# AC – Opioids

## Advantage

#### Drug Overdoes from addictive opioids are rooted in patents – they incentivize companies to aggressively market and overprescribe them which leads to huge amounts of people becoming addicted

Vertinsky 8-2 [Liza Vertinsky, Associate Professor, Project Leader for Global Health Law & Policy Project, Global Health Faculty Fellow, Emory University School of Law, 8-2-2021, “To Address the Overdose Epidemic, Tackle Pharma Industry Influence” The Harvard Law Petrie-Flom Center, Accessed 8-18-2021, <https://blog.petrieflom.law.harvard.edu/2021/08/02/opioids-pharma-regulatory-capture/> ww

A recently released government report estimates that 93,000 people died from drug overdose in 2020. This estimate reflects a jump in the death toll of almost 30% from 2019 to 2020, with opioids as a primary driver.¶ In response, President Biden has called for historic levels of funding for the treatment and prevention of addiction and drug overdose.¶ Transforming mental health and addiction services is a critical part of tackling the overdose crisis, but it is not enough, on its own, to address this epidemic, or to prevent a future one. We must also alter the conditions that fueled expanded use, and abuse, in the first place. As I argue in Pharmaceutical (Re)capture, a forthcoming article in the Yale Journal of Health Policy, Law and Ethics, this includes a change in how we regulate markets for prescription drugs.¶ To truly combat the epidemic, I suggest, we have to understand how pain became such a lucrative business and how regulators failed to protect the public health as the market for prescription opioids grew. Then, we need to put this understanding to work in the redesign of pharmaceutical regulation.¶ Although an increase in the illegal use of synthetic opioids, such as fentanyl, accounts for many of the current overdose deaths, the overdose epidemic has its roots in the increased prescribing of opioids. As I describe in a case study of the opioid epidemic, these are drugs that have been developed through the direct and indirect use of public funds, incentivized by government grants of patent, data, and market exclusivities, approved for use by the U.S. Food and Drug Administration, prescribed by state-licensed physicians, paid for by highly regulated public and private insurers, and otherwise subject to government approval and oversight. I show how this epidemic emerged as the result of an intertwined evolution of medical approaches to treating pain, growth of the business of treating pain, and patient beliefs about the appropriate treatment of pain, an evolution largely driven by those with the largest financial stakes in opioid prescriptions and sales.¶ Pharmaceutical (Re)capture provides a framework for understanding the multi-faceted ways in which the largest industry players influence the operation of pharmaceutical markets, and uses this framework to expose the limitations of current regulatory approaches.¶ In an ideal world, regulations are designed to protect the public interest, but, in reality, special interests can sometimes dominate regulatory decisions – a phenomenon generally referred to as regulatory capture. While helpful in explaining why regulators may sometimes fail to adequately protect the public interest, this concept is too narrow to encompass broader forms of industry influence over all material aspects of pharmaceutical markets and their regulation.¶ Instead, I develop the concept of pharmaceutical capture to encompass the myriad of ways in which the largest corporate actors influence markets for prescription drugs, with the market for prescription opioids as a particularly salient example.¶ Pharmaceutical capture occurs when the magnitude and scope of corporate influence is significant enough to alter the incentive structures, and corresponding decisions, of a sufficient number of pharmaceutical industry stakeholders in ways that ensure that relevant markets yield the outcomes desired by the industry captors. Understanding how pharmaceutical capture occurs is an essential first step in improving the effectiveness of regulatory strategies in pharmaceutical markets.¶ Although recent court settlements with some of the largest manufacturers and distributors of opioids have resulted in industry payouts of as much as $26 billion, these payments pale in comparison to the profits reaped from opioid sales. More importantly, the court settlements do little to change the market conditions that allowed for the growth of opioid profits at the expense of public health. With the exception of Purdue, which is now in the midst of a bankruptcy reorganization, major manufacturers and distributers of opioids continue to operate in much the same fashion as they did before, with court settlements operating more like parking tickets than drivers of change. Indeed, some of the very companies that benefitted from opioid sales are now reaping profits from the sale of treatments for addiction. Even the addiction treatment industry now has its own share of problems arising from the increasing demand for, and profitability of, addiction treatment services.¶ I conclude that an effective regulatory response towards the opioid epidemic must be geared towards addressing, and curtailing, pharmaceutical capture. Drawing lessons from the sophisticated corporate strategies used to influence market design, I offer three guiding principles for regulatory redesign. The first is the need for a holistic, systemic approach to regulation to replace current fragmented approaches. The second is the need to recalibrate key underlying policy assumptions about pharmaceutical markets and their appropriate regulation. The third is the need to make regulation more robust to corporate interests through strategies that narrow the divergence of private interests from the public interest, make capture more costly, and/or provide greater resources and rewards for regulating in the public interest.

#### Patents created the opioid crisis – Patents reward companies that make addictive drugs, and market exclusivity allows for aggressive marketing that allowed over prescription of opioids.

