### Framework

**The standard is util. Prefer:**

1. **Pleasure and pain are intrinsically valuable**

**Moen 16** [Ole Martin Moen, Research Fellow in Philosophy at University of Oslo “An Argument for Hedonism” Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281] SJDI

Let us start by observing, empirically, that a widely shared judgment about intrinsic value and disvalue is that **pleasure is intrinsically valuable and pain is intrinsically disvaluable**. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for **there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels**, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative.2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values. If you tell me that you are heading for the convenience store, I might ask: “What for?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. The reason is that the **pleasure is not good for anything further;** it is simply that for which going to the convenience store and buying the soda is good.3 As Aristotle observes: “We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” **We take for granted that if something is painful, we have a sufficient explanation of why it is bad.** If we are onto something in our everyday reasoning about values, it seems that **pleasure and pain are both places where we reach the end of the line in matters of value.**

1. **Death is the worse possible thing since it erases our very existence**

Paterson 03, Craig [Department of Philosophy, Providence College, Rhode Island] 2003, “A Life Not Worth Living?”, Studies in Christian Ethics

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

1. **Requires the prevention of extinction which is a pre-req to all other frameworks.**

GPP 17 Global Priorities Project, [Future of Humanity Institute at the University of Oxford, Ministry for Foreign Affairs of Finland] 2017, “Existential Risk: Diplomacy and Governance,” Global Priorities Project, <https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf>

1.2. THE ETHICS OF EXISTENTIAL RISK In his book Reasons and Persons, Oxford philosopher Derek Parfit advanced an influential argument about the importance of avoiding extinction: I believe that if we destroy mankind, as we now can, this outcome will be much worse than most people think. Compare three outcomes: (1) Peace. (2) A nuclear war that kills 99% of the world’s existing population. (3) A nuclear war that kills 100%. (2) would be worse than (1), and (3) would be worse than (2). Which is the greater of these two differences? Most people believe that the greater difference is between (1) and (2). I believe that the difference between (2) and (3) is very much greater. ... The Earth will remain habitable for at least another billion years. **Civilization began only a few thousand years ago. If we do not destroy mankind, these** few thousand **years may be only a tiny fraction of the whole of** civilized **human history**. The difference between (2) and (3) may thus be the difference between this tiny fraction and all of the rest of this history. If we compare this possible history to a day, what has occurred so far is only a fraction of a second.65 In this argument, it seems that Parfit is assuming that the survivors of a nuclear war that kills 99% of the population would eventually be able to recover civilisation without long-term effect. As we have seen, this may not be a safe assumption – but for the purposes of this thought experiment, the point stands. **What makes** existential catastrophes especially bad is that they would “destroy the future,” as another Oxford philosopher, Nick Bostrom, puts it.66 **This future could potentially be extremely long and full of flourishing, and would therefore have** extremely large value. In standard risk analysis, when working out how to respond to risk, we work out the expected value of risk reduction, by weighing the probability that an action will prevent an adverse event against the severity of the event. **Because the value of preventing existential catastrophe is so vast, even a tiny probability of prevention has huge** expected **value**.67 Of course, there is persisting reasonable disagreement about ethics and there are a number of ways one might resist this conclusion.68 Therefore, it would be unjustified to be overconfident in Parfit and Bostrom’s argument. In some areas, government policy does give significant weight to future generations. For example, in assessing the risks of nuclear waste storage, governments have considered timeframes of thousands, hundreds of thousands, and even a million years.69 Justifications for this policy usually appeal to principles of intergenerational equity according to which future generations ought to get as much protection as current generations.70 Similarly, widely accepted norms of sustainable development require development that meets the needs of the current generation without compromising the ability of future generations to meet their own needs.71 However, when it comes to existential risk, it would seem that we fail to live up to principles of intergenerational equity. Existential catastrophe would not only give future generationsless than the current generations; it would give them nothing. Indeed, **reducing existential risk** plausibly **has a quite low cost for us in comparison with the huge expected value it has for future generations**. In spite of this, relatively little is done to reduce existential risk. Unless we give up on norms of intergenerational equity, they give us a strong case for significantly increasing our efforts to reduce existential risks. 1.3. WHY EXISTENTIAL RISKS MAY BE SYSTEMATICALLY UNDERINVESTED IN, AND THE ROLE OF THE INTERNATIONAL COMMUNITY In spite of the importance of existential risk reduction, it probably receives less attention than is warranted. As a result, concerted international cooperation is required if we are to receive adequate protection from existential risks. 1.3.1. Why existential risks are likely to be underinvested in There are several reasons why existential risk reduction is likely to be underinvested in. Firstly, it is a global public good. Economic theory predicts that such goods tend to be underprovided. The benefits of existential risk reduction are widely and indivisibly dispersed around the globe from the countries responsible for taking action. Consequently, a country which reduces existential risk gains only a small portion of the benefits but bears the full brunt of the costs. Countries thus have strong incentives to free ride, receiving the benefits of risk reduction without contributing. As a result, too few do what is in the common interest. Secondly, as already suggested above, existential risk reduction is an intergenerational public good: most of the benefits are enjoyed by future generations who have no say in the political process. For these goods, the problem is temporal free riding: the current generation enjoys the benefits of inaction while future generations bear the costs. Thirdly, many existential risks, such as machine superintelligence, engineered pandemics, and solar geoengineering, pose an unprecedented and uncertain future threat. Consequently, it is hard to develop a satisfactory governance regime for them: there are few existing governance instruments which can be applied to these risks, and it is unclear what shape new instruments should take. In this way, our position with regard to these emerging risks is comparable to the one we faced when nuclear weapons first became available. Cognitive biases also lead people to underestimate existential risks. **Since there have not been any catastrophes of this magnitude, these risks are not salient to** politicians and **the public**.72 This is an example of the misapplication of the availability heuristic, a mental shortcut which assumes that something is important only if it can be readily recalled. **Another cognitive bias affecting perceptions of existential risk is scope neglect**. In a seminal 1992 study, three groups were asked how much they would be willing to pay to save 2,000, 20,000 or 200,000 birds from drowning in uncovered oil ponds. The groups answered $80, $78, and $88, respectively.73 In this case, the size of the benefits had little effect on the scale of the preferred response. **People become numbed to the effect of saving lives when the numbers get too large**.74 Scope neglect is a particularly acute problem for existential risk because the numbers at stake are so large. Due to scope neglect, **decision-makers are prone to treat existential risks in a similar way to problems which are less severe by many orders of magnitude.** A wide range of other cognitive biases are likely to affect the evaluation of existential risks.75

### Adv. 1: Infectious Disease

#### Drug prices rising rapidly in the US

NASEM 18 National Academies of Sciences, Engineering, and Medicine. 2018. Making Medicines Affordable: A National Imperative. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24946>. The National Academies of Sciences, Engineering, and Medicine are private, nonprofit institutions that provide expert advice on some of the most pressing challenges facing the nation and the world. Our work helps shape sound policies, inform public opinion, and advance the pursuit of science, engineering, and medicine. Over many decades we have earned a solid reputation as the nation's premier source of independent, expert advice on scientific, engineering, and medical issues.

