# 1AC vs. Pennsbury EH

## 1AC – Framing

#### The standard is minimizing oppression and structural violence.

#### 1] [Winter and Leighton] Oppression is a pre-requisite to other frameworks – all other frameworks are already starting from a flawed moral circle that has excluded certain groups – we need to include the voices of those who cannot be heard

Winter and Leighton 01 Deborah DuNann Winter and Dana C. Leighton. Winter: [Psychologist that specializes in Social Psych, Counseling Psych, Historical and Contemporary Issues, Peace Psychology. Leighton: PhD graduate student in the Psychology Department at the University of Arkansas. Knowledgeable in the fields of social psychology, peace psychology, and justice and intergroup responses to transgressions of justice] “Peace, conflict, and violence: Peace psychology in the 21st century.” Pg. 4-5]

Finally, to recognize the operation of structural violence forces us to ask questions about how and why we tolerate it, questions which often have painful answers for the privileged elite who unconsciously support it. A final question of this section is how and why we allow ourselves to be so oblivious to structural violence. Susan Opotow offers an intriguing set of answers, in her article Social Injustice. She argues that our normal perceptual cognitive processes divide people into in-groups and out-groups. Those outside our group lie outside our scope of justice. Injustice that would be instantaneously confronted if it occurred to someone we love or know is barely noticed if it occurs to strangers or those who are invisible or irrelevant. We do not seem to be able to open our minds and our hearts to everyone, so we draw conceptual lines between those who are in and out of our moral circle. Those who fall outside are morally excluded, and become either invisible, or demeaned in some way so that we do not have to acknowledge the injustice they suffer. Moral exclusion is a human failing, but Opotow argues convincingly that it is an outcome of everyday social cognition. To reduce its nefarious effects, we must be vigilant in noticing and listening to oppressed, invisible, outsiders. Inclusionary thinking can be fostered by relationships, communication, and appreciation of diversity. Like Opotow, all the authors in this section point out that structural violence is not inevitable if we become aware of its operation, and build systematic ways to mitigate its effects. Learning about structural violence may be discouraging, overwhelming, or maddening, but these papers encourage us to step beyond guilt and anger, and begin to think about how to reduce structural violence. All the authors in this section note that the same structures (such as global communication and normal social cognition) which feed structural violence, can also be used to empower citizens to reduce it. In the long run, reducing structural violence by reclaiming neighborhoods, demanding social jus- tice and living wages, providing prenatal care, alleviating sexism, and celebrating local cultures, will be our most surefooted path to building lasting peace.

#### 2] [Nixon 11] You should privilege everyday violence for two reasons- A) social bias underrepresents its effects B) its effects are exponential, not linear which means even if there is a small amount of structural violence, its terminal impacts are huge

Nixon, Rob. "Slow Violence And The Environmentalism Of The Poor.” 2011. Web. August 18, 2021. <https://www.jstor.org/stable/j.ctt2jbsgw>.

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.

#### 3] [Matheson 15] Large scale extinction impacts are impossible to predict or simulate and will almost always be wrong – prefer impacts we know are happening

Matheson 15 (Calum Matheson – This is his PhD dissertation at the University of North Carolina at Chapel Hill, “Desired Ground Zeros: Nuclear Imagination and the Death Drive”, https://cdr.lib.unc.edu/indexablecontent/uuid:4bbcb13b-0b5f-43a1-884c-fcd6e6411fd6, pgs. 77 – 86,)