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Opioid overdoses killed an estimated 46,802 people in the US in 2018.1 That is a very slight decline from the previous year, but it is still a stunning number. To put that figure in perspective, more Americans now die from opioid over doses than from motor vehicle accidents2 or from the AIDS epidemic at its peak.3 Over one-third of US adults are estimated to have used prescription opioids in 2015, and nearly 5 percent to have misused them.4 The ubiquity of opioids not only put those patients who had prescriptions at risk of addiction but also unleashed a flood of pills that could be used and abused by family members and friends.5 Prescription opioids further fed into the spread of other opioids—including heroin, the use of which increased almost five - fold in a decade,6 and fentanyl, a synthetic opioid that has seen an even more dramatic and deadly surge.7 The economic costs of the epidemic are staggering, likely topping $500 billion annually.8 Without a doubt, the opioid crisis is among the primary policy challenges facing the US today. Two dominant narratives have emerged in scholarly and popular commentary on the opioid crisis's causes. One narrative casts opioid abuse as a 'disease of despair'-a by-product of poverty and lack of economic opportunity that has hit hardest in deindustrializing regions.9 This account may capture some important social trends, but identifying causal mechanisms behind the growth in opioid overdoses has proven challenging. '0 Econometric evidence suggests that overdoses have more to do with the availability and cost of drugs than with regional economic trends. As one prominent health economist recently wrote, 'efforts to improve local economies, while desirable for other reasons, are not likely to yield significant reductions in overdose mortality.'"¶ A second narrative-which we refer to as the 'disease of deception' account- emphasizes the role of pharmaceutical companies in hiding addiction risks from the public even as they aggressively marketed opioids for ever-broader uses. The chief antagonists in this narrative are members of the Sackler family that owned and ran Purdue Pharma, the maker of the now-infamous opioid drug OxyContin." The disease-of-deception narrative draws strong support from documents that have surfaced in litigation against Purdue Pharma revealing that company officials knew shortly after OxyContin's introduction in 1996 that the drug was being abused widely-yet concealed that information from the public."¶ Even Purdue Pharma's most withering critics do not allege that the company's cover-up was the sole cause of the opioid crisis, however. Widespread OxyContin abuse was a front-page news story as early as 2001 , when the opioid epidemic was still in its nascent stage. ' 4 '[N]o prescription drug in the last 20 years has been so widely abused so soon after its release as OxyContin,' the New York Times reported in May 200] , citing officials at the federal Drug Enforcement Administration (DF.A).'5 Talk radio host Rush Limbaugh drew greater attention to OxyContin in 2003 when he acknowledged on air that he had become addicted to prescription painkillers." And in 2007, a full decade before the annual death toll from opioid abuse reached its peak, Purdue Pharma and three of its executives entered a widely publicized guilty plea to federal criminal charges of misbranding charges related to the company's concealment of OxyContin's addictive properties. '7 None of this is to suggest that Purdue Pharma and other pharmaceutical companies that marketed prescription opioids are immune from blame for the current crisis. They are not. But deception alone cannot explain how opioids continued to inundate American medicine cabinets long after the addiction risks were widely publicized.¶ How did opioids overwhelm a nation well aware of their addictive properties, claiming victims across the socioeconomic spectrum? To understand that, one must understand not only how opioid manufacturers aggressively marketed their wares and why physicians profligately prescribed these drugs but also why alternative pain management strategies failed to emerge and why opioid antidotes and abuse treatments were so much slower to spread. Purdue Pharma and 'pill mills' play a part in this story," but so does Medicaid's 'best price' mandate and the National Institutes of Health's (N IH) allocation of research funding. Comprehending the origins and persistence of the crisis requires a deep dive into the organizations and policies that drove the opioid wave as well as those that failed to produce a robust response.¶ This article takes up that task. We suggest that the opioid epidemic is, in important respects, a disease of design. By this, we do not mean to suggest that the opioid crisis is the outgrowth of any single person's grand plan. What we mean instead is that the design of institutions created conditions that allowed the crisis to arise and proliferate. We focus in particular on the design of innovation institutions-the legal arrangements that structure the production and allocation of knowledge goods. '9 These include not only intellectual property law (patents, trade secrets, trademarks, regulatory exclusivity, etc.), but also the regulatory structures of the Food and Drug Administration (FDA) that determine whether knowledge goods can reach the market and the public benefit programs like Medicare and Medicaid that subsidize access to knowledge goods."¶ The design of innovation institutions enabled the opioid epidemic in a number of ways. First, US innovation institutions produced powerful incentives for pharmaceutical firms to develop and commercialize highly addictive prescription pain medicines while imposing weaker constraints on the rollout of new and more addictive products. Second, systems for allocating access to medical technologies promoted the use of addictive medicines while creating barriers to access for addiction treatments. Third, innovation institutions allowed-and indeed, encouraged-manufacturers of opioid antidotes to charge sky-high prices for products that, if more widely accessible, likely could have saved the lives of thousands of opioid overdose victims. Fourth, even while encouraging the rapid diffusion of addictive opioids, innovation institutions failed to sufficiently reward firms for formulating, refining, or popularizing alternative treatments for addiction or for the underlying problem of chronic pain. Again, no one sat down and designed the system to work this way. But a series of institutional design choices-some conscious, others unconscious-allowed a perfect storm to coalesce.