### Advantage

#### The advantage is drug prices,

#### Drug prices are high now, Rajkumar 20

[S. Vincent Rajkumar](https://www.nature.com/articles/s41408-020-0338-x#auth-S_-Vincent_Rajkumar), 6-23-2020, "The high cost of prescription drugs: causes and solutions," Blood Cancer Journal, <https://www.nature.com/articles/s41408-020-0338-x> //Lex AT

Global spending on prescription drugs in 2020 is expected to be ~$1.3 trillion; the United States alone will spend ~$350 billion[1](https://www.nature.com/articles/s41408-020-0338-x#ref-CR1). These high spending rates are expected to increase at a rate of 3–6% annually worldwide. The magnitude of increase is even more alarming for cancer treatments that account for a large proportion of prescription drug costs. In 2018, global spending on cancer treatments was approximately 150 billion, and has increased by >10% in each of the past 5 years[2](https://www.nature.com/articles/s41408-020-0338-x#ref-CR2). The high cost of prescription drugs threatens healthcare budgets, and limits funding available for other areas in which public investment is needed. In countries without universal healthcare, the high cost of prescription drugs poses an additional threat: unaffordable out-of-pocket costs for individual patients. Approximately 25% of Americans find it difficult to afford prescription drugs due to high out-of-pocket costs[3](https://www.nature.com/articles/s41408-020-0338-x#ref-CR3). Drug companies cite high drug prices as being important for sustaining innovation. But the ability to charge high prices for every new drug possibly slows the pace of innovation. It is less risky to develop drugs that represent minor modifications of existing drugs (“me-too” drugs) and show incremental improvement in efficacy or safety, rather than investing in truly innovative drugs where there is a greater chance of failure.

#### Trade secrets allow middle players to reap profits by hiding information from health plan companies and regulators, Feldman 1

Robin Feldman, 6 Oct 2020, "Naked Price and Pharmaceutical Trade Secret Overreach," No Publication, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3426225> //Lex AT

Other perverse incentives flow from the structure of industry, with its central players the **Pharmacy Benefit Managers** (PBMs). PBMs are middle players between drug companies and insurance plans— including both private insurers and Medicare. On behalf of insurance plans and patients, PBMs negotiate the prices of drugs with the companies. PBMs also help the plans set formularies, which determine **whether patients will have access to a particular drug** and the terms of that access. In an ideal world, this system would allow insurance plans and patients to pay the lowest cost possible for brand-name drugs. In reality, the deals between PBMs and brand companies frequently operate to **channel patients into more expensive drugs**, with resulting long-term and short-term effects on the system. Although a full discussion of the PBMs and the drug supply chain is beyond the scope of this Article, 29 certain aspects are important for understanding the role that assertions of trade secrecy are playing in this space. In simplified form, PBMs stand between their clients (the health plans) and drug companies. Although a health plan knows what it pays when a patient buys a particular drug at the pharmacy, **the true price is hidden**. Somewhere down the line, the health plan will receive a rebate check from the PBM that includes rebates for this, and many other, drug transactions. Along the way, **PBMs pocket a large portion of the rebate dollars**—as much as $166 billion each year30 by one estimate—although the health plans are not permitted to know the size of the rebates or the portions retained. In fact, the true net price, and the terms of the agreements between PBMs and drug companies are highly guarded secrets; even the health plan’s auditors are not given full access to the agreements.31 Moreover, given that PBMs help create their clients’ formularies, PBMs and drug companies **can strike deals that may not be in the patient’s long-term interests**. Recent case allegations and press reports have described patients **who are forced to pay more for generics** than for brand name drugs and patients **completely blocked from access** to generic versions of a drug. For example, a complaint filed in 2017 alleges that Allergan’s rebate scheme for its blockbuster dry-eye drug Restasis blocked access for competing generics. 32 One Medicare plan administrator quoted in the complaint explained that with the particular scheme, **a new entrant could give its drug away for free and still would not be able to gain a foothold in the market**.33 Similarly, a recent case alleges that Johnson and Johnson launched a rebate scheme for its rheumatoid arthritis drug Remicade that induced hospitals and health plans to essentially exclude the lower-priced biosimilar. 34 One physician called practices such as these “Alice-in-Wonderland” in the drug world.35 Moreover, these deals can maximize the payments that the PBMs are able to keep, while keeping patients away from cheaper generic drugs. In addition, although PBMs represent the health plan as its clients, the PBMs receive various large payments directly from the drug companies. As well as the rebate portions mentioned above, PBMs also receive various fees from drug companies, such as “data management fees” and “administrative fees.”36 With the formulary power of PBMs, these **fees** have the potential to **encourage PBMs to drive patients toward the companies that are offering more attractive terms** to them as a middle player, regardless of whether those terms benefit patients in either the short or long-term. Again, these fees are **hidden from the health plan, from regulators, and from the public**.37 One might think that the health plans and their patients, let alone government auditors, would have the right to know the net prices they are paying for each drug and to access the terms of agreements made on their behalf. So, just how is it that these terms are so deeply hidden? PBMs and drug companies claim that net price is a **trade secret**. It is under the cloak of **trade secrecy** that this system, and its impact on rising prices, remains sheltered from view.