Herman Kahn and Bernard Brodie, perhaps the most prominent American strategists of the early Cold War, tried to make nuclear war “thinkable” in the sense that they tried to explain how such a war might start and what options would exist for national leaders. At the same time, both acknowledged that the outcome of a full-scale nuclear war was indescribable. In Brodie’s words, to “make an intellectual prediction of the likelihood of war is one thing, to project oneself imaginatively and seriously into an expected war situation is quite another” (Ghamari-Tabrizi 149). The unwillingness or inability to think “seriously” about a nuclear war—in other words, to understand it instrumentally rather than through dislocating language of the sublime—was met by organizations like the RAND Corporation with an attempt to systematize nuclear strategy and develop the intellectual and technical means to actually fight and control a nuclear war. Before RAND exercised its power through the “Whiz Kids” of the Kennedy Administration, the Strategic Air Command’s “Sunday punch” nuclear plan, enshrined in SIOP-62, was an all-out nuclear attack on the USSR, Eastern Europe, and the People’s Republic of China. It might have killed 285 million people in the initial attack (Kaplan 269). Despite its intricate planning and detailed execution strategies, SIOP was immensely inflexible. Asked whether the U.S. had any options to attack without striking China, which might not even be a combatant in the war, General Thomas Power replied “Well yeh [sic], we could do that, but I hope nobody thinks of it because it would really screw up the plan” (Kaplan 270, emphasis in original). Starting in the 1960s, a set of war games of various complexity was developed to test a broader range of nuclear theories and attack options at RAND and elsewhere (Arbella 35). Games like them continue to be used for strategic military planning today (Raatz). Most of these games—or at least their results—are classified, as they became the basis for US nuclear plans. In politicomilitary games, a number of military officers, civilians, and generally mid- to lowranking government officials would play various roles as US and/or foreign. decisionmakers. Another group, “control,” would feed them information about the actions of countries or groups not played by the participants or about world events that might influence the context of their actions. In more limited military simulations, extant or proposed war plans would be evaluated by computer or human players to identify possible flaws and improvements. The games themselves never had a guarantee of accuracy and were often quite obviously flawed. In one Navy game, American aircraft carriers were declared to be unsinkable. In others, the Soviet Union was assumed to have no effective airpower. Because factors like air pressure, prevailing winds, defense effectiveness, early warning, and missile failure rate were largely random or incalculable, a “fudge factor” simply declared estimated success. Even their designers sometimes admitted that the games were inaccurate, unprovable, or simply wishful thinking (Ghamari-Tabrizi 8; Allen 78). Especially in the case of nuclear war, these games cannot possibly be understood as accurate simulations of a real-world system, because there is no empirical data on the compound effects of many near-simultaneous nuclear explosions and no data on what factors cause states to cross the nuclear threshold against other similarly-armed states, a fact that bedevils nuclear planning in general and always has (Kaplan 87). By the admission of many of those who create and play them, they are “social science fiction” with no tangible effect other than that they are entertaining (Ghamari-Tabrizi 160-1). Some contemporary social science work supports this claim especially in the context of extinction-level events. Human beings simply aren’t wired to think at such a scale, and they perform very poorly assessing probability and calculating magnitude (Yudkowsky). Others have suggested that warfare is a stochastic system that we could never identify laws for, no matter how diligent we might be, because its initial conditions are simply too complex a model and they do not conform to linear causality (Beyerchen; Buchanan 62). Indeed, military planners tended to be far less willing to predict the conduct and outcome of a conventional war—despite an enormous data set spanning thousands of years—than a nuclear war fought between two superpowers, an event that has never occurred in recorded history. Fred Iklé, former RAND strategists who was at times head of the Arms Control and Disarmament Agency and Undersecretary of Defense for Policy, criticized these semi-mathematical abstractions in harsh terms that deserve to be quoted at length: The prominence of the calculations continues because we know how to make them…we have tailored the problem to our capability to calculate. The seemingly rigorous models of nuclear deterrence are built on the rule: "What cannot be calculated, leave out’”…Such thoughts, especially those focusing on deterrence, lack real empirical referents or bases. No other field of human endeavor demands—absolutely compels—one to work out successful solutions without obtaining directly relevant experience, without experimenting. There can be no trial and error here, no real learning. Curiously, we are far more skeptical in accepting the calculations of traditional conventional military campaigns than the calculations of nuclear warfare. In fact, the more battle experience and information military analysts have, the more modest they become in predicting the course of conventional war. Such modesty is missing for nuclear war, where pretentious analyses and simplistic abstractions dominate and blot out the discrepancies existing between abstractions and possible reality—a reality that for so many reasons is