¶ Some of these design flaws are relatively familiar. Intellectual property (IP) is an innovation institution that relies on signals of social value generated by market mechanisms, and market-generated signals can yield inefficient allocations of goods in the presence of externalities. Addictive pain medications generate negative externalities, and overdose and addiction treatments produce positive externalities, so it is perhaps unsurprising that America ended up with too many addictive prescription opioids and too few overdose and addiction treatments. Furthermore, IP distorts investments in research and development toward patentable technologies like pharmaceuticals," so it is no surprise that the patent-centric US innovation institutions resulted in a nation awash in pills but wanting for alternative pain treatments.¶ In other respects, our examination of the role of innovation institutions in the opioid epidemic challenges traditional understandings of IP in particular, and innovation institutions more broadly. The conventional view posits that IP policy's fundamental trade-off is between innovation and access, or what economists call dynamic efficiency and allocative efficiency.22 IP incentivizes the development and commercialization of new and better products (the dynamic-efficiency benefit), but it also encourages IP holders to raise prices and restrict access (the allocative-inefficiency cost). The opioid epidemic presents a contrasting image of IP’s potential consumption-expanding effects. Opioid patents induced investments in efforts to create demand for products that consumers did not previously believe they wanted." This demand-creation effect was especially powerful because the patented product was habit-forming-Purdue's lower prices for OxyContin in the short term could thus raise consumption in the long term.24 And this problem was exacerbated by the effective cost often being lowered through prescription drug insurance. Although scholars typically view the increased use of patented technologies as a welfare gain, the example of prescription opioids illustrates that patents' consumption-expanding effects can be pernicious. ¶ Ideally, the government would counteract the biases embedded in the patent system through other innovation institutions, including regulations, taxes, and government directed financial rewards such as grants and prizes. For example, market-based prizes in the form of insurance reimbursement policies appear to be a particularly promising intervention.2S But in the context of pain treatment, the federal government's non-patent interventions exacerbated the skew toward prescription opioids and away from other pain management and mitigation strategies. At the same time, government policies created barriers that limited access to addiction treatments. Additionally, and paradoxically, the federal governments subsidies for opioid antidotes may have reduced access to these lifesaving products, challenging the view that demand-side subsidies are a solution to the patent system's pitfalls.¶ Recognizing the role of America's innovation institutions in the opioid epidemic helps inform the search for paths out of the current crisis, but it is essential to emphasize that no magic-bullet policy will bring the opioid epidemic to an end. The proliferation of prescription opioids was both a function of incentives generated by the current innovation ecosystem and a response-misguided as it may have been-to the very real problem of chronic pain afflicting an estimated one in five US adults." Any comprehensive effort to curtail opioid abuse will require interventions aimed at addressing chronic pain in ways that do not put patients at risk of addiction. The solution likely will involve regulated use of opioids by the populations for which they are justified as well as both existing and novel nonaddictive analgesics." At the same time, wider access to existing non-pharmacological pain treatments such as acupuncture, physical therapy, exercise, meditation, and cognitive behavioral therapy may do as much to mitigate the overuse of prescription opioids as any pharmacological leap." Moreover, any comprehensive national strategy to contain the opioid epidemic also will require interventions aimed at individuals already in the throes of addiction (medically known as 'substance use disorder' or 'opioid use disorder').29 Initiatives at the federal, state, and local levels suggest progress in this regard, though still on a scale far too small relative to the problem that they aim to solve.30¶ This article is an attempt to understand how innovation institutions are bound up in the opioid crisis, how they might help to bring the crisis to an end, and what lessons the opioid crisis offers for innovation policy going forward. Part II investigates the relationship between innovation institutions and the sky-high rates of opioid use, abuse, and overdose. Part 111 draws on insights from the study of innovation policy and comparative institutional analysis to evaluate the ways in which innovation institutions can respond to the opioid epidemic. For example, distortions caused by patent law might be addressed through interventions in areas such as FDA regulation, tort law, and antitrust. And direct public support can address problems on both the incentive and allocation side of innovation policy. As we discuss, there are significant political hurdles to reform, although it is at least promising that opioid misuse is now being viewed as a public health problem. Finally, Part IV asks what lessons we can learn from the opioid crisis for innovation policy more broadly.