Although branded medications make up approximately 10 percent of all prescriptions in the United States, they account for nearly three-quarters of prescription drug spending (GPhA, 2015). Spending for all retail prescription drugs accelerated significantly in 2014 and 2015, before slowing in 2016 (QuintilesIMS, 2017a). The spending rate was 10.3 percent, which rose to 12.4 percent between 2014 and 2015 before falling to 5.8 percent in 2016—still twice the 2.5 percent rate of growth in 2013 (QuintilesIMS, 2015a, 2016a, 2017a). The cost of branded drugs is influenced by their launch prices—the prices set by the manufacturer for the new drugs when they first become available on the market—and the subsequent annual increases in their list prices. Recent data on anti-cancer drugs show that on average launch prices increased by about $8,500 per year over the past 15 years (Howard et al., 2015). Other studies have found similar increases in the prices of cancer drugs after their launch (Bach, 2009; Bennette et al., 2016; Shih et al., 2017). A 2009 report from the U.S. Government Accountability Office (GAO) estimated that between 2000 and 2008, 416 brand-name drug products displayed “extraordinary” price increases (GAO, 2009). The 416 products represented 321 specific medications, with some medications being available in different drug strength and dosage forms; for example, the 416 products included eight different strength and dosage forms of the beta blocker Inderal. Most often the increases in price reported in the study were between 100 and 499 percent, but in a few cases, specifically for drugs used to treat such conditions as fungal or viral infections or heart disease, a drug’s price increased by 1,000 percent or more. The absolute price increases for branded drugs ranged from $0.01 per unit to $5,400 per unit. The unit price of a drug is, of course, only one factor in determining the cost of a full course of treatment for a medical condition. The cost for a full course of treatment for one drug used to treat one rare form of cancer increased from $390 to more than $3,000 during the study period (GAO, 2009). Figure 3-1 shows how the prices of 268 top branded drugs rose throughout the period 2006–2015, with the yearly increases being consistently higher than the increases in the overall consumer price index—sometimes much higher. Spending on specialty medicines has nearly doubled over the past 5 years, clearly outpacing the consumer price index and accounting for more than two-thirds of the overall growth in spending on medicines between 2010 and 2015 (AHIP, 2015; QuintilesIMS, 2016a). One result of this increase is that Medicare beneficiaries face rapidly growing out-of-pocket payments for specialty drugs. This trend is likely to continue as the population ages and more treatments become available for difficult-to-manage diseases (Dusetzina and Keating, 2015; Dusetzina et al., 2017; Trish et al., 2016). On the challenge of how to go about financing very expensive branded drugs, see Box 3-1. Whether existing or new drug therapies are actually effective in patients is another issue that must be considered.1

#### Majority of pharmaceutical resources focused on evergreen drugs – stifling innovation and raising prices

Feldman 18 Robin Feldman, May your drug price be evergreen, Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, Pages 590–647, <https://doi.org/10.1093/jlb/lsy022> Robin Feldman is professor of law and director of the Institute for Innovation Law at UC Hastings College of the Law in San Francisco and author of [“Drugs, Money, and Secret Handshakes”](https://www.cambridge.org/us/academic/subjects/law/us-law/drugs-money-and-secret-handshakes-unstoppable-growth-prescription-drug-prices?format=HB)

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 obtainedthrough our analysis in detail, but below arethe keytakeaways fromthe study: Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. In fact, 78% ofthe drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs. In some years, the percentage reached as high as 80%. Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70% extended their protection at least once, with more than 50% extending the protection cliff more than once. Looking at the full group, almost 40% of all drugs available on the market created additional market barriers by having patents or exclusivities added to them. Many ofthe drugs addingtothe Orange Book are ‘serial offenders’—returning to the well repeatedly for new patents and exclusivities. Of the drugs that had an addition to the Orange Book, 80% of those had an addition to the Orange Book on more than one occasion, and almost half of these drugs had additions to the Orange Book on four or more occasions. The number of drugs with a high quantity of added patents in a single year has substantially increased. For example, the number of drugs with three or more patents added to them in one year has doubled. Similarly, the number of drugs with five or more added patents has also doubled. Overall, the quantity of patents added to the Orange Book has more than doubled, increasing from 349 patents added in the year 2005 to 723 in 2015. The number of drugs that had a patent added to them in the Orange Book almost doubled. There were striking increases in certain exclusivities, such as orphan drug exclusivity, new patient population exclusivity, and new product exclusivity. In particular, the number of drugs with an added orphan drug exclusivity tripled. In addition, the number of times a use code was added to a patent more than tripled, suggesting that this has become a new favored game. To provide a broad sense of the types of metrics we are using, some could be characterized as ‘intensity’ measures, which capture the breadth and depth of patent and exclusivity activity in the industry. Another set of our metrics can be characterized as ‘temporal’ measures, which evaluate whetherthere are anytrends inthe behavior under examination across time during our 11-year timeframe from 2005 to 2015. IV.B. Number of drugs that had patents and/or exclusivities added to them in the Orange Book, compared to the total number of drugs available As an initial inquiry, we wanted to determine the extent to which companies are adding patents and exclusivities to drugs. Is this a limited activity, confined to well-worn anecdotes that everyone repeats, or does it occur throughout the industry? Our results demonstrate that adding patents and exclusivities is a common behavior, endemic to pharmaceuticals. In fact, between 2005 and 2015, almost 40% of all drugs available on the market had patents, exclusivities, or other changes added to them. Table 1 shows the total number of FDA-approved drugs available on the market in each year of our study. Table 2 shows the number of drugs that had a patent or exclusivity added to them as a percentage of the total number of drugs. The figure is broken down in terms of the number of drugs with an added patent, the number of drugs with an added exclusivity, and the number of drugs that had any relevant change made to it (which includes not only adding a patent and/or exclusivity, but also other significant changes such as adding a use code.)