hard even to imagine. (Iklé 246). Iklé is drawing attention to two unique aspects of nuclear war planning: first, that no empirical date (or at least very little) can be gathered for the species of war that planners concerned themselves with, and second, that unlike other military problems where little data exists, defense intellectuals were willing to display great confidence in untested (and untestable) theories. Despite this lack of empirical grounding, nuclear war simulations have been repeated again and again over the decades while nuclear doctrine has remained fundamentally the same (McKinzie et al. ix-xi). There has been some dispute in military circles about whether these exercises should be called simulations or games, with “simulations” becoming more popular by the 1980s (Allen 7). To call politico-military exercises “roleplaying games” conjures images of adolescent boys rolling dice and weaving fantasies about orcs and dragons. To call battle simulations “war games” might associate them with videogames produced for entertainment. Still, even military officers responsible for the creation of these artifacts had trouble distinguishing between game, model, and simulation and used them interchangeably. In his comprehensive history of U.S. wargaming, Thomas Allen writes that the three words “hover over imaginary battlefields like a mysterious, ever-shifting concept of the Trinity” (64, emphasis added). Berger, Boulay and Zisk, writing in the journal Simulation & Gaming acknowledge that “[d]efinitions of simulation are legion,” but center on representations of a system that allow users to model behavior (Berger et al. 416). Brewer and Shubik define games as a subset of simulation and simulation as a subset of modelling, the key defining feature of a game being the inclusion of human beings playing roles. Still, their extended attempt to define these terms results in the acronym MSG, grouping them all together (3-8). The difficulty in Brewer and Shubik’s definition is that all models and simulations require that human beings make decisions at least indirectly, at a minimum defining the independent variables and the parameters of the exercise. As a result, they all create some possibility for investment in the outcome. In common usage, the difference between simulations and models, on the one hand, and games, on the other appears to be a ludic dimension. Games are for play, with an agent making decisions within a set of prescribed rules to change the outcome, while simulations and models may simply represent the rules of a system. The least common denominator is that one rules-bound system—the game— stands in for another. Games, simulations, and models therefore have a metaphorical quality to them.10 In his work on videogames, Ian Bogost has identifies what he calls procedural rhetoric as “the practice of persuading through processes in general and computational processes in particular…a technique for making arguments with computational systems and for unpacking computational arguments others have created” (3). Whereas oral rhetoric attempts to persuade an audience to adopt a particular viewpoint through speech and written rhetoric does the same through writing, procedural rhetoric has its own unique goals and characteristics suited to the medium of games. Videogames create a digital process that simulates a real-world process, allowing the player to model something extant in the world of flesh, blood, steel and glass that exists outside of the game. Procedural rhetoric is the persuasive aspect of simulation. Bogost’s argument might be adapted to this understanding of metaphor. The replacement of the tenor (the thing represented) with the vehicle (the signifier standing in for it) makes an enthymematic argument that draws the audience to do the work of cathexis in connecting the two based on the shared principle that allows the substitution. This does not suggest that we read games as texts. Games require their players to invest in a specific way because they are called on to make choices that alter the outcome. Players identify with their characters in a powerful way: what is shared is not just a set of traits, but decisions over time that, to maintain the interest that keeps players playing, require at least some minimal attachment. One can identify deeply with Sauron, but no reading of Lord of the Rings can make him finally subjugate his haughty human and elven foes, let alone order the Scourging of the Shire and its disgustingly bourgeois hobbits when he still has a chance to succeed.11 This is the procedural element of Bogost’s theory: it is the procedure that links the system with its representation in the game, and the sense of control that binds us, something that differentiates this medium from others. One doesn’t have to decide that play matters and narrative doesn’t—it is the interaction between the two that channels the player’s investment in a game. In war games, attachments are formed even when a computerized Sam fights a computerized Ivan to test the SIOP and RSIOP.12 Allen’s book is full of examples of war game players becoming emotionally tied to their games, sometimes in perverse ways. Failing in a game that he was allowed to play, Allen himself described his team reacting with shock, real shock, not just a reaction to a bad break in a game. We were really feeling upset about what was happening in our imaginary world. ‘What is happening to our institutions?’ someone indignantly asked, as if real institutions were really going through what the situation paper had described. I had an unreasonable feeling of helplessness and failure. Some of us spoke softly to each other about having failed. (18). The prevalence of this reaction is confirmed in more recent scholarship by Paul Bracken, himself a war game participant. Bracken puts the case simply: “People get emotionally involved in games” (20).