#### IPP rewards addictive medicines and punishes alternative medicines – the plan shifts patients towards non addictive meds through reducing the amount of opioids

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While our primary focus in this article is on the ways in which America's innovation institutions have contributed to the opioid crisis and can hasten its end, the opioid epidemic also yields lessons for innovation scholars that apply to other areas of public health and scientific knowledge.¶ The stories of OxyContin, Suboxone, and Evzio confirm some truths that we have long known about the IP system. IP is an effective innovation incentive for aggregating dispersed information about consumers' willingness to pay for new knowledge goods-but when markets fail, so too will IP. Two familiar reasons why markets fail to produce socially optimal outcomes are (1) the externalization of harms and (2) the externalization of benefits. OxyContin is an example of a product that generates negative externalities, and-unsurprisingly-we ended up with too much OxyContin. Suboxone and Evzio are examples of products that generate positive externalities, and-unsurprisingly-we have ended up with too little of these drugs. ¶ America's apparent underinvestment in non-pharmacological pain treatments likewise fits into our existing mental models. Non-pharmacological pain treatments such as yoga and acupuncture are almost inevitably nonexcludable and ineligible for patent protection. Our innovation ecosystem is well designed to reward patentable technologies, such as pharmaceuticals, and poorly structured to support the development of processes and practices such as checklists, cognitive behavioral therapy, and alternative medicine317¶ Yet in other ways, our study of the opioid crisis has challenged our beliefs about innovation policy and led us toward new insights. In this final part, we highlight five lessons from the opioid context for innovation policy more broadly: ¶ First, we think that the traditional view of IP as a trade-off between dynamic efficiency and allocative efficiency is less accurate than we once believed.3'8 In the case of OxyContin, patent protection appears to have encouraged Purdue Pharma's extraordinary investment in demand creation. Aggregate data on the consumption of patented and post-patent pharmaceuticals suggest that the OxyContin story is not an outlier in this regard.3 '9 Especially when a pharmaceutical manufacturer follows a relatively standard pricing strategy (such that the product is available to Medicaid and Medicare beneficiaries and is included in most private health plan formularies), above- marginal-cost pricing seems less likely to prevent the vast majority of US patients from gaining access than conventional IP models suggest.¶ Second, and relatedly, the fact that IP encourages demand creation should affect our view of IP's overall welfare effects. Do we want to encourage patentees to create demand for products for which demand does not currently exist? There are, perhaps, cases in which the answer is yes-for example, Eli Lilly's promotion of Prozac arguably generated greater attention toward untreated depression.32Â° But we should be aware that the patent system creates incentives for firms to promote products that consumers did not know they wanted (and indeed might not have needed).321¶ Third, the interaction between IP and addiction can be particularly pernicious. As we sought to illustrate in Section ll.B.l, firms have an especially strong incentive to promote habit-forming products-perhaps by initially charging below-marginal-cost prices-if they anticipate that they can maintain a medium- to long-term monopoly over that product. When the habit-forming nature of a product generates negative externalities, as is the case for medical addiction, the combination of this effect with the more general demand-creation incentives can have devastating social consequences. It is possible that this misalignment of IP rewards with social welfare could be addressed by reforms internal to IP. For example, Michael Risch has called for a revitalization of patent law's utility requirement to deny patents on inventions from which society reaps no benefit (even if the innovator can reap significant profits).322 Margo Bagley has suggested legislative restrictions on patentable subject matter to revive moral utility doctrine and move away from the US's current (and distinctively American) 'patent first, ask questions later' approach. As another example, Ted Sichelman suggests that patent law remedies should be reformed to better reflect the social value, not market value, of an invention.32" But, non-LP innovation institutions also have an important- and perhaps paramount-role to play in correcting the 11' systems biases.325 ¶ A fourth lesson from the opioid crisis for other areas of innovation policy is that the notion that government subsidies can promote access to IP-protected products turns out to be less than clear-cut. Medicaid's best-price mandate incentivizes pharmaceutical firms to charge higher prices to the private sector, and as the number of patients covered by Medicaid increases, so too does the incentive for firms to set private sector prices with Medicaid in mind. This is not an argument against Medicaid expansion, and removing the best-price mandate without creating an alternative means to control government drug spending would lead to different (and perhaps worse) pathologies. But, it does suggest that government subsidies should be designed with attention to their impact on private pharmaceutical pricing. ¶ Indeed, in a world without Medicaid's best-price mandate or other limits on incentives to offer discounts to some purchasers, pharmaceutical firms might seek to maximize profits through price discrimination (ie seeking to ensure that every consumer who values a product at more than its marginal cost will be charged her willingness to pay and no more). Perfect price discrimination entails no deadweight loss. Medicaid changes the incentive to engage in price discrimination, however, because the lowest price charged to other purchasers becomes the ceiling for Medicaid reimbursement. The limit on charging CMS more than the 'usual and customary charges to the general public' has a similar effect.326 In such cases, IP does lead to serious allocative inefficiencies, but the inefficiencies are because of the way IP interacts with other government policies. To be sure, perfect price discrimination will almost never be possible, and deadweight loss in the IP system is inevitable. But the opioid crisis illustrates that subsidies can do as much to increase deadweight loss as to reduce it.¶ Finally, and notwithstanding our criticisms of the IP system, we again emphasize that non-IP innovation incentives and allocation mechanisms are imperfect. ln the case of the opioid epidemic, CMS created powerful non-IP incentives for hospitals to prescribe more opioids.327 That turned out to be a disaster. The root causes of this particular policy failure are unclear, but we should be cognizant in our critique of certain aspects of market-based IP policies that the grass is not always greener on the non-market side.