#### Three impacts,

#### 1] That uniquely hurts low- and middle- income countries, Yadav 20

[Prashant Yadav, 1-24-2020, "When Fewer Is Better: Pharmaceutical Wholesaling and Distribution in Low- and Middle-Income Countries", Center For Global Development, <https://www.cgdev.org/blog/when-fewer-better-pharmaceutical-wholesaling-and-distribution-low-and-middle-income-countries>, date accessed 9-16-2021] //Lex AT

That’s the case for high-income countries, but let’s switch gears to low- and middle-income countries (LMICs). In most LMICs [there are too many wholesalers](https://www.researchgate.net/publication/323813667_Pharmaceutical_Company_Strategies_and_Distribution_Systems_in_Emerging_Markets), meaning the market is too fragmented. Wholesalers/distributors have to recover their fixed costs over a relatively small volume base. Sub-scale wholesalers/distributors either shirk from making fixed capital investments in warehousing, IT, skill development, and transport infrastructure; or charge higher gross markups. Few wholesalers/distributors have national distribution reach and a multi-layered channel emerges in which a national wholesaler sells onward to a sub-wholesaler, who then sells to another sub-sub-wholesaler and so on. In some regions, there can be as many as six intermediaries to reach the retail pharmacy or clinic. Each channel intermediary charges a markup, creating a much wider wedge between ex-manufacturer price and the retail price. Multiple channel intermediaries also create challenges related to accounts receivable collection. LMIC drug regulators who are stretched for resources find it harder to audit and enforce quality in such a fragmented and multi-tiered wholesaling/distribution market. The structure of the wholesaling/distribution market in many LMICs, especially in sub-Saharan Africa, is detrimental to patients, payers and regulators on the dimensions of availability, affordability, and quality.

#### High drug prices leads to use of substandard drugs which cause antimicrobial resistance, WBG 17

World Bank Group, March 2017, “DRUG-RESISTANT INFECTIONS A Threat to Our Economic Future”, <https://documents1.worldbank.org/curated/en/323311493396993758/pdf/final-report.pdf> //Lex AT

Even as there is overuse and misuse of antimicrobials, some poor populations still lack access to effective medicines. For example, one million children are estimated to die each year from untreated pneumonia and sepsis, which can be effectively managed with antibiotics (Laxminarayan et al. 2016). Weak health care systems, AMR, and the penetration of many countries’ antimicrobials markets by substandard and counterfeit drugs— these conditions all contribute to low access to effective antimicrobials. Relatively high prices of the more powerful, later-generation, antimicrobial drugs are also a factor. The development and marketing of these drugs occurred since the first-line, relatively inexpensive antimicrobials lost their effectiveness because of AMR. High drug prices then squeeze the finite health care budgets of governments, charities, and households, resulting in diminished access to treatment, especially for the poor and vulnerable. In addition to the effect on individual health outcomes, shrinking access to effective antimicrobials hinders progress toward universal health coverage (UHC), a pillar of the Sustainable Development Goals for 2030.4 We will discuss the potential development impacts of AMR extensively in Part II. In Part IV, we will show how country action to promote UHC can simultaneously enable more effective AMR control.