## 1AC – Plan

#### Plan text: The member nations of the World Trade Organization ought to reduce intellectual property protections on insulin.

\*\*\*Ask in cx for clarifications, otherwise we get an auto we-meet on interps

#### A medicine is

a compound or preparation used for the treatment or prevention of disease, especially a drug or drugs taken by mouth.

<https://www.google.com/search?q=what+is+a+medicne&rlz=1C1CHBF_enUS857US857&oq=w&aqs=chrome.1.69i60j69i59l3j35i39j69i60l3.804j1j7&sourceid=chrome&ie=UTF-8> [its literally a google link, if u want what exactly I looked up to find it, type “what is a medicine” in the google search bar]

#### Insulin falls under this definition

#### Prefer additionally –

#### 1] Accessibility – it’s the google definition 😐

#### [Hanson 20] Reducing IP protections breaks apart the insulin oligopoly - reduces the prices of Insulin while raising innovation

Hanson 20 [Emily Hanson, JD Candidate at the University of Georgia School of Law, 2020, “Economic Burdens of Life: Trade Secrecy and the Insulin Pricing Crisis in the United States,” Journal of Intellectual Property Law, https://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?article=1457&context=jipl]/Kankee//edited by Arjuwan

The discussion above paints a grim picture. The abbreviated pathway to approval provided for under federal law has not achieved its goal of increasing competition and lowering prices in the insulin market. As progress stalls, many people with diabetes continue to struggle to pay for the medication they need as insulin prices continue to rise. It should be noted that some steps have been taken in 2019 by both corporations and governments to alleviate the insulin pricing crisis. For example, the three major insulin manufacturers, Eli Lilly, Sanofi, and Novo Nordisk, have each announced that they will lower the list prices of their insulin products.180 Furthermore, pharmacy benefits manager, Express Scripts, announced a price cap of twenty-five dollars per month for its members.181 Colorado recently passed legislation capping the price of insulin at $100 per month for insured patients.182 These efforts have one thing in common: they illustrate the fact that attention is increasingly being directed at this issue. The increase in attention, however, does not mean that the issue is solved. Unfortunately, all of the measures identified above are too limited in scope to serve as a complete solution to the problem. After all, Novo Nordisk or Express Scripts, for example, may decide tomorrow that the price guarantees they make today are no longer economically viable, which will leave diabetic patients in much the same place they are now. Many diabetics with health insurance in Colorado are seemingly out of immediate danger, but Colorado is home to only a very small percentage of all diabetics in the U.S.183 This is why legislation at the federal level is necessary to correct this issue for good. As discussed in section III(C) infra, trade secret is one of the three forms of intellectual property protection available to pharmaceutical innovators. In order for an innovation to qualify for this protection, it must: (1) confer economic benefit upon the holder, (2) not be generally known, and (3) be the object of reasonable steps by the holder to maintain its secrecy.184 Makers of pharmaceutical products, and biologic drugs in particular, avail themselves of trade secret protection quite liberally.185 Trade secret is particularly attractive for protecting the manufacturing processes for insulin and other biologics, which has a major impact on competition.186 Biologics like insulin differ considerably from chemical medications in terms of the difficulty of manufacturing them.187 Small-molecule chemical medications are relatively simple to describe scientifically,188 and a generic manufacturer can use any of a number of methods to synthesize the compound, all of which produce a result easily proven to be identical to the reference product.189 Insulin and other biologics, by contrast, have much more complex chemical structures.190 Small differences in the method of synthesis can lead to broad variation in the final result.191 This means that showing biosimilarity is very difficult unless the manufacturer uses the same method that the maker of the reference product used.192 Furthermore, the precise molecular identity of some biologic drugs is not known because the analytical techniques needed to make that determination do not yet exist.193 Crucially, to qualify for abbreviated approval under the Biosimilars Act, the maker of the biosimilar must make a product that not only is biosimilar, but can be shown to be biosimilar.194 Because trade secret protection can theoretically last indefinitely,195 makers of would-be biosimilar insulins may never have access to manufacturing process information, all but foreclosing the possibility of producing a follow-on insulin that the maker is able to prove is biosimilar to the reference.196 A claim that X is the same as Y is impossible to prove or disprove when Y’s identity is not known. A scaling back of trade secret protection for pharmaceuticals would ameliorate this problem. The Biosimilars Act does not require the maker of a reference product to disclose manufacturing information to any greater extent than is required under Hatch-Waxman, which means that it is unlikely to be successful in increasing competition in the insulin market now that insulin is within its scope.197 Insulin will likely continue to be more trouble than it is worth to biosimilar manufacturers. The Defend Trade Secrets Act of 2016 provides an extremely broad scope of the type of information that may be eligible for trade secret protection: [A]ll forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing.198 The breadth of the protection available under the DTSA means that makers of follow-on insulins will have an extremely difficult time showing that their products are biosimilar. Statutorily eliminating biologics manufacturing process information from trade secret eligibility (as an amendment to the Biosimilars Act, for example) would force pharmaceutical companies to choose among three alternatives. They could: (a) include process information in their patent application, (b) apply for separate patent protection for the process and the product, or (c) leave the process information with no protection at all. Acknowledging choice (c) to be in all likelihood the least popular of these, the net effect would be that the process by which biologics like insulin are manufactured would become part of the public domain once the patent expires, rather than remaining secret indefinitely as it does today. This change would naturally have downstream effects, both positive and negative. The first advantage would be that insulin and other biologics would become more attractive to makers of follow-on products. Armed with the knowledge needed to create a biosimilar without going through the costly process of additional research and development, follow-on firms could produce biosimilar insulins more cheaply. The second advantage would be that the growing fund of public knowledge about insulin and other biologics would facilitate greater innovation in the field over time.199 By keeping critical information about their discoveries secret, pharmaceutical companies prevent other companies, universities, and private research firms from benefitting from it.200 Trade secret law is often criticized for its tendency to cause redundancy and duplication of effort,201 and repetition of clinical trials to prove that a follow-on is biosimilar or interchangeable can cost hundreds of millions of dollars.202 A free flow of information about process in a field where process has a tremendous influence on the identity and quality of the final product203 would have substantial value to society.204 To that end, the third advantage to reducing trade secret protections would be a rebalancing of the public and private interests at stake in the market for insulin. The free-market approach to drugs and other medical products that operates in the U.S. presumes that the same forces at work in the markets for CocaCola and iPhones are at work in similar ways in the markets for insulin and other healthcare products.205 As discussed previously, the free-market approach has undoubted advantages,206 but the ethical implications of letting the market decide who can afford insulin and who cannot should not be ignored. A reduction of protection for an already immensely profitable industry207 would ease the burden on people who rely on insulin for survival. On the other hand, this approach does have drawbacks. For example, as with any limitation on intellectual property protection, there is the concern that this would decrease incentives to innovate.208 Insulin makers may decide to slow or halt development of costly new products if they fear that they will not be able to recoup their losses.209 However, this particular issue seems to be of less concern here than in other situations in which cutting edge biologics are not yet on the market. Insulin’s age and long history in the market will likely shield it from this negative effect because several safe and effective varieties already exist. Thus, while reducing trade secret protections for biologics may have the effect of making some drug manufacturers more reluctant to develop entirely new biologic drugs, it will likely have the opposite effect of improving competition for drugs that are already on the market. Furthermore, a compromise might be made to restrict the scaling-back of trade secret protection to insulin alone, rather than to all biologics. Using insulin as a sort of pilot for a broader scheme of reducing trade secret protections in the pharmaceutical industry would provide lawmakers and the public with some context for the effectiveness of such a scheme. A second potential drawback to this proposal is the possibility of a chilling effect on insulin production in general. Once information about manufacturing insulin enters the public domain, regulatory agencies like FDA will have the ability to set manufacturing standards accordingly.210 The more that is known about a substance, the easier it is to regulate.211 An increase in the minimum standard may raise production costs, thus deterring current producers from continuing to make insulin, and discouraging new firms from entering the insulin market in the first place. Trade secrecy has kept the barriers to entry high for competitors in the insulin market.212 There is no question that, in general, insulin and other biologics are more difficult and more expensive to produce than chemical medications.213 Thus, the U.S. is unlikely to see drastic price reductions for these products such as those that resulted from the enactment of Hatch-Waxman.214 However, the current situation is clearly untenable for patients, and a scaling back of trade secrecy in the insulin market would likely help facilitate price reduction. VI. CONCLUSION For the reasons outlined above, a relaxation of trade secret protection for insulin is the intellectual property policy that is most likely to improve the current state of the insulin market from the patient’s perspective. With a decrease in trade secret protection, pharmaceutical companies will be forced to patent their manufacturing processes, thus ameliorating the problem of under-disclosure.215 The patent system’s balancing of individual and public interest will lower the barriers to entry for follow-on firms once patents expire,216 and the expansion of the public fund of knowledge will facilitate further innovation in the future.217