#### The plan spurs on innovation for non-opioid pain killers

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Conventionally, innovation scholars have focused on patent law as the main policy tool to increase production of new knowledge goods.226 Patents, at least in theory, leverage private information from market actors about the value and viability of potential projects and provide strong incentives for investments in promising ideas.227 But as emphasized in Section ll.B, these same features of the patent system encouraged the development and commercialization of prescription opioids. Given the patent system's pro-pharmaceutical skew-and, in particular, its bias toward addictive goods-one natural response might be to write all patents as a potential solution to a problem that, in many respects, is a product of too many pills.¶ We think that would be a mistake. As awareness grows among physicians and patients about the addiction risk associated with prescription opioids, demand for nonaddictive pain treatments will increase too. The patent system will generate strong financial incentives for pharmaceutical and biotech firms to invest in the development of non-opioid painlkillers,228 abuse-resistant opioids,'229 drugs that can be used to 230 and easier delivery methods for the overdose antidote naloxone.23' treat addiction, (Indeed, many firms already have.232) There is, to be sure, something unseemly about the very firms that fueled the spread of prescription opioids also profiting from the problem they helped create. Many Americans were thus understandably outraged to learn that Purdue Pharma has filed for a patent on a drug that could 'help wean addicts from opioids,' given that Purdue had helped to hook some of those same people on opioids in the first place.233 It would be an even crueler irony, though, if the patent system failed to reward investments in innovations that could bring the opioid epidemic under control and thereby encouraged the proliferation of prescription opioids but not the development of solutions to addiction.¶ Of course, these powerful patent incentives still may be subject to the same distortions described in Part 11. Patents also skew research toward treatments that require repeated use-and thus generate steady streams of revenue-rather than preventatives which are effective after a single administration.7"l'4 Patent law may therefore be more helpful, for example, in encouraging the development of nonaddictive painkillers than in the development of anti-addiction vaccines.235 Patent law likewise will do little to facilitate research and development directed at ideas that are difficult for a single firm to commodify—for example, reducing the default number of pills per prescription,236 informing doctors when their patients overdose,237 or encouraging the use of alternative pain treatments such as physical or behavioral therapy.238 Patents are also ineffective incentives for non-pharmaceutical addiction recovery tools such as mobile phone reminders that track the number of days that a patient has remained substance-free,239 for creative ideas like using reverse motion detectors in clinic bathrooms (ie devices that detect lack of motion) to prevent fatal overdoses,240 and for research on the comparative value of supervised drug use clinics241 or different drug court protocols or streamlined ER-to-outpatient transfers for preventing relapse.242¶ Episodes such as Indivior’s effort to undermine the tablet form of Suboxone243 highlight the need to consider broad changes to patent law and its interactions with FDA regulatory law, antitrust law, tort law, and other institutions that might cabin its pathologies.244 These changes, however, may take years to formulate and implement. In the meantime, the opioid epidemic’s daily death toll reminds us of ‘the fierce urgency of now.’245 While patents may play a role in promoting the development and commercialization of opioid alternatives, antidotes, and addiction treatments, we think it is clear enough that America will not patent its way out of the opioid crisis. Policymakers will need to look elsewhere for solutions.

## Plan

#### Plan: The Member Nations of the World Trade Organization Should Terminate current and ban secondary patents of opioid painkillers.

#### The plan solves the evergreening of opioid patents – companies will renew their patents over and over without making any substantial changes – banning the evergreening of these patents will deter the aggressive marketing that’s incentivized by patents

