadvertent essentialism remains. The medicalization critique’s narrow conception of the goals of medicine harbors other problematic assumptions as well. For one thing, it usually if not always entails the dualistic notion that the proper target of medical intervention is the disordered body, as distinct from the troubled mind. One familiar variation on this theme suggests that medicine should deal with disorders of the body, not disorders of the mind; or that it should treat disorders that are ‘organic,’ not ones that are context-dependent. For example, in a recent essay Jonah Lehrer recounts the tale of a psychiatrist who was taken aback to notice that, in his enthusiasm for prescribing antidepressants, he had failed to distinguish between suffering rooted in his patients’ dysfunctional bodies and suffering rooted in their minds or social contexts. The psychiatrist’s epiphany came when he asked one of his patients whether her antidepressants were working. She answered, ‘Yes, they’re working great . . . I feel so much better. But I’m still married to the same alcoholic son of a bitch. It’s just now he’s tolerable.’16 Lehrer and the psychiatrist’s point of course is that, because the woman’s problem was rooted in her relationship with her alcoholic husband rather than in her dysfunctional body, it was a mistake to treat her. That line of criticism’s great virtue is that it can be used to shelter some dimensions of human life from the raging storm of medical intervention. But it is important to beware of the lurking mind-body dualism. In the case Lehrer describes, the alternatives seem to be that the source of the woman’s suffering is either her body or her mind (and relationships). If we successfully jettisoned mind-body dualism, however, we would be wary of that disjunction. We might wonder, for example, about the role her embodied mind played in her entering into such a relationship in the first place. Such a question would not aim to blame the victim (!), but to remind us of how staggeringly complex mind-body (-world) interactions are. It would remind us to be on the lookout for an assumption that we would normally reject. Yet another problem with the critics’ narrow conception of the goals of medicine is that it usually entails – whether explicitly or inexplicitly – some notion of normal or species-typical functioning.17 The idea is that that we can look out into nature, discern the line between species typical and atypical functioning (or between behaviors inside and outside of the normal range), and thereby know whether to intervene. If the individual exhibits species-atypical (or ab-normal) functioning, she occupies a disease category and we should intervene, and if her functioning is typical (or normal), she doesn’t occupy a disease category and we shouldn’t intervene. It would be lovely if we could look to nature and discern the line between species-atypical and species-typical functioning, between the categories of disease and health. That way it wouldn’t be our ethical responsibility to decide, based on our understanding of the facts and our values, whether to intervene. We’d just point to nature. Alas, one would be hard pressed today to find a natural scientist who studies the etiology and diagnosis of disease and believes that those lines and categories are there for us to discover. Geneticists, neuroscientists, and others increasingly abandon the species-typicality model, which seeks to discover typical functioning, to embrace an individual-differences model, which seeks to understand why it is that, within populations, there is almost always continuous variation with respect to any trait or cluster of traits. On the individual differences view, what we call disorders are almost always ‘dimensional,’ not ‘categorical.’ As the psychiatric geneticists Ian Craig and Robert Plomin put it: Whereas the species typicality model . . . assumes that mental illness is a broken brain, . . . the individual differences model considers variation as normal. . . . Common mental illness is thought to be the quantitative extreme of the normal distribution.18 According to the individual-differences model (and the dimensional view that goes with it), there is no value-free, readily visible line between behaviors and traits that really are – and really aren’t – disordered. This is unfortunate in at least two very different ways. First, it means that purveyors of cures have ever more grounds to assert that even if we aren’t floridly ill, we’re still ill enough to purchase their cure; they can – and do – argue that we are within in the penumbra of illness.19 Second, it means that the ethical responsibility for deciding whether or not to intervene falls to us and our valueladen interpretations of nature; we can’t rely on the hoped-for, value-free guidance from nature. II. THE PHARMACOLOGICAL CALVINISM CHARGE HAS TRADITIONALLY ILLUMINATED AND OBFUSCATED In principle, the medicalization charge can be used to criticize the use of any means to achieve what is construed to be a non-medical purpose. But in our current context, with the avalanche of ever more pharmaceuticals, the medicalization charge often refers to the use of pharmacological means to deal with some normal human problem. When enthusiasts about self-shaping hear the medicalization charge, they sometimes exasperatedly counter that the critics suffer from ‘pharmacological Calvinism.’ Gerald Klerman first used that now-famous phrase in the early 1970s, in an article in the Hastings Center Report.20 According to Klerman, pharmacological Calvinists think that ‘if a drug makes you feel good, it not only represents a secondary form of salvation but somehow it is morally wrong and the user is likely to suffer retribution with either dependence, liver damage, . . . ,or some other form of medical-theological damnation.’ Klerman continues, ‘Implicit in the theory of therapeutic change is the philosophy of personal growth, basically a secular view of salvation through good works.’21 As Klerman was a psychiatrist, not a theologian, we can set aside his unconventional understanding of Calvinism and try to understand the insight at work in his charge. A less snarky version might read: ‘If pharmacological and psychotherapeutic means can both achieve the same end – improving how one experiences herself and the world – then it is irrational and perhaps inhumane to prefer the more strenuous and expensive means. It’s irrational not to take a shortcut when improving human well-being is the destination.Weshould be slower to imagine that suffering leads to growth and understanding, and quicker to remember that sometimes it just crushes human souls.’ Even if the chances of finding a ‘pharmacological Calvinist’ in the USA today are about as good as spotting a bald eagle in Manhattan, Klerman was surely right to observe that we come from long and particular traditions (originating in both Jerusalem and Athens), which have taught that with suffering comes understanding. Those traditions have valorized the suffering that goes with large and small normal human problems.22 Insofar as those traditions celebrated suffering for which there were no medical remedies, Klerman must be right that at least to some extent those traditions made a virtue of necessity. But he must be wrong to the extent that his charge invites us to ignore the respect in which suffering can be a crucial element in a good human life. To take but one example, which I mentioned above: even the staunchest self-shaping enthusiasts acknowledge the respect in which suffering from the loss of someone we love is ‘proper’ – and as such should be endured rather than erased. (Yes, I did suggest above that the notion of ‘the proper’ can obfuscate and here I amsuggesting that it can illuminate.) Moreover, the charge of pharmacological Calvinism must be wrong to the extent that it ignores how the means we use to reduce the suffering associated with normal problems can matter morally. As critics of medicalization argue, using medical means to solve normal human problems can lure us into thinking that the individual rather than her social context is the source of the problem. It can lure us into attending only to the respect in which we are objects – and ultimately to forgetting that we are also subjects, who can remedy some problems by giving and taking reasons to change our minds and contexts. Klerman’s charge can also obfuscate the fact that different means can emphasize different values in an even more obvious sense. Insofar as means like medications can be cheaper or work more quickly than, say, means like words, they can emphasize the value of efficiency. Insofar as means like words require the giving and taking of reasons between persons, they can emphasize the value of engagement. So, like the medicalization charge, the ‘pharmacological Calvinism’ charge can both help us to think and give us an excuse to stop thinking. If that’s right, we are saddled with a daunting ethical responsibility. By ‘we’ I mean those who think it is important to respond to the suffering of individuals and that it is important to attend to the social roots of that suffering; those who think it is important to consider ourselves as subjects and that we should be grateful for the ways in which considering ourselves as objects can help us to diminish human suffering; and those who worry that medicalization can be bad and believe that choosing for or against ‘medicalization’ full stop could be lazy or unhelpful. By ‘ethical responsibility’ I refer to the responsibility to attempt to distinguish between good and bad forms of medicalization. III. TOWARD A CONVERSATION ABOUT THE DIFFERENCE BETWEEN GOOD AND BAD FORMS OF MEDICALIZATION To start, it helps to remember the respect in which we already do embrace some forms of medicalization. When for example Dostoyevsky wrote The Idiot, the cluster of traits that today we call **epilepsy was called a divine gift**. In the beginning of the 20th century, that cluster of traits was construed as a ‘psychological’ disorder, and today we are **confident that ‘it’ is a proper medical disorder**. None of us