#### 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

#### 2] Court legitimacy is declining which shreds democracy—bipartisan legislation key, Brown 8-25

Tristin Brown, 8-25-2021, "The Missing Voices on the Supreme Court Commission," No Publication, <https://news.bloomberglaw.com/environment-and-energy/the-missing-voices-on-the-supreme-court-commission> //Lex AT

Just 10 months under the most conservative U.S. Supreme Court in modern history, the implications of a 6-3 conservative majority are being felt. This past term, the court dealt devastating blows to voting rights and the labor movement, siding repeatedly with the [privileged and powerful](https://www.theusconstitution.org/series/chamber-study/) at the expense of everybody else. And they’re just getting started: The court has already agreed to take on cases in the next term that could decimate abortion access, gun control laws, and more. On issue after issue, the court is on the wrong side of the democratic will, serving as a rubber stamp for corporate and conservative interests. This is by design:For decades, organizations like the Federalist Society have organized with Republican elected officials to capture the judiciary, no matter the cost. The result is a court in which a third of the justices have been appointed by a president who lost the popular vote—twice—and two-thirds have been nominated by Republican presidents, despite Democratic control of the White House for the majority of the last 30 years. ‘Fundamentally Flawed’ In response to these concerns about the court’s basic legitimacy, President Joe Biden [established a bipartisan commission](https://news.bloomberglaw.com/us-law-week/bidens-supreme-court-commission-whos-on-it-and-why-explained) to study court reform. From the outset, however, the commission has been fundamentally flawed: It is a body in which those who have been invited to participate actively benefit from the inequities being examined, while the voices left out of the conversation are those most impacted by the far-right capture of the court. The commission is largely composed of individuals who teach at elite law schools. Of 82 members and witnesses at the first two hearings, [57 were professors](https://news.bloomberglaw.com/us-law-week/professor-heavy-scotus-commission-leaves-out-real-life-people). Of those, 36 teach at either Columbia, Harvard, N.Y.U., Yale, Duke, or the University of Chicago—among the nation’s most elite law schools. Of the commissioners and panelists called thus far, only a third have been women. These are individuals who have little incentive to honestly critique the court and its threat to our democracy. They are people who appear before the court, who have vested interests in maintaining good relationships with the very institution they’re being asked to analyze.

#### The plan allows the USFG to fight for price reform, Pierson 8-12

Brendan Pierson, 8-12-2021, "PBMs sue U.S. to keep prescription drug prices hidden from public," Reuters, <https://www.reuters.com/legal/litigation/pbms-sue-us-keep-prescription-drug-prices-hidden-public-2021-08-12/> //Lex AT

(Reuters) - The Pharmaceutical Care Management Association, an organization representing pharmacy benefit managers, has sued the federal government in an effort to block a rule requiring them to disclose the net prices they negotiate with drug companies. In a [complaint](https://www.pcmanet.org/wp-content/uploads/2021/08/2021-08-12-1-PCMA-v.-HHS-Complaint.pdf) filed Thursday in Washington, D.C., federal court, the PCMA said the November 2020 rule would drive up prescription drug prices. The lawsuit targets the Department of Health and Human Services, Internal Revenue Service and Department of Labor, all of which were involved in the rule. The agencies did not immediately respond to requests for comment. Pharmacy benefit managers (PBMs) serve as intermediaries between drug manufacturers, health insurance plans and pharmacies to negotiate prescription drug prices. PBMs typically negotiate concessions below the nominal list prices of prescription drugs. The PCMA is challenging a provision of the rule set to take effect in January that would require them to disclose the historical net prices (list price minus a rebate) they negotiate with manufacturers. The information would have to be available to the public in a so-called machine-readable file, which can be processed by a computer. The rule, the organization said, threatens to "drive up the total drug price ultimately borne by health plans, taxpayers and consumers by advantaging drug manufacturers in negotiations over price concessions." Armed with information about prices negotiated between manufacturers and PBMs, the group said, manufacturers will be able to "tacitly collude with each other to increase drug prices." The group also said that the rule "offers consumers no actionable information because net prescription drug prices are not charged to consumers and never appear on a bill," and "will likely only confuse them." Furthermore, it said, ordinary consumers will not be able to interpret a machine-readable file. The PCMA alleges that the Affordable Care Act does not give the government the authority to require PBMs to disclose proprietary information. It also alleges that the requirement that the information be in a machine-readable file, which received negative comments during the notice and comment rulemaking period, is arbitrary and capricious under the Administrative Procedure Act. The lawsuit is the latest in a string of healthcare industry challenges to rules passed late in former President Donald Trump's administration aiming to curb prescription drug prices. While it is not yet clear whether President Joe Biden will seek to defend those specific rules, he has also pledged to lower drug prices. The Biden administration in February agreed to postpone a last-minute Trump administration rule aimed at lowering drug prices by restricting rebates from drug companies to PBMs, which had sued to block the rule. PhRMA, the nation's largest drug manufacturer group, also won a notable victory last December when a federal judge blocked a rule that would have tied Medicare reimbursement for some drugs to prices paid by other countries.