#### The plan is key – Other stratagies can’t solve patent abuse

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The US opioid epidemic seems to many to have come out of nowhere, and there’s been much finger-pointing in recent years about how this state of affairs came to be. Some have argued that inadequate mental healthcare is to blame. Others have postulated that doctors were naively over prescribing them as a way to quickly treat pain and please their patients. But, according to a recently published draft report, at least some of the blame should be attributed to the way pharmaceutical companies have manipulated patent extensions over the past decade.¶ In the 1970s and 80s, doctors were looking for better ways to control pain, and many believed opioids a good, non-addictive option. In the 1990s, drug manufacturers began aggressively marketing the painkillers to doctors and patients. Soon, patients (or their loved ones who stole their pills) were developing tolerances for low doses, and graduated to abusing the drugs by crushing them and either snorting or liquefying and injecting the powders, or turning to heroin, often fatally. By the time the science caught up in the early 2000s, it was too late: Thousands of people were addicted to opioids. Opioids have killed over 560,000 people in the US since 2000. Last month, president Donald Trump declared the crisis a public health emergency.¶ Pharmaceutical companies profited from this demand, and the exclusive rights they had to make these compounds. This allowed them to pump even more money into marketing, which inevitably led to doctors prescribing more of them.¶ From the moment a drug company patents a compound, it has 20 years of exclusive manufacturing and selling rights on it. In theory, a company’s monopoly on a drug dissolves after its patents expire and generics flood the market. But drug companies usually file for patents in the discovery stages as a way of staking their territory in the field. The approval process for drugs from the US Food and Drug Administration involves lengthy clinical trials, which usually take around 12 years—meaning that manufacturers typically only get to actually sell their drugs exclusively for about eight years before generics come onto the market. So they often seek ways to extend this exclusive period.¶ Perhaps the most common way is to change a drug ever so slightly. For example, a company can file a new patent if it makes a version of a drug with a slightly different dosage, or with a different way it’s released in the body over time.¶ “Our patent system doesn’t require something to be better, just different,” says Robin Feldman, the director of the Institute for Innovation Law at the University of California Hastings College of Law. “Rather than creating new medicines, pharmaceutical companies are largely recycling and repurposing [drugs].” The manufacturer can then hold off generic competition for a few more years. Competitors (or anyone else) could theoretically make the case in court that these compounds aren’t actually different, but the legal battle would likely be too costly and time consuming to be worth it.¶ Feldman, together with Connie Wang, a law student at Stanford University, meticulously went through a decade’s worth of versions of the US Food and Drug Administration’s “Orange Book” and US Patent and Trademark Office website listings to investigate the relationship between patent filings, exclusivity extensions, and drug approvals. They found that of the 100 best-selling drugs from 2005 to 2015, about 80% had a patent extension filed on them at least once. About 50% of these drugs had multiple extensions.¶ That, Feldman argues, can create a dangerous cycle. “The immense monopoly profits allow drug companies like Purdue to aggressively market their drugs to doctors,” explains Feldman. “Physicians preferentially prescribe these particular drugs. Where drugs are addictive and problematic, that’s dangerous.”¶ Purdue Pharma is the company behind one of the most popular prescription opioids. OxyContin first came on the market in 1996 and has since brought in billions of dollars of revenue. Purdue’s patent for OxyContin was originally supposed to expire in 2013. But by making minor tweaks to the drug’s chemical structure to create a slow-release pill the company markets as “abuse-proof,” Purdue has been able to file new patents for OxyContin 13 times with the US Patent and Trademark Office over the past decade, thereby extending its exclusive selling rights on the drug through 2030.¶ Purdue did not respond directly to Feldman’s analysis when forwarded a copy by Quartz, instead providing a statement noting, “One potentially important step towards the goal of creating safer opioid analgesics has been the development of opioids that are formulated to deter abuse. FDA considers the development of these products a high public health priority. Purdue reformulated OxyContin with abuse-deterrent properties recognized by FDA, and the Patent and Trademark Office granted Purdue patents for inventions that went into the development of those properties.”¶ The most prominent example is a patent Purdue filed in 2003 for “abuse-proof” OxyContin. It was made of materials that are harder to crush, and forms a gel that is more viscous and harder to inject. In theory, it would make for a safer alternative to regular OxyContin. However, the same patent claims that “intravenous administration of such a gel would most probably result in obstruction of blood vessels, associated with serious embolism or even death of the abuser.” In all likelihood, people crushing these pills to get high would still seriously harm, if not kill, themselves.¶ Technically, the abuse-proof pills worked: When researchers from Washington University in St. Louis informally surveyed more than 2,500 people taking opioids to see if this pill really was more abuse-proof than before, they found that the number of people who admitted to using it to get high dropped from about 35% to about 13% two years later. However, two thirds of respondents said they had switched to other opioids instead—often heroin, which is less expensive and easy to use.¶ It’s not Purdue’s fault doctors kept prescribing (and overprescribing) these pills in an attempt to alleviate pain, nor that the loved ones of patients often took instead to get high. It’s also not the company’s fault there weren’t better resources for those who found themselves addicted—drugs like buprenorphine, methadone and naltrexone can help ease addiction, but as recently as 2016, they still weren’t being given to patients in two-thirds of US addiction clinics.¶ That said, Purdue spent many years and huge sums of money convincing doctors that OxyContin was non addictive. In fact, the company has paid over $600 million in fines to federal and state agencies, as well as individual patients, to settle claims that it falsely marketed OxyContin as safe from abuse. Three of the company’s executives pled guilty to “misbranding,” which is a criminal violation.¶ The company is still profiting off “abuse-deterrent” OxyContin. Though there are currently “authorized generics” of OxyContin available, these are made by manufacturers with licenses to use Purdue’s formula. In other words, Purdue makes money off them. And there are currently no approved abuse-deterrent generics in the US. In September of this year, FDA commissioner Scott Gottlieb said that soon the agency plans to issue guidelines to assist companies who are trying to file applications for these types of generics. No word on when that document will be published, however.

## FW

#### The Standard is maximizing expected well-being.

#### 1] Aggregation is inevitable for governments since they have to make tradeoffs – actor specificity o/w since different agents have different obligations.

#### 2] Consequences matter – if you knew taking an action would result in a consequence, it becomes in line with your intent since you intend for that consequence to happen.

#### 3] Binding – pain and pleasure are the only things with intrinsic value and disvalue – if I put my hand on a hot stove I will pull away – ethics must be binding bc if they aren’t then it’s impossible to generate obligations

#### 4] “Scenario” based probability calculus is logically bankrupt and misunderstands IR. Prefer small, probable impacts

Kanwisher 89 [Nancy Kanwisher “*Cognitive Heuristics and American Security Policy*” Published: The Journal of Conflict Resolution, December 1989, Vol. 33, No. 4] [https://www.jstor.org/stable/173995; pp. 654–656] [PDF available upon request] [Kanwisher: Professor of Cognitive Neuroscience at MIT. Ex-faculty member at UCLA and Harvard. 1999 received the National Academy of Sciences Troland Research Award. Elected to the National Academy of Sciences in 2005 and to the American Academy of Arts and Sciences in 2009.] || SM

In a study of heuristics used in probability judgments, Tversky and Kahneman asked the participants of the 1982 Second International Congress on Forecasting to evaluate hypothetical scenarios (Tversky and Kahneman, 1983). All participants were professional forecasters and planners, and many had used scenarios in their work. One group evaluated the probability of "a complete suspension of diplomatic relations between the USA and the Soviet Union, sometime in 1983"; the other group judged the probability of "a Russian invasion of Poland, and a complete suspension of diplomatic relations between the USA and the Soviet Union, sometime in 1983."

The suspension-and-invasion scenario was judged to be much more probable than the suspension-only scenario, even though the latter event is a strict subset of the former. Tversky and Kahneman call this the "conjunction fallacy," because the conjunction of two events is judged more likely than one of them, even though this is a logical impossibility. People's probability judgments seem to follow their impressions of the plausibility of different scenarios: They find the suspension-and-invasion scenario more "representative," or typical, of superpower behavior than the suspension-alone scenario, which may seem inexplicable and hence not representative. This fallible evaluation method is an example of what Tversky and Kahneman call the "representativeness heuristic."