criticizes the process whereby that particular constellation of traits was transformed from a divine gift into a medical problem. Nor does any of us criticize the process whereby what today we call **Alzheimer’s** disease **went from** being interpreted as the **moral** problem of ‘senility’ **to** being interpreted as a **medical** [disorder] ~~problem~~. One could counter that these aren’t examples of ‘good’ medicalization. Rather, they are only examples of us overcoming past mistakes: calling epilepsy a disease instead of a divine gift is just an example of aligning our everyday practice with our deeper scientific or medical knowledge. Mistaking epilepsy for a divine gift, goes this argument, is no more interesting than mistaking whales for fish. Fair enough. But this brings us to straightforward, harder-to-dismiss examples to support my suggestion that we should be skeptical about assuming that medicalization is bad, full stop. Many feminists and fellow travelers have in the past, with good reason, lamented the medicalization of everything from childbirth, to menstruation, to menopause.23 More recently, the institution of medicine has brought within its purview ‘labia-plasty,’ which its practitioners say can be used to treat ‘emotional problems such as embarrassment, anxiety, and loss of self-esteem’24 related to the shape of one’s labia minora. The profound, amplysupported concern is that, by bringing ever more normal features of women’s bodies and lives within the purview of medicine, disease mongers diminish women’s power to control their own bodies and, more generally, diminish their ability to flourish. While there may be no better arena than what gets called ‘women’s health’ to witness dis-empowering forms of medicalization, there may also be no better place to see empowering forms. As feminist philosopher Laura Purdy has argued in this journal25 – and others have argued elsewhere26 – a blanket condemnation of medicalizing ‘normal facets’ of women’s (and men’s) lives fails to acknowledge the respect in which women (and men) use medical technologies to gain control over their lives to promote their own flourishing.27 Consider for example the normal human capacity of producing eggs (or sperm), or the normal capacity of bringing a fertilized egg to term. Given that those capacities can’t be construed as symptoms of disease, and given that becoming pregnant when one doesn’t want to is a perennial human problem, we must grant that **using medical technologies** to control those capacities (**from birth control** pills**, to vasectomies**, to IUDs) **are forms of medicalization** – forms of medicalization **that seem good** to many of us. Even many of us who are in general deeply, wholeheartedly critical of the idea that more control is always better, embrace technologies that allow women to determine if and when they will become pregnant. We embrace those technologies not only **because** we believe that **women have a right to self-determination**, but because we know that women who cannot control if and when they become pregnant are at significantly increased risk of living (along with their children) lives blighted by poverty. For this observer, **fertility control counts as a good form of medicalization**. Of course, ‘many of us’ isn’t all of us. Who, though, objects to the process whereby what once was considered chronic pain associated with normal aging came to receive labels like Complex Regional Pain Syndrome (CRPS)?28 Before we could do anything to treat such pain, we construed it as a normal, if difficult part of the aging process. But once it’s technically feasible for healthcare professionals to reduce such pain, the door swings wide open to new diagnostic labels and ‘treatments’. What was once a problem of everyday living becomes a medical problem. It is a classic example of the medicalization process – but, I am suggesting, an example of ‘good’ medicalization. IV. THE MEDICALIZATION OF LOVE In the conclusion of a forthcoming essay, ‘Bioethics and Medicalization,’ the sociologist John Evans, writes: Most scholars of medicalization seem to have reached the normative conclusion that they do not want to live in a world where increasing swaths of human experience are under the logic of medicine. There are, or should be, experiences that use an older logic, which are under the jurisdiction of another profession or under no jurisdiction at all. We can all fear the medicalization of love (emphasis added).29 At work in Evans’s claim, is the at-first seemingly obvious assumption that medicalizing love is bad, full stop. But I want to suggest that even in the case of love, we need to try to distinguish between good and bad forms of medicalization. Indeed, I want to suggest that in the bioethics literature we can already begin to glimpse progress toward making such a distinction. Even mortal academic foes can sometimes agree on the difference between good and bad forms of medicalization In its characteristically heterocentric and fuddy-duddy tone, in Beyond Therapy the President’s Council on Bioethics offers a scenario that makes a deeply important point. They invite us to imagine a young man at a party who is under the influence of Ecstasy and begins a conversation with a woman he has never met before. He tells her that he loves her and wants to marry her. The Council invites us to imagine that the man means what he says ‘insofar as the feeling he now has is indistinguishable from what he might one day feel when he truly falls in love with a woman.’30 Then the Council asks, ‘Should the fact that this man’s feelings are produced by the drug, rather than inspired by the woman, matter?’ The Council argues that it should matter to the woman and to the man. It should matter to her because she wants to be seen as she truly is, not as the drug makes her seem. She wants recognition. And it should matter to him, too, insofar as he should want his love to be real. As the Council puts it, ‘The young man’s drug induced ‘love’ is not just incomplete – an emotion unconnected with knowledge of and care for the beloved. It is also unfounded, not based on anything – not even visible beauty – from which such emotions normally grow.’ Even we post postmodernists are here thrown back on some version of the distinction between the true and false, authentic and inauthentic. Even we have to accept the inescapability of such a distinction in the context of thinking about the sort of love we want for ourselves and for those we love. We want our feelings of love to grow out of knowledge of and care for the other. We want them to grow out of engaging in activities with the person we love. We want the other’s love for us to be chosen freely. We, even we post postmodernists, don’t want to settle for the feelings that grow out of a drug alone. No one familiar with the bioethics literature will be surprised to find this sort of argument in a report by the President’s Council, which is known both for its critique of self-shaping in general and medicalization in particular. It may be more surprising, however, to find a similar argument being made by enthusiasts about technological self-shaping. In a recent paper, Julian Savulescu and Anders Sandberg define a good marital relationship as ‘one which both parties desire and which gives each pleasure, and allows or facilitates each to lead lives which are objectively valuable.’31 To advance their argument, they make a distinction, which reveals an important value commitment they share with their academic foes, The President’s Council. Savulescu and Sandberg distinguish between using a drug to maintain a loving attachment and using a drug to create such an attachment. Specifically, they endorse using technology to maintain a relationship that is founded on shared perceptions of the goodness of the other, and the shared experiences that grow out of such perceptions, but they reject using technology to create the feelings normally associated with such perceptions and experiences. As the President’s Council might put it, we don’t want the illusion of love, we want the real thing. To make their point, Savulescu and Sandberg even use the language of authenticity, which is as unusual for them as it is usual for the Council. They write, ‘The use of drugs to instill a new love is more likely to create inauthentic love, since the causal reasons for the love may lie in the drug . . . , rather than the particular person loved.’ So at least we can say that, insofar as being without love is a normal, human, non-medical problem, and insofar as both sides would oppose using a technology to remedy that problem by creating a love out of whole cloth (i.e. in the absence of the feelings and experiences normally associated with love), it is fair to say that both sides agree that using a technology to create love out of whole cloth would be a bad form of medicalization. The problem is normal but the medical-technological solution is bad. But can both sides agree on a good form of medicalization? Well, Savulescu and Sandberg say that marriage counseling is a perfectly fine way to maintain a love relationship. The President’s Council doesn’t speak directly to this issue, but I see no evidence that they would disagree. Insofar as relationship difficulties are a normal human problem, and insofar as marriage counseling is sometimes done by people with medical degrees, it seems fair to say that both sides could in principle agree that relationship counseling to maintain a marriage relationship could be a good form of medicalization. While both sides might agree that using words (as in counseling) to treat relationship problems is a good form of medicalization – or at least is not a form of ‘overmedicalization’ – things might become more contested if someone proposed using drugs to remedy those problems. For example, would both sides agree that it is a good form of medicalization for marriage counselors to use Ecstasy to facilitate marriage counseling? (This is not hypothetical; Ecstasy has been used for this purpose.)32 30 President’s Council on Bioethics. 