#### IP evergreening causes high prices by squashing generic competition

I-Mak 18 <https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf> I-mak.org. N.p., 2018. Web. 15 Aug. 2021. I-MAK (Initiative for Medicines, Access & Knowledge) is a nonprofit that challenges systemic injustice and advocates for health equity in drug development and access.

Such filings allow drugmakers to a) increase the price of the branded drugs by an average of 68% in six years, and b) seek to stall generic competition by an average of 38 years. While these average figures are disconcerting, examples among specific drugs run even more extreme in each category. Among the top grossing and best known drugs on the market today, some of the ‘worst offenders’ include AbbVie having filed 247 patent applications for Humira, Pfizer’s 163% price hike over six years for Lyrica, and Roche’s and Genentech’s efforts to seek 48 years of patent exclusivity for Herceptin. These examples are not outliers; our analysis indicates that patent holders for the other top twelve drugs also abuse the patent system, hike the price of drugs, and delay generic competition. Enabling drugmakers to maintain patent monopolies far beyond twenty years has significant consequences on the American healthcare system. The strategy to expand monopolies without any meaningful new science or invention exacts a heavy cost on American payers and households. Specifically, these twelve highest grossing drugs cost $96 billion to health insurers, government payers, and consumers in 2017 alone. Since drugmakers often continue to increase the prices of medicines once or twice a year, even after the product has already been on the market for many years, revenues may continue to grow for these medicines until there is generic competition. Generic competition, with two or more generic suppliers competing to reduce the price of a medicine, consistently lowers prescription drug prices by more than half. Yet policy makers have not put enough effort into accelerating generic competition, or at least ensuring that drugmakers do not extend monopolies beyond the twenty years intended under U.S. patent law. Measures must be taken to limit the power of the pharmaceutical industry to abuse the patent system and reverse the drug industry’s dramatic expansion of patent monopolies

#### Evergreening leads to high drug prices through lack of generics – insulin proves

Amin 18 Amin, Tahir. "Patent Abuse Is Driving Up Drug Prices. Just Look At Lantus - STAT." STAT. N.p., 2018. Web. 25 Aug. 2021. Tahir Amin is the co-founder and co-executive director of [I-MAK.org](http://www.i-mak.org/overpatented-overpriced-excessive-pharmaceutical-patenting-extending-monopolies-driving-drug-prices/), a global nonprofit organization that works to lower drug prices.

A rare point of consensus following the midterm elections is that Americans are adamant about lowering drug prices. [Bipartisan pledges](https://www.statnews.com/2018/11/07/mcconnell-could-work-with-democrats-on-drug-prices/) to seek common ground on this vexing issue suggest we might finally see action to make medicines more affordable. What should this new common ground look like? Beyond important proposals like allowing drug importation or Medicare negotiation, policymakers should take a hard look at one of the key factors affecting market competition, transparency, and affordability: patents. Patent abuse by drug makers is one of the most influential drivers of our pricing problem. U.S. law provides 20 years of patent exclusivity for inventions such as a new medicine — meaning two decades that a drug maker has monopoly power to develop a medicine and set prices however they wish. Even if it takes eight years to develop a medicine, that leaves 12 years for the drug to have market exclusivity. While rewarding invention is important, under the U.S. patent system those rewards have become inflated and unmerited as drug makers have developed defensive strategies that include overly broad patent claims and filing large numbers of follow-on or secondary patents to extend their monopolies. Patients are paying the price. Diabetes provides a good snapshot of the problem. Approximately 7 million Americans rely on insulin to live. Surging insulin prices have gotten so out of hand that 1 in 4 Americans are [rationing their own treatment](https://www.cbsnews.com/news/study-almost-half-of-diabetics-skip-medical-care-due-to-costs/), putting their lives in jeopardy and, in some cases, [dying](https://www.statnews.com/2018/11/27/insulin-prices-protest-sanofi/). Without insurance, one five-pen carton of Lantus Solostar costs $280 [at all major pharmacies](http://www.goodrx.com/) in the U.S. The exact same branded — not generic — package costs about $50 in a [leading diabetes clinic in Mexico](https://www.clinicasdelazucar.com/insulinas/). Lantus, made by Sanofi, is the leading drug for people with type 1 diabetes. The company makes $15 million every day selling this type of insulin. As shown in [a new report](http://www.i-mak.org/wp-content/uploads/2018/10/I-MAK-Lantus-Report-2018-10-30F.pdf) from I-MAK, the organization I help direct, the price of Lantus jumped 18 percent each year from 2012-2016. During that time, U.S. taxpayers bought more than $22 billion worth of Lantus through Medicare and Medicaid. In fact, [Lantus ranked number two](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html) for total overall expenditure in 2016 for both Medicare and Medicaid. Lantus is also [highly overpatented](http://www.i-mak.org/overpatented-overpriced-excessive-pharmaceutical-patenting-extending-monopolies-driving-drug-prices/). Though Sanofi’s primary patents on Lantus expired in 2015, the company has filed 70 secondary patent applications in the U.S. — 95 percent of its total — since the drug was first approved and put on the market in 2000. If granted, these additional patents would give Sanofi monopoly protection for up to 37 more years — almost double the duration provided under U.S. law. Why would a pharmaceutical company file so many patents after a drug is already on the market? Quite simply to preserve and extend its ability to keep competition at bay while hiking prices. The company — which along with Eli Lilly and [Novo Nordisk](https://www.statnews.com/2018/05/15/diabetes-insulin-novo-nordisk-north-carolina/) control nearly the entire U.S. insulin market — has further prevented insulin competition in America by pursuing litigation against two companies that want to offer cheaper biosimilars. (Biosimilars are the generic-like equivalents for complex molecules such as insulin and other biologic drugs.) Like overpatenting, this tactic works against the millions of Americans who must take insulin. Putting two or more generics on the market has been shown to drastically reduce drug prices. In Europe and Japan, fewer patent applications and more friendly biosimilar regulatory requirements have led to multiple biosimilar competitors of Lantus, helping drive down prices and improve access to treatment. Gestures like Sanofi’s recently expanded [patient assistance programs](https://twitter.com/SanofiUS/status/1057969582244274176) offer savings to struggling patients. But Americans in need of treatment should not have to jump through hoops for medicine that ought to be affordable in the first place. Put another way, “I shouldn’t have to go beg for my insulin. It should be affordable to me,” Myranda Pierce, a graduate student at Boston University School of Medicine who has type 1 diabetes, [told STAT](https://www.statnews.com/2018/11/27/insulin-prices-protest-sanofi/). Unfortunately, the mix of [patent thickets](https://www.statnews.com/pharmalot/2018/11/07/abbvie-biosimilars-humira-patents/), prolonged exclusivity, delayed competition, and jacked-up prices is typical of America’s best-selling medications. Overpatenting is so pervasive that [a new report](https://diabetescaucus-degette.house.gov/sites/diabetescaucus.house.gov/files/Congressional%20Diabetes%20Caucus%20Insulin%20Inquiry%20Whitepaper%20FINAL%20VERSION.pdf) from the bipartisan Congressional Diabetes Caucus calls for outlawing [“evergreening,”](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/) and also proposes other patent reforms because such practices block competition and prevent affordable generics from reaching Americans. To get patent reform right, policymakers should not only stop evergreening and [pay-for-delay agreements](https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay) that keep generic alternatives off the market. They must also remember what’s at the core of a patent: invention. To deserve the title “patent” — and the reward of exclusivity that comes with it — a discovery must be truly inventive, not just an incremental improvement. Top of Form Bottom of Form Unfortunately, the current patent system too often forgets the inventive part of patent law and hands out 20-year monopolies for “improvements” based on routinely practiced science — whether that’s putting three pills into one pill to improve adherence or making a slight adjustment to the dosage formulation, as Sanofi claimed in one of its later patents on Lantus. To provide real incentives to help companies usher in the next medical breakthroughs, we need to raise the bar for what is deemed inventive under patent law. If we don’t, we should no longer call it a patent system but a monopoly-handout-in-return-for-an-investment system. As cited in the I-MAK report on Lantus, Erin Little, an entrepreneur in Kansas City, Mo., told T1International, “No one I know can afford this drug without assistance, and patient assistance programs, if you even qualify, eventually run out. I had to pay $1,000 for a month’s supply of Lantus before I found a way to get the same version in Mexico for just $100. It’s not right. Drug companies are squeezing us for every possible penny. It’s forcing people to ration drugs and putting lives at risk.” Americans deserve better. That’s why [Minnesota’s attorney general](https://www.statnews.com/pharmalot/2018/10/16/minnesota-sues-insulin-makers/) recently sued the big three insulin makers for price gouging the U.S., why the American Medical Association has [called for federal interventions](https://www.ama-assn.org/ama-urges-federal-action-respond-insulin-price-hikes) on insulin pricing, and why there’s a lot riding on the next Congress to rein in rising drug costs. As part of the solution, patent reform can help boost competition and transparency and stop companies from dictating sticker-shock prices. There are too many stories of agonized patients struggling to afford treatment, forced to ration their medicine, and left to absorb the cost of high drug prices with their very own bodies.