#### [Johnson 18] Reducing IP protections on Insulin will reduce prices

Johnson 18 [Judith A. Johnson, Specialist in Biomedical Science Policy at Congressional Research Service with an MS in molecular biology from Yale, 11-19-2018, “Insulin Products and the Cost of Diabetes Treatment,” Congressional Research Service, <https://fas.org/sgp/crs/misc/IF11026.pdf>] //avery

Insulin Regulation and Production In the past, all biologics, including insulin, were regulated by the National Institutes of Health (or its precursors) under the Public Health Service Act (PHSA). In 1941, Congress gave the Food and Drug Administration (FDA) authority over the marketing of insulin. As a result, insulin has been regulated as a drug under the Federal Food, Drug, and Cosmetic Act (FFDCA) rather than as a biologic under the PHSA. In the United States “generic” insulin products are referred to by FDA as “follow-on” products and are not called biosimilars (which are regulated under the PHSA). Insulin Products and the Cost of Diabetes Treatment www.crs.gov | 7-5700 However, under a provision of the Biologics Price Competition and Innovation Act (BPCIA) of 2009, biologics approved as drugs under the FFDCA will transition to biological licenses under the PHSA in March 2020. BPCIA was enacted as Title VII of the Patient Protection and Affordable Care Act (ACA, P.L. 111-148). Currently, three firms—Eli Lilly, Novo Nordisk, Sanofi Aventis—account for over 90% of the global insulin market and produce the entire insulin supply for diabetic patients in the United States. For the most part, insulins produced by these companies are brand-name drugs. In general, brandname drugs cost more because the drug manufacturer has free rein in setting the drug price due to a government sanctioned monopoly for a defined period of time. Brand drugs are protected from market competition by (1) patents issued by the U.S. Patent Office and (2) a regulatory exclusivity period granted by FDA under the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417), also called the Hatch-Waxman Act. According to some analysts, lack of price competition in the U.S. insulin market is a contributor to the high cost of this vital drug. The price of a drug is directly affected by the number of different manufacturers marketing the drug. According to an FDA analysis of generic chemical drugs, “the first generic competitor prices its product only slightly lower than the brand-name manufacturer. However, the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price. As additional generic manufacturers market the product, the prices continue to fall, but more slowly. For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower.” One “generic” insulin product—or what FDA calls a “follow-on” product—is being marketed in the United States. Eli Lilly received tentative approval for Basaglar from FDA in August 2014. Final approval occurred in December 2015 following resolution of patent issues with Sanofi-Aventis, maker of the brand product, Lantus (insulin glargine). The Basaglar application was submitted to FDA under Section 505(b)(2) of the FFDCA and relied on the FDA’s finding of safety and effectiveness for Lantus. Eli Lilly began marketing Basaglar in the United States in December 2016; by the end of December 2017, Basaglar had captured about 17% of the U.S. Lantus volume share. Because three firms manufacture all the insulin used in this country, the market behaves differently from the usual case in pharmaceutical markets where generic competition results in price reductions following patent expiration and the end of the exclusivity period granted by FDA under Hatch-Waxman. Basaglar, the only follow-on insulin available in the United States, is made by one of the three insulin-making firms, Eli Lilly. Basaglar’s approval has not resulted in a new insulin manufacturer on the U.S. market. Industry observers believe that as other pharmaceutical companies enter the insulin market, price reductions may begin to occur. In July 2017, FDA granted tentative approval to a second insulin glargine product, Lusduna Nexvue, made by Merck. However, in October 2018 Merck announced that it is discontinuing Lusduna. Some industry analysts believe Merck’s decision was due to the drug rebates offered by the three manufacturers of insulin products. For drugs such as insulin with a high list price, manufacturers may use a high rebate to gain placement on an insurance company formulary. This results in making the drug more affordable for insurance plans, but the drug remains expensive for the uninsured, as well as for those with high cost-sharing insurance plans.