#### Price reform is bipartisan, Lawson 21

Alex Lawson, June 17, 2021, "Support for Lowering Drug Prices is Bipartisan," Data For Progress, <https://www.dataforprogress.org/blog/2021/6/17/support-for-lowering-drug-prices-is-bipartisan-among-voters-democrats-must-listen> //Lex AT

Republican, Democratic, and Independent voters [agree](https://socialsecurityworks.org/wp-content/uploads/2021/06/dfp_21_5_ssw_toplines-1.pdf): Drug prices are too high. 75 percent of Republicans, 86 percent of Democrats, and 81 percent of Independents are “very” or “somewhat” concerned by the prices of prescription drugs. Voters are outraged, and we want our government to take action. 77 percent of voters, including 70 percent of Republican voters, say the government should be doing more to reduce the prices of prescription drugs.

#### US democracy is key to stopping extinction,

Kendall-Taylor 16 - deputy national intelligence officer for Russia and Eurasia at the National Intelligence Council and a nonresident senior associate in the Human Rights Initiative at the Center for Strategic and International Studies in Washington, D.C.. Andrea, 7-15, How Democracy’s Decline Would Undermine the International Order, Center for Strategic & International Studies, https://www.csis.org/analysis/how-democracy%E2%80%99s-decline-would-undermine-international-order

It is rare that policymakers, analysts, and academics agree. But there is an emerging consensus in the world of foreign policy: threats to the stability of the current international order are rising. The norms, values, laws, and institutions that have undergirded the international system and governed relationships between nations are being gradually dismantled. The most discussed sources of this pressure are the ascent of China and other non-Western countries, Russia’s assertive foreign policy, and the diffusion of power from traditional nation-states to nonstate actors, such as nongovernmental organizations, multinational corporations, and technology-empowered individuals. Largely missing from these discussions, however, is the specter of widespread democratic decline. Rising challenges to democratic governance across the globe are a major strain on the international system, but they receive far less attention in discussions of the shifting world order. In the 70 years since the end of World War II, the United States has fostered a global order dominated by states that are liberal, capitalist, and democratic. The United States has promoted the spread of democracy to strengthen global norms and rules that constitute the foundation of our current international system. However, despite the steady rise of democracy since the end of the Cold War, over the last 10 years we have seen dramatic reversals in respect for democratic principles across the globe. A 2015 Freedom House report stated that the “acceptance of democracy as the world’s dominant form of government—and of an international system built on democratic ideals—is under greater threat than at any point in the last 25 years.” Although the number of democracies in the world is at an all-time high, there are a number of key trends that are working to undermine democracy. The rollback of democracy in a few influential states or even in a number of less consequential ones would almost certainly accelerate meaningful changes in today’s global order. Democratic decline would weaken U.S. partnerships and erode an important foundation for U.S. cooperation abroad. Research demonstrates that domestic politics are a key determinant of the international behavior of states. In particular, democracies are more likely to form alliances and cooperate more fully with other democracies than with autocracies. Similarly, authoritarian countries have established mechanisms for cooperation and sharing of “worst practices.” An increase in authoritarian countries, then, would provide a broader platform for coordination that could enable these countries to overcome their divergent histories, values, and interests—factors that are frequently cited as obstacles to the formation of a cohesive challenge to the U.S.