#### High drug prices increase risk of infectious disease – two warrants:

#### Hospital Resiliency

#### High drug prices cause hospitals to slash services and staffing decreasing quality of care

Daly 19 Daly, Rich. "Drug Prices An Increasing Challenge For Hospitals: Survey." hfma. N.p., 2019. Web. 22 Aug. 2021. Rich Daly is a senior writer/editor in HFMA’s Washington, D.C., office.

Jan. 15—Most hospitals have had to juggle their budgets in recent years to accommodate increasingly expensive drugs, according to a new survey. From FY15 to FY17, almost two-thirds of hospitals responding to a [recent survey](https://fah.org/fah-ee2-uploads/website/documents/AHA_Drug_Pricing_Study_Report_FINAL_01152019.pdf) reported that changes in drug prices had a moderate or severe impact on their budgets, with over 15 percent of hospitals indicating that the increase in drug prices impacted their budgets “to a large extent.” The survey was accompanied by interviews with some responding executives, who reported that increased drug spending impacted many aspects of their operations. In response to drug prices, they implemented a range of approaches to control spending, including changes in day-to-day operations and systemwide strategies. “This report confirms that we are in the midst of a prescription drug spending crisis that threatens patient access to care and hospitals’ and health systems’ ability to provide the highest quality of care,” Rick Pollack, president and CEO of the American Hospital Association (AHA), said in a release. “Solutions must be worked on to rein in out-of-control drug prices and ease the drug shortages that are putting a strain on patient care.” The survey, interviews, and an accompanying study on hospital impacts from drug prices were analyzed by NORC at the University of Chicago for several national hospital advocacy groups, including AHA. According to the survey of 1,184 hospitals, among measures taken to address budget pressures associated with increasing drug prices were identifying alternative therapies (90 percent); doing more in-house compounding (69 percent); delaying investments in or replacement of equipment (28 percent); reducing staffing (25 percent); and reducing services offered (17 percent). “All interviewees described intensive efforts and close collaboration with healthcare providers to establish formularies for drugs used at their facilities and, when possible, to pursue therapeutic interchange,” the report stated. Additionally, pharmacy department staff work with other hospital clinical staff to change the delivery frequency of drugs to patients and patient care areas to avoid unnecessary waste. Larger operational impacts of drug price increases, as identified in the survey, included a reduction in the services available to patients. For instance, one medical center curtailed plans to open an outpatient chemotherapy site, citing uncertainty around payment relative to the acquisition cost for the drugs. The accompanying study found that from FY15 to FY17, total spending for inpatient and outpatient hospital drugs at U.S. community hospitals increased by 18.5 percent per adjusted admission (from $468.5 to $555.4). That increase cost the average hospital $1.8 million. The increase also eclipsed the 6.4 percent increase in overall medical inflation during the same period. Specifically, spending on outpatient drugs during the period increased by 28.7 percent on an adjusted admission basis, while inpatient drug spending per admission increased by 9.6 percent. That followed a 38.7 percent increase in inpatient drug spending from FY13 to FY15, according to a previous [NORC study](https://www.aha.org/guidesreports/2018-01-24-trends-hospital-inpatient-drug-costs-issues-and-challenges) for hospital advocates. That study did not evaluate outpatient spending.

#### Hospital resilience and quality key to combatting pandemics

Thobaity and Alshammari 20 Thobaity A, Alshammari F: Nurses on the Frontline against the COVID-19 Pandemic: An Integrative Review. Dubai Med J 2020;3:87-92. doi: 10.1159/000509361Farhan Alshammari is the Dean, College of Nursing [University of Hail](https://scholar.google.com/citations?view_op=view_org&hl=en&org=18023216350956736549) and Thobaity is the Assistant Professor - Dean - Applied Medical Sciences at Taif University.