#### [Barker 20 - 1] Current IPP causes high insulin prices – only the aff can solve

Barker 20 [Erin M Barker, Executive Editor at the Campbell Law Review with a JD, 2020, "When Market Forces Fail: The Case for Federal Regulation of Insulin Prices," Campbell Law Review, [https://heinonline.org/HOL/P?h=hein.journals/camplr42&i=331]/Kankee//edited](https://heinonline.org/HOL/P?h=hein.journals/camplr42&i=331%5d/Kankee//edited) by Arjuwan

A. Economics-Based Justifications Effective federal regulation will alleviate at least two causes of high insulin prices: patents preventing competition from manufacturers of "generic" insulins, and the failure of normal market forces due to the lack of competition.4 5 U.S. patent law provides patent-holders with twenty years of patent exclusivity for the development of new drugs.46 Exclusivity permits patent-holders to set prices and control the market for at least twenty years.4 7 Currently, there are three primary pharmaceutical companies manufacturing insulin in the U.S. market: Eli Lilly, Novo Nordisk, and Sanofi. 4 8 These three pharmaceutical companies "minimize competition by patenting incremental changes" to their insulin formulas, making it extremely difficult for other manufacturers to develop affordable, effective generics known as biosimilars. 49 For example, even though Sanofi's primary patents for the insulin Lantus expired in 2015, Sanofi has filed around seventy patents for incremental changes since 2000.s0 These secondary patents will allow Sanofi to receive patent protection over the formula for Lantus through at least March 2028. Thus, the three pharmaceutical companies that manufacture insulin have developed what is essentially a monopoly over the insulin market through this patent-based barrier to potential competitors. 52 Because it is so difficult for other manufacturers to create biosimilar insulins due to patents, there is currently very little room for competition from other drug manufacturers." In fact, Eli Lily and Sanofi produce the only two biosimilar insulins currently on the market, meaning these manufacturers can maintain the monopoly.54 In a typical market, product price usually falls as time goes on. Common causes of a decrease in market value include competitors entering the market and introducing similar, cheaper alternatives, or a current manufacturer making an advancement that lowers the value of older versions of a product.5 6 Consumers can choose to either purchase a cheaper alternative or upgrade to the newer, more advanced product-either choice would lower demand for the original product, thus lowering the market value of the older version.5 7 Insulin is not a typical consumer product." Not only do patents prevent competitors from entering the market, but type 1 diabetics cannot exert pressure on the pharmaceutical companies to lower prices by simply choosing to not purchase insulin.59 Instead, "[tlype 1 diabetics without adequate insurance coverage are vulnerable to price increases because they can't live without the drug . . . . 'People have to buy insulin no matter what the cost is . .. [giving] a lot of strength to the people selling insulin."' 0 When the marketplace is unable to self-regulate a monopoly through competition, the traditional solution is the passage of regulation rather than leaving the monopoly free within "the unregulated marketplace or to the antitrust laws for correction."61 When determining the most appropriate type of regulation, there are several options available, the most viable of which are discussed below. 6 2 B. Regulations Available to Increase Competition

#### [Chaudhry 20] IP has caused global rent-taking by Big Pharma – Insulin supply is shortened across the globe and prices are kept inaccessible

Chaudhry 20 Faisal Chaudhry Professor of Law, University of Dayton A secret reason Rx drugs cost so much: A global web of patent laws protects Big Pharma January 28, 2020 8.11am EST <https://theconversation.com/a-secret-reason-rx-drugs-cost-so-much-a-global-web-of-patent-laws-protects-big-pharma-122028> //avery