Thus, intuition tells us that the more detailed a scenario is, the more probable it is. Logically, however, the exact opposite is true. Tversky and Kahneman conclude that

scenarios can usefully serve to stimulate the imagination.... However, the use of scenarios as a prime instrument for the assessment of probabilities can be highly misleading. . A detailed scenario consisting of causally linked and representative events may appear more probable than a subset of these events. This effect contributes to the appeal of scenarios and to the illusory insight that they often provide [Tversky and Kahneman, 1983: 308].

Consideration of particular war-fighting scenarios has long played a key role in strategic analysis. Herman Kahn, who developed a complex taxonomy of different possible war-fighting scenarios, argued that scenarios "serve to call attention, sometimes dramatically and persuasively, to the large range of possibilities that must be considered in strategic analysis, some of which may escape notice if an analysis is done using conventional analytic techniques" (Kahn, 1962: 144). But while Kahn correctly recommends that the scenario not be used as a "predictive device," his position reflects some psychological naivete. People find causal sequences highly compelling and will often judge a representative scenario to be more likely than any of its component events. Thus, even if the purpose of developing scenarios is not to make or influence probability judgments, this may be the unintended consequence.

In fact, there is evidence that strategic priorities have in the past become distorted by overemphasizing the most extreme scenarios at the expense of less flashy but more likely ones. In 1960, although 90% of RAND studies used a bolt-out-of-the-blue surprise attack as a starting point, Herman Kahn and Tom Schelling polled their RAND colleagues and found that this was considered the least likely scenario (Herken, 1985: 205). Overemphasis on first-strike scenarios is not restricted to Hawks. Rathjens and Reed (1986) point out that while the most important arguments that Doves raised against the MX missile were that it was unnecessary and expensive, "it was most effectively opposed, however, by calling attention to its threatening characteristics as a first-strike weapon and its attractiveness as a target for a first-strike by the Soviet Union" (1986: 45). But, they contend, such arguments are unrealistic and lead to a distortion in perceptions of what are the most likely scenarios for the initiation of conflict.

Thus, while scenarios may be helpful in some respects, they may distort the focus of both strategic analysis and arms control. If scenarios must be used, one way to guard against biased probability estimates might be to estimate the probability of independent components in the causal sequence and multiply them together to estimate the overall probability of the overall scenario. Unfortunately, using confidence intervals may not be very helpful, because of the strong tendency for experts to be overconfident of their estimates (Lichtenstein, Fischoff, and Phillips, 1982). At the very least, however, strategic analysts should carefully consider the consequences of providing the defense community with esoteric but deceptively compelling stories about nuclear war.

It might be argued that biases in the subjective probabilities of scenarios do not matter because in "worst-case planning" probability is irrelevant; one simply prepares for the worst case - no matter how improbable - and assumes this preparation will suffice for less drastic scenarios. Two things are wrong with this argument. First, preparations for a worst-case scenario may make other undesirable events more probable. For example, preparing for what to do if deterrence fails may well increase the probability that it will in fact fail. As Les Aspin, chairman of the House Armed Services Committee, said recently on the issue of MX vulnerability to surprise attack, "the chances for a true, bolt-from-the-blue surprise attack are extremely small. But even in times of crisis, our political leaders may choose not to put our nuclear forces on wartime alert for fear of triggering a nuclear shoot-out" (reported in New York Times, March 24, 1989: A 9). Thus, the overall utility of preparing for the worst case cannot be determined without assessing how such preparations affect the likelihood of that worst case and of other scenarios. Second, since the domain of possible scenarios (and the range of attributes used to characterize those scenarios) is unbounded, it is impossible to define the worst case.3 The only way to salvage the idea is to reintroduce the role of probability and deal with "worst plausible cases." But once scenario probability assessment became necessary again, the problem of psychological distortions would resurface.

#### 5] Slow violence is invisible and exponential – prefer it over flashpoint explanations of violence

Nixon 11

(Rob, Rachel Carson Professor of English, University of Wisconsin-Madison, Slow Violence and the Environmentalism of the Poor, pgs. 2-3)

Three primary concerns animate this book, chief among them my conviction that we urgently need to rethink-politically, imaginatively, and theoretically-what I call "slow violence." By slow violence I mean a violence that occurs gradually and out of sight, a violence of delayed destruction that is dispersed across time and space, an attritional violence that is typically not viewed as violence at all. Violence is customarily conceived as an event or action that is immediate in time, explosive and spectacular in space, and as erupting into instant sensational visibility. We need, I believe, to engage a different kind of violence, a violence that is neither spectacular nor instantaneous, but rather incremental and accretive, its calamitous repercussions playing out across a range of temporal scales. In so doing, we also need to engage the representational, narrative, and strategic challenges posed by the relative invisibility of slow violence. Climate change, the thawing cryosphere, toxic drift, biomagnification, deforestation, the radioactive aftermaths of wars, acidifying oceans, and a host of other slowly unfolding environmental catastrophes present formidable representational obstacles that can hinder our efforts to mobilize and act decisively. The long dyings-the staggered and staggeringly discounted casualties, both human and ecological that result from war's toxic aftermaths or climate change-are underrepresented in strategic planning as well as in human memory. Had Summers advocated invading Africa with weapons of mass destruction, his proposal would have fallen under conventional definitions of violence and been perceived as a military or even an imperial invasion. Advocating invading countries with mass forms of slow-motion toxicity, however, requires rethinking our accepted assumptions of violence to include slow violence. Such a rethinking requires that we complicate conventional assumptions about violence as a highly visible act that is newsworthy because it is event focused, time bound, and body bound. We need to account for how the temporal dispersion of slow violence affects the way we perceive and respond to a variety of social afflictions-from domestic abuse to posttraumatic stress and, in particular, environmental calamities. A major challenge is representational: how to devise arresting stories, images, and symbols adequate to the pervasive but elusive violence of delayed effects. Crucially, slow violence is often not just attritional but also exponential, operating as a major threat multiplier; it can fuel long-term, proliferating conflicts in situations where the conditions for sustaining life become increasingly but gradually degraded.