COVID-19 is considered the cause of a dangerous illness that affects people’s lives and, in many cases, threatens the lives of infected people. In addition, this virus presents an immediate danger to the functioning of communities across the world. Such impacts include the loss of jobs and its effects on families, changes in the mode of education because attendance and interaction have shifted to online and distance learning, and many other changes in people’s lives [[1](https://www.karger.com/Article/Fulltext/509361#ref1), [2](https://www.karger.com/Article/Fulltext/509361#ref2)]. Despite these facts, in many countries, disease mitigation, preparedness, and responses were implemented; however, these measures for coping with the events of COVID-19 were insufficient. The affected countries called for help when COVID-19 massively harmed healthcare systems and hospitals and, in many countries, consumed their medical resources. It was found that the detection of COVID-19 cases was not identical across countries, as in some countries the number of infected cases was large and rapidly increased, and sudden critical care was necessary in countries such as Italy [[3](https://www.karger.com/Article/Fulltext/509361#ref3)]. However, in some countries, the number of cases either remained steady or fluctuated, which is expected in biological disasters [[2](https://www.karger.com/Article/Fulltext/509361#ref2)]. The majority of infected or symptomatic people seek medical treatment in medical facilities, particularly hospitals, as a high number of cases, especially those in critical condition, will have an impact on hospitals [[4](https://www.karger.com/Article/Fulltext/509361#ref4)]. The concept of hospital resilience in disaster situations is defined as the ability to recover from the damage caused by huge disturbances quickly [[2](https://www.karger.com/Article/Fulltext/509361#ref2)]. The resilience of hospitals to pandemic cases depends on the preparedness of the institutions, and not all hospitals have the same resilience. A lower resilience will affect the sustainability of the health services. This also affects healthcare providers such as doctors, nurses, and allied health professionals [[5](https://www.karger.com/Article/Fulltext/509361#ref5), [6](https://www.karger.com/Article/Fulltext/509361#ref6)]. Despite the impact on healthcare providers, excellent management of a pandemic depends on the level of preparedness of healthcare providers, including nurses. This means that if it was impossible to be ready before a crisis or disaster, responsible people will do all but the impossible to save lives. Be it in daily routine or disasters, nurses are on the frontline and are responsible for providing holistic care for all types of patients. Considering the fact that nurses constitute the majority of healthcare providers, they have a critical function in healthcare systems [[2](https://www.karger.com/Article/Fulltext/509361#ref2), [5](https://www.karger.com/Article/Fulltext/509361#ref5)]. Their roles in treating patients with COVID-19 involve triaging patients and detecting suspected cases with infections; providing essential treatment in an emergency and dealing with suspected patients with precautions; helping in decontamination and coordination with other healthcare providers; supplying holistic nursing practices in managing multiple infections simultaneously; playing critical roles in expanding care services; and dealing with relatives [[7](https://www.karger.com/Article/Fulltext/509361#ref7)]. In crises, they have more tasks to satisfy patients and their families; therefore, nurses must be well equipped with essential knowledge and skills in managing crises involving clinical treatment, decontamination, isolation, communication, triaging, psychological support, and palliative care if necessary [[8](https://www.karger.com/Article/Fulltext/509361#ref8)-[11](https://www.karger.com/Article/Fulltext/509361#ref11)]. However, when they respond to a crisis such as COVID-19, they face problems that hinder them from caring for the infected patients. Exploring the issues that nurses face when caring for patients with COVID-19 will help increase nurse and hospital resilience in response to the crisis, as well as enhance preparedness and recovery from the crisis. Additionally, understanding these issues will help support nurses by informing leaders and decision-makers about these issues and providing recommendations and implications. Therefore, this integrative review aims to explore the issues facing nurses during their response to the COVID-19 crisis.

#### Decrease in coverage

#### Drug prices result in decrease access to healthcare: coverage gets cut and uninsured gets priced out

AAA 18 Prescription Drug Spending In The U.S. Health Care System An Actuarial Perspective. American Academy of Actuaries, 2018. Web. 25 Aug. 2021. The American Academy of Actuaries is a D.C.-based 19,500+ member professional association whose mission is to serve the public and the U.S. actuarial profession.

In many situations, use of prescription drugs may lead to better overall health outcomes and even lower overall health care costs. However, increased prescription drug use without an accompanying increase in quality of care or life, or lower overall health care costs, may have a negative effect. Rapidly increasing prescription drug costs can have a significant effect on the various stakeholders in the health care system: • Insurers, Government, and Other Payers— Prescription drug costs represent a significant issue for payers as they try to maintain a balance between revenue and costs. Increases in costs due to utilization increases, unit cost increases, and changes in the mix of drugs increase the burden on budgets, as well as making prescribed drug costs difficult to predict. Copay coupons can influence the mix and often make the brand less expensive than or comparable in cost to the generic to the patient, but at the expense of the insurer and patient over time. Insured Members—As plan costs for prescription drugs increase, insured member costs will likely increase through higher cost sharing and premium contributions. The Affordable Care Act (ACA) does provide for a maximum out of pocket (MOOP) limit for drug and medical costs combined for the commercial market. The MOOP for 2018 is $7,350 per person per year, which can represent a substantial percentage of income for most individuals. Cost increases to employers and other plan sponsors over the past several decades have resulted in increased cost sharing, increased member contributions to premiums, and even elimination of some employer or other sponsored health plans. Pharmacy claims are subject to the deductible in high-deductible health plans, exposing members to more cost sharing. • Government Programs—Increasing plan costs for government health care programs will likely cause issues for individuals enrolled in these programs and for the public as a whole. Individuals enrolled in government programs may be forced to pay higher premium contributions and/or cost sharing, or incur more rigid plan eligibility requirements. Government programs also may consider not covering or restricting the use of some of the highest-cost drugs for fiscal reasons. • Uninsured Population—Drug prices are usually higher for uninsured individuals than for insured members because some payers can negotiate lower prices due to their contracting efforts, so price increases can be more of a challenge for this population. Costs and subsequent increases in costs may be offset partially by a discount drug card, copay coupons, or subsidies provided by patient assistance programs. Discount drug cards have also been used in commercial populations. While these cards can help reduce out-ofpocket spending, especially for the uninsured and low-income population, they can cause increased prescription drug spending as costs shift to higher-cost drugs. This, in turn, can lead to higher premium increases.

#### A decrease in coverage exacerbates infectious diseases and poses a risk to public health

East and Marcus 20 East, Chloe, and Michelle Marcus. "Disparities In Access To Health Care During A Pandemic | Econofact." Econofact | Key facts and incisive analysis to the national debate on economic and social policies. N.p., 2020. Web. 29 Aug. 2021. Chloe East is an Assistant Professor. Expertise is in Public Economics, Labor Economics, and Health Economics at the University of Colorado. Michelle Marcus is an Assistant Professor, Department of Economics. Research specializes in health economics, environmental economics, and applied microeconomics at Vanderbilt University.