-led international system. Recent examples support the empirical data. Democratic backsliding in Hungary and the hardening of Egypt’s autocracy under Abdel Fattah el-Sisi have led to enhanced relations between these countries and Russia. Likewise, democratic decline in Bangladesh has led Sheikh Hasina Wazed and her ruling Awami League to seek closer relations with China and Russia, in part to mitigate Western pressure and bolster the regime’s domestic standing. Although none of these burgeoning relationships has developed into a highly unified partnership, democratic backsliding in these countries has provided a basis for cooperation where it did not previously exist. And while the United States certainly finds common cause with authoritarian partners on specific issues, the depth and reliability of such cooperation is limited. Consequently, further democratic decline could seriously compromise the United States’ ability to form the kinds of deep partnerships that will be required to confront today’s increasingly complex challenges. Global issues such as climate change, migration, and violent extremism demand the coordination and cooperation that democratic backsliding would put in peril. Put simply, the United States is a less effective and influential actor if it loses its ability to rely on its partnerships with other democratic nations. A slide toward authoritarianism could also challenge the current global order by diluting U.S. influence in critical international institutions, including the United Nations , the World Bank, and the International Monetary Fund (IMF). Democratic decline would weaken Western efforts within these institutions to advance issues such as Internet freedom and the responsibility to protect. In the case of Internet governance, for example, Western democracies support an open, largely private, global Internet. Autocracies, in contrast, promote state control over the Internet, including laws and other mechanisms that facilitate their ability to censor and persecute dissidents. Already many autocracies, including Belarus, China, Iran, and Zimbabwe, have coalesced in the “Likeminded Group of Developing Countries” within the United Nations to advocate their interests. Within the IMF and World Bank, autocracies—along with other developing nations—seek to water down conditionality or the reforms that lenders require in exchange for financial support. If successful, diminished conditionality would enfeeble an important incentive for governance reforms. In a more extreme scenario, the rising influence of autocracies could enable these countries to bypass the IMF and World Bank all together. For example, the Chinese-created Asian Infrastructure and Investment Bank and the BRICS Bank—which includes Russia, China, and an increasingly authoritarian South Africa—provide countries with the potential to bypass existing global financial institutions when it suits their interests. Authoritarian-led alternatives pose the risk that global economic governance will become fragmented and less effective. Violence and instability would also likely increase if more democracies give way to autocracy. International relations literature tells us that democracies are less likely to fight wars against other democracies, suggesting that interstate wars would rise as the number of democracies declines. Moreover, within countries that are already autocratic, additional movement away from democracy, or an “authoritarian hardening,” would increase global instability. Highly repressive autocracies are the most likely to experience state failure, as was the case in the Central African Republic, Libya, Somalia, Syria, and Yemen. In this way, democratic decline would significantly strain the international order because rising levels of instability would exceed the West’s ability to respond to the tremendous costs of peacekeeping, humanitarian assistance, and refugee flows. Finally, widespread democratic decline would contribute to rising anti-U.S. sentiment that could fuel a global order that is increasingly antagonistic to the United States and its values. Most autocracies are highly suspicious of U.S. intentions and view the creation of an external enemy as an effective means for boosting their own public support. Russian president Vladimir Putin, Venezuelan president Nicolas Maduro, and Bolivian president Evo Morales regularly accuse the United States of fomenting instability and supporting regime change. This vilification of the United States is a convenient way of distracting their publics from regime shortcomings and fostering public support for strongman tactics.