2003. Beyond Therapy: Bioetechnology and the Pursuit of Happiness New York, NY, Regan Books: 253. This is of course a variation on Robert Nozick’s famous ‘experience machine’ thought experiment in Anarchy, State, and Utopia. 31 J. Savulescu & A. Sandberg. Neuroenhancement of Love and Marriage: The Chemicals between Us. Neuroethics 2008; 1: 33–44. 32 S. Braun. 2001. Seeking Insight by Prescription. Cerebrum. 1 April. Available at: http://www.dana.org/news/cerebrum/detail.aspx?id=3046 [accessed 20 Jan 2011]. On Good and Bad Forms of Medicalization 34 © 2011 Blackwell Publishing Ltd. We can imagine that whereas the President’s Council might object, Savulescu and Sandberg would not. Indeed, even if Savulescu and Sandberg would oppose the creation of relationships with drugs, their conception of the appropriate use of drugs to maintain a relationship is far more expansive than the Council’s. Indeed, they invite their readers to imagine a woman who takes herself to be in a good and loving relationship with a man who happens to be promiscuous, and then invite us to accept that, in an effort to maintain her relationship, this woman might autonomously choose to take a drug that allowed her to tolerate her husband’s promiscuity. It strikes me that, for Savulescu and Sandberg to be consistent, they should reject the promiscuity-toleration pill on the same grounds that they rejected a pill that created the feelings of love out of whole cloth. In both cases, rather than facilitating engagement with the world as it really is, the pill distances the relevant parties from the world as it is. Again, however, their published article indicates that they could condone a drug that made the promiscuity of one partner tolerable for the other. But even if Savulescu and Sandberg agreed that, to be consistent, they should reject the promiscuity-toleration drug, I am surely not suggesting that they and the President’s Council agree on precisely how to articulate the difference between good and bad forms of medicalization – or between ‘medicalization’ and ‘over-medicalization.’ I am only suggesting that self-shaping critics and selfshaping enthusiasts do agree – at least implicitly – that we should attempt to articulate that difference. Insofar as some forms of medicalization can maintain or facilitate, as opposed to create or thwart, human relationships and experience, both sides – no matter how different their tones – need some version of that distinction. CODA Early on in this paper, I mentioned Jonah Lehrer’s example of the unhappy woman who was married to an alcoholic man. Following Lehrer, I suggested that construing her normal human unhappiness as depression would be a distressingly bad form of medicalization. No matter how much the medication might attenuate her suffering, that could not justify her becoming complicit in cutting herself off from an important feature of her life as it truly was. In that case, however, ‘the alcoholic husband’ was a sort of prop (not unlike ‘the promiscuous husband’ was for Savulescu and Sandberg). Lehrer and I were using the alcoholic husband to try to understand what we thought of the woman using an antidepressant to manage her unhappiness. But now we can ask, What should our attitude be toward her husband? Would it be bad to construe his alcoholism – and his accompanying unhappiness – as a medical disorder? Would it be bad to medicalize his bad behavior? I don’t think it would. Above I rehearsed some of the ever-present, very real social and philosophical dangers associated with medicalizing such behavior. I think, however, that if we remain vigilant about the ever-present dangers associated with the process of medicalization, and if the medical model of alcoholism can help someone to remedy the common human problem of excessive drinking, then medicalizing the alcoholic husband’s bad behavior might be good. To the extent that construing his bad behavior as a ‘medical’ problem can help him to take responsibility for his life and to start engaging in the sorts of meaningful relationships and activities that human beings seem to need and want, this seems to be a good form of medicalization This may make me a prime exhibit for (the sociologist) John Evans’s case that ‘bioethics’ has itself become an ‘engine’ of medicalization.33 And perhaps beginning to say out loud that some medicalization can be good puts us at still greater risk of creating exactly what Goethe feared: a world turned into one huge hospital, where everyone is everybody else’s humane nurse. I don’t dismiss or minimize either of those concerns. On the contrary, they trouble me deeply. But if we are committed to ‘ambiguity and complexity’ (as Evans says sociologists are, and I would say we all should be), if we are committed to helping flesh-and-blood human beings to engage in meaningful activities and relationships, then we might have to try to distinguish between good and bad forms of medicalization. That would take time and energy, and would delay the rest we all desire, but it might also be what we owe each other if flourishing for all is what we’re really after.