The Issue: The coronavirus crisis has shone a spotlight on existing disparities in access to health care in the United States and on the implications that this uneven access can have in the context of an infectious disease pandemic. Immigrants, especially non-citizens, are less likely to be insured than natives. Moreover, non-citizens are less likely to have a usual place for health care and to cite cost being a barrier to health care. The gap in insurance is driven by differences in access to both public and private health insurance. This gap can lead to worse health among non-citizens, but also, can have negative public health consequences for the general population, particularly in the setting of communicable diseases, such as COVID-19. Immigrants are less likely to have health insurance than natives. Lack of access to medical care can adversely impact public health in a pandemic. The Facts: In 2017, the majority of the U.S. working-age population received coverage through private health insurance (almost 70 percent). An additional roughly 19 percent were covered by Medicaid or other public programs, and 12 percent remained uninsured. However, there are large disparities in access to health insurance between immigrants (foreign-born) and natives (U.S.-born). Immigrants, especially those who have not acquired citizenship through naturalization, are less likely to have private health care coverage than those who are native-born. Working-age adult non-citizens are 24 percentage points less likely to have private health insurance than U.S.-born adults (85 percent of all non-citizens are working-age adults.) This gap is slightly wider when comparing Hispanic non-citizens to Hispanic U.S.-born adults (26 percentage points, see chart above). Much of this gap is explained by differences in the availability of employer-provided health insurance. Non-citizens are more likely to work at smaller, non-public firms, which are less likely to provide insurance. Additionally, non-citizens have shorter job tenure and earn lower wages, which limits their access to employer-provided insurance (see [here](https://pubmed.ncbi.nlm.nih.gov/17355593/) and [here](https://www.kff.org/disparities-policy/fact-sheet/health-coverage-of-immigrants/)). Due to limitations on eligibility, Public Health Insurance does not fill in this gap in private insurance coverage; non-citizen adults are 26 percentage points more likely to be uninsured than the U.S.-born adults. The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 introduced new limits on access to Public Health Insurance programs for lawfully present non-citizens. At the federal level, newly-arrived adult permanent residents were made ineligible for Medicaid for their first five years of residence in the U.S. While states could use their own funds to restore eligibility during this period, [only eight states](https://gspp.berkeley.edu/assets/uploads/research/pdf/Bitler-Hoynes-Immigrants-Safety-Net-fin.pdf) did so. Comparing within disadvantaged individuals, who are more likely to meet income eligibility criteria for Public Health Insurance, U.S.-born Hispanics with at most a high school degree are twice as likely to receive Public Health Insurance than non-citizen Hispanics with at most a high school degree (40 percent compared to 19 percent). Roughly [40% of non-citizens are undocumented](https://www.kff.org/disparities-policy/fact-sheet/health-coverage-of-immigrants/) and face greater difficulties in accessing health insurance. However, the gap in insurance between citizens and non-citizens is not solely driven by undocumented individuals: lawfully present immigrants have rates of uninsurance that are [double](https://www.kff.org/disparities-policy/fact-sheet/health-coverage-of-immigrants/) that of citizens. The Kaiser Family Foundation [estimates](https://www.kff.org/disparities-policy/fact-sheet/health-coverage-of-immigrants/) that undocumented immigrants have rates of uninsurance that are four times that of citizens. Undocumented immigrants are ineligible for federal Public Health Insurance programs, except for payment for emergency services (see [here](https://econofact.org/do-undocumented-immigrants-overuse-government-benefits)). Undocumented immigrants are also more likely to work in low wage jobs compared to lawfully present non-citizens and citizens, which may reduce their access to employer-provided insurance. Eligible non-citizen adults have [lower participation rates](https://www.aeaweb.org/articles?id=10.1257/pol.6.3.313) in public health insurance programs compared with eligible citizen adults. This is in part due to fear that receiving public benefits might affect immigration status decisions, which was likely made worse by changes to the Public Charge Rule announced in [Fall 2019.](https://econofact.org/will-the-public-charge-rule-reduce-safety-net-expenditures) With this ruling, the United States Citizenship and Immigration Services (U.S. CIS) expanded the definition of what constitutes "public charge" to include consideration of prior use of food and medical assistance benefits in order to deny immigration to the United States. U.S. CIS [has clarified](https://www.uscis.gov/green-card/green-card-processes-and-procedures/public-charge) that COVID-19-related health services will not affect immigrants’ status decisions under the public charge rule even if they are paid for by Medicaid. However, immigrant advocates have expressed [concern over confusion](https://www.insideedition.com/public-charge-rules-could-impede-coronavirus-response-immigration-advocates-worry-58708) about the public charge rule reducing COVID-19 testing and treatment [among immigrants](https://www.healthaffairs.org/do/10.1377/hblog20200416.887086/full/). Non-citizen adults are 15 percentage points less likely than U.S.-born adults to have a usual place to go for health care (see chart below). The most common reason cited for this lack of access to regular health care is concerns about cost. Without access to regular care, non-citizens are likely to have less preventative care, which may lead to costly emergency care in the future. For example, we estimate, with data from the National Health Interview Survey, that only about 29 percent of non-citizens receive the influenza vaccine, compared to 36 percent of U.S.-born adults. Increased vaccination rates would help slow the spread of infectious disease among both the non-citizen and citizen populations. In the context of infectious diseases, including COVID-19, reduced access to health care can create a public health risk. Uninsured non-citizens are less likely to have a primary care physician to call in case of symptoms. Large out-of-pocket costs and fear of using public benefits may lead non-citizens to wait to seek care until their symptoms are life-threatening. This avoidance of health care is likely to increase the spread of infection. [Borjas (2020)](https://www.nber.org/papers/w26952.pdf) finds that people residing in immigrant neighborhoods in New York City were less likely to be tested, but, among those tested, were more likely to test positive for COVID-19. We find a similar pattern at the national level across counties: a positive correlation between the rate of deaths per person for COVID-19 and the percent of the county population that is foreign-born. While this correlation persists after taking into account urbanicity, number of hospital beds, demographics (age, race, education, and income), and stay-at-home policies, many other factors may contribute to this correlation. For example, Hispanic immigrants may be more likely to work in [frontline service jobs](https://econofact.org/essential-and-frontline-workers-in-the-covid-19-crisis) requiring face-to-face interaction and a greater risk of infection during the pandemic. At this time, the extent to which lack of health care coverage and fear of interaction with the health care system contributes to this association with COVID-19 severity is unknown. What this Means: Non-citizens are less likely to have employer-provided health insurance offered to them through their job. Moreover, limitations on non-citizen’s eligibility for public health insurance, and fear of receiving public benefits, means that non-citizen adults are much less likely to be covered by any health insurance compared to citizens. This also translates into reduced access to health care, including preventative care such as the flu vaccine among non-citizen adults. In the context of infectious disease, barriers to preventive care, testing, and medical attention, can have ripple effects that go beyond the uninsured individuals. People who lack coverage could delay testing or seeking help even when they feel unwell, making it more likely to expose others to contagion in the meantime, which will adversely affect public health. This gap in non-citizens’ access to health care is crucial for policy-makers to consider as the country works to fight the COVID-19 pandemic.