#### 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.

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.

### Solvency

#### Plan – The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by implementing thin trade secret protections in the TRIPS agreement.

#### The plan solves price abuse, Feldman 2

Robin Feldman, 6 Oct 2020, "Naked Price and Pharmaceutical Trade Secret Overreach," No Publication, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3426225> //Lex AT

With trade secret becoming a weapon of choice in contemporary intellectual property litigation, there is a growing risk that it will be used in manners far beyond its animating logic of balancing interests between parties, generally those who were in privity with one another, regarding ordinary-course business information. Thus, courts should consider borrowing from copyright to develop its own version of thinness. 185 Thin trade secret would exist when the independent economic value or creation aspect of the secret is scant, such that the item of information qualifies for protection, but only just so.186 Unlike secret formula and manufacturing techniques, thin information would exist near the margins of trade secret protection. At this distance from the core conceptualization of what is protectable, they would rest on a lighter limb of the trade secret tree. In that case, the tug of a countervailing public policy interest would have particular force. One would not want defendants to simply claim any interest in the guise of public policy, however. Thus, thin copyright could be designed primarily for circumstances in which trade secret comes into conflict with other doctrinal areas embodying their own public policies. In those circumstances, the doctrine of thin trade secret creates space for navigating the boundaries. The doctrine of thin trade secret is distinct from the notion of confidential-but-not-secret information that a relational, nonproperty conception of trade secret law would entertain. Thin trade secret operates only when the information is within the bounds of statutory trade secret status, albeit at the edge of those bounds. In this manner, thin trade secret avoids the trap of creating a vague second tier of protectable information that falls outside the bounds of statutory trade secret protection, a development which would only incentivize the aggressive litigation of weak and nebulous claims, without the framework of rules and defenses the trade secret statutes provide to adjudicate and rebut such claims. There is a risk, of course, that with the existence of thin trade secret, judges could inadvertently sweep unwarranted information into the trade secret fold. Information might be easier to declare a trade secret, given the comfort of being able to deny protection in a particular case through the public interest. Without great care, such an approach could allow the boundaries of trade secret to creep ever wider across time. All jurisprudential arenas, however, face the temptation of rules of convenience, and the antidote is the same throughout. Regardless of the doctrinal area, courts and commentators must find analyses that can be applied with logical consistency across the regime, rather than resting on handy decisions in a particular case that create distinctions without a difference.187 The concept of thin trade secret has the potential to protect trade secret regime from a societal backlash as new claims stray into uncharted territory. Without such an outlet, courts, in frustration over expansive claiming, could be tempted to slash large and ambiguous swaths of territory, generating confusion in trade secret doctrine. By delineating an area of greater force for public policy, thin trade secret would cabin analysis into a common zone for discussion and thus lessen the chance of mayhem throughout the regime. To be sure, developing a theory of thin trade secret cannot be accomplished in one step. Practical questions, such as what justifications permit application of the concept and what degree of use or disclosure in particular concepts are weighed against protection, await future commentary. One could conceivably consider borrowing from copyright to develop a fair use trade secret defense. In that vein, courts could examine whether other policies might outweigh a finding that a party’s trade secret has been used. Thinness, however, has the advantage of signaling that the supposed trade secret just barely makes it over the line, a conclusion that seems particularly appropriate for these circumstances. Although intellectual property misuse may provide a useful pathway, we believe that more narrow and targeted rules will be important. In particular, at the dawn of doctrinal development, one would be welladvised to proceed with caution. Thus, the concept of thin trade secret provides a careful approach for recognition of expanding areas of innovation without trampling the public policies reflected in doctrinal areas with which trade secret must interact. Once again, the example of drug prices and regulatory disclosure is illustrative. As described above, naked price does not fall within the bounds of trade secrets. Even if a court were to find that bare negotiated price points between PBMs and pharmaceutical manufacturers fell within the bounds of trade secrets, those rights would be achingly close to the line. At most, if pricing information in the special context of PBM agreements were deemed to be a trade secret at all, it would be a thin and untraditional right, not core intellectual property. It should pale in comparison to thick IP rights such as manufacturing process details, formula details, and other scientific work products. A thin, barely-over-the-line trade secret hardly deserves the same deference in a regulatory disclosure context as the latter types of information.

#### Regulations exist in the status quo—BUT lack of transparency is the only barrier, Feldman 3

Robin Feldman, 6 Oct 2020, "Naked Price and Pharmaceutical Trade Secret Overreach," No Publication, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3426225> //Lex AT

Public outcry over rising prices in the United States, particularly in contrast to comparable countries across the globe, has prompted numerous legislative and regulatory attempts to reform the system. More than 40 states have introduced legislation to address rising pharmaceutical pricing, with many of those bills directed at transparency in drug pricing. Transparency has been an issue for Congress and federal regulators as well, with the introduction of transparency bills and regulations.45 As state actors have sought to regulate or even investigate pharmaceutical pricing and practices, they have run into claims of trade secrecy. For example, Caremark is one of three major Pharmacy Benefit Managers that control 85% of the market. When the State of Ohio investigated in 2018 how PBMs spent state and federal funds, a third party prepared a report for the state which included details of such spending. Caremark then objected to publication of the report, filed a lawsuit seeking to suppress the report. In shrill language, the Pharmacy Benefit Manager argued that pricing information regarding prescription drugs in its contracts with entities that manage Medicaid for patients constituted “proprietary” “trade secrets,” such that publication would be “devastating,” with “severe financial harm” to its business.46 Trying to have it both ways, Caremark represented that the report it did not want the public to read found that “allegations against Caremark were not true” with respect to “preferential pricing.”47 Along the same lines, a California court enjoined the state from publishing information about a pharmaceutical company’s planned drug price increases before those prices would go into effect on the ground that for purposes of the order, the information constituted trade secrets.48

#### Err Aff—lack of transparency makes it impossible to calibrate effective innovation policies, Durkin 21

Allison Durkin, June 23, 2021, "Addressing the Risks That Trade Secret Protections Pose for Health and Rights," PubMed Central (PMC), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233014/>

Pharmaceutical companies have invoked trade secret protections and trade secret-like protections to limit access to various types of financial information, including drug prices, research and development costs, manufacturing costs, and details regarding financial arrangements. In the United States, for example, companies have litigated against transparency laws that sought to require them to make the prices of their medicines known to the public (when they might otherwise remain obscured by secret rebates or other deals). Collectively, we refer to these as “drug pricing data” because they are all relevant to the matter of fair pricing. The consequences of protecting this information are significant. A lack of transparent pricing information fuels high drug prices, while obscuring the research and development costs limits our ability to calibrate innovation policy and to identify price gouging.