The high price of insulin, which has reached as [much as US$450 per month](https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive), has raised outrage across the country. Sen. Bernie Sanders (I-Vt.) has called it a [national embarrassment](https://www.freep.com/story/news/politics/elections/2019/07/28/bernie-sanders-diabetes-canada-cheaper-insulin/1852000001/), wondering why U.S. residents should have to drive to Canada to buy cheaper insulin. As a [legal scholar](https://udayton.edu/directory/law/chaudhry_faisal.php) who focuses on the contradictory role of property rights on economic well-being, including through the role of intellectual property rights, [my research makes it clear that](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3192074) drug pricing is far more complicated than any candidate on the debate stage has time to explain. To fully understand these complexities requires looking at a web of international patent law and trade agreements. Insulin was discovered almost 100 years ago, saving the lives of many people with diabetes. Its soaring costs in recent years has brought outcries from patients and politicians. [John Fredricks/NurPhoto via Getty Images](https://www.gettyimages.com/photos/insulin?agreements=pa:77130&family=editorial&page=2&phrase=insulin&sort=best#license) Why no generic insulin? Scientists working in Canada’s public sector [discovered insulin](https://www.thecanadianencyclopedia.ca/en/article/the-discovery-of-insulin) nearly a century ago. The first techniques for synthesizing the compound, which should have more readily allowed for the production of generic versions, emerged some four decades ago. Yet today insulin remains [unavailable in any significant generic version](https://www.npr.org/sections/health-shots/2015/03/19/393856788/why-is-u-s-insulin-so-expensive). One of the three companies that [control 90% of the world insulin market](https://www.t1international.com/blog/2019/01/20/why-insulin-so-expensive/), Eli Lilly, recently did bow to public pressure by announcing a forthcoming “authorized generic” version called Lispro. But that could still run some people [$140 per prescription](https://khn.org/news/how-much-difference-will-eli-lillys-half-price-insulin-make/). U.S. consumers are not alone in facing high prices of insulin and other life-saving drugs. For the last two decades, intense controversy has raged around multinational pharmaceutical giants [being able to monopolize access](https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive) to vital medicines the world over. A key means of doing so is through the legal power of patents, and the monopoly-like profits – or what some experts call [unearned economic rents](https://www.investopedia.com/terms/e/economicrent.asp) – they guarantee. Think of rent as a windfall gained for making little effort of one’s own. Being “unearned,” rents are thus usually distinguished from ordinary business profits. In this way, they are comparable to the fees a medieval lord would charge for access to cropland on a vast estate. To fully explain the problem of economic rents and access to medicines, however, we need to look still further: to the [controversies that have swirled around pharmaceutical patents](https://ssrn.com/abstract=3192074) in countries far less wealthy than the U.S. A worldwide problem, but hidden from sight For more than 20 years, in various parts of Africa, Asia and Latin America, countries have been battling a [global system of rent-taking,](https://www.npr.org/sections/goatsandsoda/2019/07/08/737786567/drug-prices-can-take-a-surprising-turn-when-a-poor-country-gets-richer) or “rentierism” for short, that disproportionately benefits Big Pharma. This state of affairs could not exist without the government officials whom Big Pharma has [lobbied successfully in wealthy countries](https://newrepublic.com/article/149438/big-pharma-captured-one-percent). Patents and other intellectual property rights allow the multinationals to capture rent by evading competition for years on end. This global battle around pharmaceutical patents began in earnest with the founding of the World Trade Organization(WTO) in 1994. This included an annex agreement on intellectual property rights known as [the Trade-Related Aspects of Intellectual Property Rights](https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm). Many countries already allowed for patents before 1994, but only on “processes” of manufacture or synthesis. After 1994, WTO member countries were required to extend patents to the vital end products of such processes as well. For inhabitants of developing countries, whose greatest public health problems at the time derived from diseases like malaria, tuberculosis and HIV-AIDS, this crystallized various questions of great import. Should the agreements enable Big Pharma’s monopoly-like patent rights to trump the ability of the sick and dying to obtain generic versions of life savings medicines? And if so, to what extent? By 2001, all WTO member states officially [had conceded the rights of developing countries](https://www.who.int/medicines/areas/policy/doha_declaration/en/) to take measures to increase access to lifesaving medicines. But Big Pharma and its allies have never relented in [pressing for more, not less](https://msfaccess.org/spotlight-trips-trips-plus-and-doha), stringent intellectual property protections [around the world.](https://bfogp.org/publications-and-projects/the-transatlantic-colossus/) Shaky justifications Since 1994, Big Pharma has imposed ever [more severe requirements](https://heinonline.org/HOL/LandingPage?handle=hein.journals/wisint20&div=24&id=&page=) around patent rights. They have insisted that patent rights are necessary to “incentivize” the availability of drugs for conditions like tuberculosis and malaria that, having no markets in the developed world, [require guaranteed premiums from whatever countries they are sold in.](https://lawcat.berkeley.edu/record/1120730) Yet for just as long, critics have alleged that Big Pharma typically uses [inflated, misleading](https://www.keionline.org/22646) or [otherwise opaque cost data](https://www.citizen.org/news/pharmaceutical-research-costs-the-myth-of-the-2-6-billion-pill/) to tout the billions of dollars it claims to spend on drug development. Likewise, critics have continuously called attention to the way that most drug development is [built on publicly](https://marianamazzucato.com/research/health-innovation/) [funded research](https://www.latimes.com/opinion/op-ed/la-oe-1027-mazzucato-big-pharma-prices-20151027-story.html). And, finally, critics have never stopped highlighting the fact that Big Pharma long ago largely abandoned research and development for drugs for infectious ailments in developing nations, and increasingly switched to spending on blockbuster [noninfectious disease drugs](https://ssrn.com/abstract=3192074). Yet as diseases such as cancer and heart disease begin to [take an even greater toll in the developing world](https://www.who.int/global-coordination-mechanism/ncd-themes/poverty-development/en/), patents will extract an ever greater toll on patient populations across the world. In a developing world where public health problems increasingly look similar to the developed world’s, in fact, multinational pharmaceutical corporations could become better – not worse – placed to expand their profits by tapping new markets for drugs like insulin and beta blockers. A convergence between the sick across the globe One unexpected lesson from this is that ordinary people around the world will increasingly find themselves in the same boat when it comes to accessing the medicines they need. Therefore, if countries in the developing world are forced to give up the fight against patent rentierism, it should be a concern both to their own residents and to residents of wealthy countries too. Just this past September, for example, Indian Prime Minister Narendra Modi signaled that his country – which has a robust generic drugs industry that supplies low-cost medicines to people around the world – was ready to concede to the demands of Big Pharma by moving toward abdicating his country’s vital role as [“the pharmacy of the world](https://www.thehindubusinessline.com/news/science/pharmacy-of-the-world-is-in-peril/article10048324.ece).” India has now signed an interim trade agreement with the Trump administration that will require it to more [strictly enforce the patent rights of pharmaceutical multinationals](https://www.livemint.com/news/india/india-us-expected-to-sign-interim-trade-agreement-today-1569327945744.html), with the latest news reports indicating it may [even now be finalized](https://www.wsj.com/articles/u-s-india-draft-trade-pact-for-unveiling-in-possible-trump-visit-11579266484). Over the course of the current battle for the Democratic nomination, many will have heard about the plight of residents of Michigan who are left asking how insulin costs 10 times in the U.S. what it costs 10 minutes away across our northern border. Given the larger conversation about patent rents and access to medicines that we should be having, however, it behooves those of us who live in places like the U.S. to look not only to Canada but to what is happening [around the world,](https://www.nytimes.com/2019/11/13/health/insulin-prices-generic-who.html?action=click&module=Well&pgtype=Homepage&section=Health) where the sick and dying face increasingly similar ailments – and fights – as our own.