**The next pandemic risks killing billions**

**Fletcher 20** Fletcher, Martin. "Why Stephen Emmott Fears The Next Pandemic Could Kill A Billion People". Newstatesman.Com, 2020, <https://www.newstatesman.com/politics/environment/2020/08/why-stephen-emmott-fears-next-pandemic-could-kill-billion-people>. Martin Fletcher is a former foreign editor of the Times and a New Statesman magazine contributing writer and online columnist.

In 2012 Stephen Emmott, then head of computational science at Microsoft and a professor of computational science at Oxford University, was persuaded to stage a one-man show at London’s Royal Court Theatre by theatre director Katie Mitchell, who wanted to encourage collaboration between scientists and the arts. It was called *Ten Billion*, and the *Guardian* and*Financial Times* reviewers both described it as “one of the most disturbing” productions they had ever seen. Standing in a re-creation of his cluttered laboratory, Emmott described the “unprecedented planetary emergency” that humankind faces as the global population – a mere three billion in 1960 – soars rapidly towards ten billion, plundering the planet’s resources, devastating the environment, spewing greenhouse gases into the atmosphere and triggering the sixth mass extinction of life on Earth as we pursue ever more voracious lifestyles. The sold-out show was turned into a best-selling book with the same title and the same set of graphs – all resembling L’s tipped leftwards on to their sides as humanity’s destruction of the natural world took off properly with the Industrial Revolution. “We’re fucked,” Emmott concluded, and he ended by recalling the reply of a highly intelligent young scientific colleague when asked what he could do about the situation: “Teach my son how to use a gun.”  At the time the genial, unpretentious scientist was accused of scaremongering, exaggeration and scientific distortion, but one consequence of mankind’s recklessness that Emmott predicted with absolute certainty was a global pandemic exactly like Covid-19. Indeed, he had collaborated with Neil Ferguson, the Imperial College epidemiologist, on developing the modelling framework for global pandemics that Ferguson would later use to persuade the government to order Britain’s lockdown in March. **A coronavirus-type pandemic was inevitable**, Emmott, presently professor of biological computation at University College London, tells me by telephone from his home in Camberwell, south-east London. “**This one is a very small glimpse** – thankfully not as severe as it could be – into a potential and likely future**.” The next pandemic could kill a billion people**, he warns. “**The population is set to increase from 7.7 billion to at least ten billion**, and possibly more, before the end of this century. Urbanisation is increasing rapidly. ‘**Wet markets’ have proliferated over the past two decades. The proliferation of habitat destruction, forcing animals into direct contact with humans, is increasing** rapidly,” he says. All that, **allied with the relentlessly escalating movement of people and goods around the world, means “we are increasing every day the likelihood of a Spanish flu-type pandemic that would make this one pale by comparison**... We have no idea whether that’s around the corner in a month’s time, a year’s time or two or three decades’ time, but **it’s almost certainly going to happen and that one is going to be really quite deleterious to the human species**.” Of course, there have been plagues and pandemics in the past, he adds, but “this burying our heads in the sand, this view that we have this once a century so we just have to get over it, I think that’s nonsense”. Nor are zoonotic pandemics – those caused by pathogens jumping from animals to humans – the only threat to modern man. There could well be a “crop pandemic”, Emmott says. The “Green Revolution’” of the late 20th century vastly increased food production, but it did so by breeding genetic diversity out of cereal crops, leaving “monocultures” of wheat and corn. At the same time fungicides are becoming less and less effective. That means a range of novel plant pathogens has the potential to destroy much of the world’s food supply. “The consequences of that on political stability and forced migration are unforeseen, unknowable and probably unprecedented,” he says. Yet another potential threat comes from the melting of the world’s northern permafrost due to climate change. That could release a whole range of ancient pathogens that may have been locked in the ice for thousands of years.

#### Infectious disease serves as a threat multiplier – AIDS crisis proves

Brower and Chalk 03 Brower, Jennifer and Peter Chalk, The Global Threat of New and Reemerging Infectious Diseases: Reconciling U.S. National Security and Public Health Policy. Santa Monica, CA: RAND Corporation, 2003. https://www.rand.org/pubs/monograph\_reports/MR1602.html. Also available in print form. Jennifer Brower was Co-Director of the Congressionally-mandated Advisory Panel to Assess Domestic Response to Terrorism Involving Weapons of Mass Destruction (the Gilmore Commission).  Peter Chalk is a senior analyst at [Valens Global](https://valensglobal.com/) and an adjunct political scientist at the RAND Corporation. He is a specialist correspondent for Jane’s Intelligence Review and associate editor of Studies in Conflict and Terrorism, one of the foremost journals in the international security field.