## UV

#### 1AR theory –

#### A] AFF gets it because otherwise the neg can engage in infinite abuse which outweighs their arguments

#### B] Drop the debater – the time crunched 1AR can’t win substance and theory to check abuse

#### C] Competing interps – 1AR interps aren’t bidirectional so they should defend their norm and the neg can always brute force their way through reasonability debates

#### D]They have 6 mins to answer it while I only have 3 mins to flesh it out and make it a voter which means they don’t need the RVI

#### E] 1AR theory first – it’s a bigger percentage of the 1AR than NC theory means the abuse was worse and if we win the NC is abusive you shouldn’t evaluate any of the arguments from it anyways

#### NC Theory –

#### A] It’s drop the argument since the 1AC speaks in the dark and violates countless bidirectional interps no matter what so we shouldn’t be punished for it.

#### B] Reasonability since the 1AR is too short to effectively win offense against a 6-minute 2nr dump.

#### C] Yes RVIs – k2 topic edu by deterring friv violations and forces negs to think twice before skewing the 1AR since they know each shell is another split in the 2N, also k2 reciprocity – T is a unique avenue to the ballot that the aff can’t access – makes T structurally unfair without the RVI which kills fairness.

#### P&P affirm –

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

#### 2] Illogical – presuming statements false is illogical since you can’t say things like P and ~P are both wrong.

#### Reformism is effective and brings revolutionary change closer rather than pushing it away

Delgado 9 (Richard, self-appointed Minority scholar, Chair of Law at the University of Alabama Law School, J.D. from the University of California, Berkeley, his books have won eight national book prizes, including six Gustavus Myers awards for outstanding book on human rights in North America, the American Library Association’s Outstanding Academic Book, and a Pulitzer Prize nomination, Professor Delgado’s teaching and writing focus on race, the legal profession, and social change, 2009, “Does Critical Legal Studies Have What Minorities Want, Arguing about Law,”) //BS 1-28-2018

2. The CLS critique of piecemeal reform Critical scholars reject the idea of piecemeal reform. Incremental change, they argue, merely postpones the wholesale reformation that must occur to create a decent society. Even worse, an unfair social system survives by using piecemeal reform to disguise and legitimize oppression. Those who control the system weaken resistance by pointing to the occasional concession to, or periodic court victory of, a black plaintiff or worker as evidence that the system is fair and just. In fact, Crits believe that teaching the common law or using the case method in law school is a disguised means of preaching incrementalism and thereby maintaining the current power structure.“ To avoid this, CLS scholars urge law professors to abandon the case method, give up the effort to ﬁnd rationality and order in the case law, and teach in an unabashedly political fashion. The CLS critique of piecemeal reform is familiar, imperialistic and wrong. Minorities know from bitter experience that occasional court victories do not mean the Promised Land is at hand. The critique is imperialistic in that it tells minorities and other oppressed peoples how they should interpret events affecting them. A court order directing a housing authority to disburse funds for heating in subsidized housing may postpone the revolution, or it may not. In the meantime, the order keeps a number of poor families warm. This may mean more to them than it does to a comfortable academic working in a warm office. It smacks of paternalism to assert that the possibility of revolution later outweighs the certainty of heat now, unless there is evidence for that possibility. The Crits do not offer such evidence. Indeed, some incremental changes may bring revolutionary changes closer, not push them further away. Not all small reforms induce complacency; some may whet the appetite for further combat. The welfare family may hold a tenants‘ union meeting in their heated living room. CLS scholars‘ critique of piecemeal reform often misses these possibilities, and neglects the question of whether total change, when it comes, will be what we want.

#### Politics can be criticism rather than affirmation – making demands on the state does not mean endorsing it.

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There are two aspects that I would like to address here. Firstly, the notion of demand: making certain demands on the state – say for higher wages, equal rights for excluded groups, to not go to war, or an end to draconian policing – is one of the basic strategies of social movements and radical groups. Making such demands does not necessarily mean working within the state or reaffirming its legitimacy. On the contrary, demands are made from a position outside the political order, and they often exceed the question of the implementation of this or that specific measure. They implicitly call into question the legitimacy and even the sovereignty of the state by highlighting fundamental inconsistencies between, for instance, a formal constitutional order which guarantees certain rights and equalities, and state practices which in reality violate and deny them.