#### Lower drug prices don’t impact research incentives. Prefer comprehensive studies to pharma propaganda.

Dranove et al. 20 [David Dranove, Walter J. McNerney Professor of Health Industry Management; Faculty Director of PhD Program; Professor of Strategy. September 2, 2020. “Pharma Companies Argue That Lower Drug Prices Would Mean Fewer Breakthrough Drugs. Is That True?” <https://insight.kellogg.northwestern.edu/article/pharma-companies-argue-lower-drug-prices-fewer-breakthrough-drugs>] Dhruv

Expected Profits and Innovation

The study used pharmaceutical research data from 1997 through 2018 on over 70,000 molecules developed globally by **over 4,300 biopharma companies**. This time period spanned the advent of Medicare Part D, which was created as part of the Medicare Modernization Act of 2003, and became effective in 2006. This made possible a “natural experiment” on the relationship between expected profits and innovation. Starting in 2006, pharmaceutical companies would have expected an increase in profits for drugs targeting older patients, due to the increased prescription-drug coverage for this population. The question, then, was whether that increased expected profit would yield greater innovation in drugs targeting seniors—or would companies play it safe by focusing on copycat versions of existing drugs? The Choice: Playing It Safe The study showed little change in research on scientifically novel drugs for seniors in response to Medicare Part D. “We saw an increase in drug research targeting seniors after the expansion of Medicare Part D,” Dranove says, “but it was largely for drugs with the same target-based actions as previous ones—addressing essentially the same condition in the body.” From 2012 to 2018, there was an increase of 106 percent in the number of clinical trials for less-novel drugs targeting seniors, but only a 14 percent increase in trials for the most novel pharmaceuticals. That means that in response to the new financial incentives, drug companies focused largely on copycat versions of drugs rather than truly **novel products**. “What the new Medicare Part D was affecting are drugs that are only valuable at the margin,” Garthwaite says. A Green Light for Pricing Regulation The main practical implication of the finding is that incremental changes to drug profits probably won’t affect innovation in a noticeable way. On one hand, this is discouraging news for healthcare professionals and policymakers who might otherwise champion incremental incentives in order to boost innovation. But on the other, it also suggests that policies that slightly lower drug prices won’t stifle pursuit of novel drugs. In short, the researchers argue that minor changes to drug-company profits will neither encourage nor discourage innovation. “Increasing competition or decreasing returns from developing products won’t kill the biopharma industry,” Garthwaite says. That means Americans could potentially enjoy lower drug prices—and the access that goes with these—without suffering a costly loss of biopharma innovation. “That social impact is ultimately what we care about,” Garthwaite says. The researchers also point out that copycat drugs developed in response to Medicare Part D did represent some value to patients—Lipitor was far from the first cholesterol-reducing drug to market, for example, but it improved upon existing ones and became a high-grossing product for Pfizer, a win–win. “The fifth [copycat] drug brought to market may have the fewest side effects,” Dranove says. “Or it may be the one that drives prices down.”

#### Innovation is low now

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

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

### Framework

#### The standard is maximizing expected well being or saving lives.

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

### Underview

#### 1] Aff gets 1AR theory to prevent infinite abuse it’s DTD since the 1AR needs it to make the time investment worth, no RVIs because you can dump on a 30 sec shell for 6 minutes, and competing interps since the 2n can’t dump on a reasonability bright-line that excludes only what they did wrong – 1AR theory comes first the 1AR is too short to be able to rectify abuse and adequately cover substance.

#### 2] Procedural fairness first a) probability – one round cant alter subjectivity, but it can rectify fairness skews, b) link turns their role of the ballot since it proves we couldn’t engage in it and it is exclusionary, c) answers are self-defeating since they presuppose the judge evals them fairly.

#### 3] Permissibility and Presumption Affirm

**A] Otherwise we’d have to have a proactive justification to do things like drink water.**

**B] If anything is permissible, then definitionally so is the aff.**

**C] Statements are true before false since if I told you my name, you’d believe me.**