Today, the United States and most of the world face little danger from direct military assault from an opposing state. This threat has been supplanted with concerns about “gray area” challenges that face the global community. Emerging security threats such as terrorism, drug trafficking, and environmental degradation differ significantly from traditional statecentric paradigms both in their causes and the policies designed to ameliorate them. The increasing transnational threat of infectious disease deserves special attention within this context of the evolving definition of security in the post–Cold War era. Statecentric models of security are ineffective at coping with issues, such as the spread of diseases that originate within sovereign borders, but have effects that are felt regionally and globally. Human security reflects the new challenges facing society in the 21st century. In this model, the primary object of security is the individual, not the state. As a result, an individual’s security depends not only on the integrity of the state but also on the quality of that individual’s life. Infectious disease clearly represents a threat to human security in that it has the potential to affect both the person and his or her ability to pursue life, liberty, and happiness. In addition to threatening the health of an individual, the spread of disease can weaken public confidence in government’s ability to respond, have an adverse economic impact, undermine a state’s social order, catalyze regional instability, and pose a strategic threat through bioterrorism and/or biowarfare. While infectious diseases are widely discussed, few treatises have addressed the security implications of emerging and reemerging illnesses. This report provides a more comprehensive analysis than has been done to date, encompassing both disease and security. It comes at a critical juncture, as the magnitude and nature of the threat is growing because of the emergence of new illnesses such as Acquired Immune Deficiency Syndrome (AIDS), Ebola, and hepatitis C; the increasing inability of modern medicine to respond to resistant and emerging pathogens; and the growing threat of bioterrorism and biowarfare. In addition, human actions amplify these trends by putting us in ever-greater contact with deadly microbes. Globalization, modern medical practices, urbanization, climatic change, and changing social and behavioral patterns all serve to increase the chance that individuals will come in contact with diseases, which they may not be able to survive. The AIDS crisis in South Africa provides a disturbing example of how a pathogen can affect security at all levels, from individual to regional and even to global. Approximately one-quarter of the adult population in South Africa is Human Immunodeficiency Virus (HIV) positive, with the disproportionate burden of illness traditionally falling on the most economically and personally productive segment of society. The true impact of the AIDS epidemic is yet to be felt. Deaths from full-blown AIDS are not projected to peak until the period between 2009 and 2012, and the number of HIV infections is still increasing. The disease is responsible for undermining social and economic stability, weakening military preparedness, contributing to increases in crime and the lack of a capability to respond to it, and weakening regional stability. Specific effects include creating more than two million orphans, removing about US$22 billion from South Africa’s economy, and limiting South Africa’s ability to participate in international peacekeeping missions. Many causes played a role in the development of the crisis, including promiscuous heterosexual sex, the low status of women, prostitution, sexual abuse and violence, a popular attitude that dismisses risk, as well as the failure to acknowledge the magnitude of the problem in the early and middle stages of the epidemic. The South African government has made a relatively small effort to curb the epidemic, in part due to President Thabo Mbeki’s public questioning of the link between HIV and AIDS, and this has had devastating results. This example serves as a lesson to other countries; if unaddressed, infectious disease can negatively and overwhelmingly affect a state’s functions and security. Currently the United States is managing the infectious disease threat; however, there are many indications that, if left unchecked, pathogens could present a serious threat to the smooth functioning of the country.

### Thus the Plan: Member states of the World Trade Organization ought to reduce intellectual property protections on medicine by adopting a one and done approach to medical patents.

### Solvency

#### A one and done approach would end patent walls

Feldman 19 Feldman, Robin. "Drug Patent Protection: It's Time For A 'One-And-Done' Approach - STAT." STAT. N.p., 2019. Web. 14 Aug. 2021. Robin Feldman is professor of law and director of the Institute for Innovation Law at UC Hastings College of the Law in San Francisco and author of [“Drugs, Money, and Secret Handshakes”](https://www.cambridge.org/us/academic/subjects/law/us-law/drugs-money-and-secret-handshakes-unstoppable-growth-prescription-drug-prices?format=HB)

In a perfect world, the system for conveying medications from their makers to patients should be designed to deliver the lowest-cost drugs. The system in the U.S. doesn’t even come close. Insurers should provide the lowest-cost and highest-quality drug benefit for each plan, public or private. But they don’t. Pharmacy benefit managers should use their volume buying power to obtain rebates that individuals could never obtain on their own and pass those rebates along to patients. But they don’t. Pharmacists, who know the prices of the drugs in their stock and who see patients’ cost-sharing amounts at the cash register, should be motivated to provide their customers with information on how to find the best deal so they can afford their medicines. But they aren’t. Doctors should make medication decisions that are in the best interests of their patients. But they often don’t. All of this occurs against the backdrop of a national conversation to lower drug costs and a policy to expedite and encourage vigorous competition in the pharmaceutical industry through the rapid entry of generic drugs as soon as patents expire. But even though the vast majority of prescriptions are filled with generic drugs, rising prices on existing brand-name drugs and sky-high prices for new drugs are swamping the savings from generics. Why isn’t the system working as it should? Some experts believe the U.S. can rein in drug process with [value-based pricing](https://www.statnews.com/pharmalot/2017/06/01/drug-prices-outcomes-health-plans/), which aims to tie the prices we pay for drugs to the benefits they provide, either in terms of longer life or better quality of life. Others call for [dismantling pharmacy benefit managers](https://www.statnews.com/2018/08/23/pbms-rebates-drug-purchasing/). Still others want large groups like Medicare [to negotiate with drug companies](https://www.hsgac.senate.gov/imo/media/doc/REPORT-Manufactured%20Crisis-How%20Better%20Negotiation%20Could%20Save%20Billions%20for%20Medicare%20and%20America's%20Seniors.pdf) for better drug prices. While each of these might help, they cannot solve the problem alone. Why? Because they do not reach the heart of the problem. As I explain in my new book, [“Drugs, Money, and Secret Handshakes,”](https://www.cambridge.org/us/academic/subjects/law/us-law/drugs-money-and-secret-handshakes-unstoppable-growth-prescription-drug-prices?format=HB) the government itself is giving pharmaceutical companies the power they are wielding through overly generous drug patent protection. Effective solutions must address that problem. Drug companies have brought great innovations to market. Society rewards innovation with patents, or with non-patent exclusivities that can be obtained for activities such as testing drugs in children, undertaking new clinical studies, or developing orphan drugs. The rights provided by patents or non-patent exclusivities provide a defined time period of protection so companies can recoup their investments by charging monopoly prices. When patents end, lower-priced competitors should be able to jump into the market and drive down the price. But that’s not happening. Instead, drug companies build massive patent walls around their products, extending the protection over and over again. Some modern drugs have an avalanche of U.S. patents, with expiration dates staggered across time. For example, the rheumatoid arthritis drug [Humira](https://www.statnews.com/pharmalot/2018/11/07/abbvie-biosimilars-humira-patents/) is protected by [more than 100 patents](https://www.wsj.com/articles/biosimilar-humira-goes-on-sale-in-europe-widening-gap-with-u-s-1539687603). Walls like that are insurmountable. Rather than rewarding innovation, our patent system is now largely repurposing drugs. Between 2005 and 2015, [more than three-quarters](https://academic.oup.com/jlb/advance-article/doi/10.1093/jlb/lsy022/5232981) of the drugs associated with new patents were not new ones coming on the market but existing ones. In other words, we are mostly churning and recycling. Particularly troubling, new patents can be obtained on minor tweaks such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit. 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](https://www.law.cornell.edu/wex/nonobviousness) 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.