#### [Belluz 19] Insulin is the symbol of pharmaceutical irony, a medicine intended to be accessible, only to be claimed, patented ,and then price gouged to oblivion, forcing diabetes to choose between skimping on bare necessities, or death

Belluz, Julia. “The Absurdly High Cost of Insulin, Explained.” Vox, Vox, 3 Apr. 2019, www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive. Accessed 6 Sept. 2021.

When inventor Frederick Banting discovered insulin in 1923, he [refused to put his name on the patent](http://thelancet.com/journals/landia/article/PIIS2213-8587(17)30115-8/fulltext). He felt it was unethical for a doctor to profit from a discovery that would save lives. Banting’s co-inventors, James Collip and Charles Best, sold the insulin patent to the University of Toronto for a mere $1. They wanted everyone who needed their medication to be able to afford it. Today, Banting and his colleagues would be spinning in their graves: Their drug, which many of the 30 million Americans with diabetes rely on, has become the poster child for pharmaceutical price gouging. The cost of the [four most popular types of insulin](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2717498) has tripled over the past decade, and the out-of-pocket prescription costs patients now face have doubled. By 2016, the average price per month [rose to $450](https://www.nytimes.com/2019/04/03/health/drug-prices-insulin-express-scripts.html) — and costs continue to rise, so much so that as many as [one in four people with diabetes are now skimping on or skipping lifesaving doses](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2717499). Members of Congress have been [pressuring drug companies and pharmacy benefit managers to bring insulin costs under control](https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2019/04/03/the-health-202-a-major-insurer-is-announcing-insulin-savings-amid-heavy-hill-pressure/5ca3aa251b326b0f7f38f2ee/?noredirect=on&utm_term=.1477b6dd7411) — and there have been several promising moves. In May, [Colorado](https://www.denverpost.com/2019/05/23/colorado-insulin-price-cap/) took the unusual step of capping the price of insulin in the state: A new law says people with [diabetes won’t have to shell out more than $100 per monthly copay for the drug, regardless of how much they use](https://leg.colorado.gov/sites/default/files/documents/2019A/bills/2019a_1216_enr.pdf). The state’s attorney general will also investigate rising insulin prices and make recommendations for other legislative changes. Before that, the insurance behemoth Cigna, and its pharmacy benefit arm Express Scripts, announced a program that’ll [cap the 30-day cost of insulin at $25](https://www.statnews.com/2019/04/03/cigna-reduce-insulin-cost/). That’s a 40 percent reduction from the $41.50-per-month fee people with Express Scripts benefits were paying in 2018. The program is also expected to launch later this year for insurance plans that work with Express Scripts benefits. And by next year, all diabetes patients on Cigna plans will be able to join, according to the [Washington Post](https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2019/04/03/the-health-202-a-major-insurer-is-announcing-insulin-savings-amid-heavy-hill-pressure/5ca3aa251b326b0f7f38f2ee/?noredirect=on&utm_term=.1477b6dd7411). [Federal fixes](https://www.nejm.org/doi/full/10.1056/NEJMp1909402?query=TOC) to reduce insulin prices have also been proposed — like the [Affordable Drug Manufacturing Act](https://www.vox.com/policy-and-politics/2018/12/20/18146993/elizabeth-warren-2020-election-drug-prices-bill), introduced by Senator Elizabeth Warren (D-MA) and Representative Jan Schakowsky (D-IL). It would have, among other things, allowed the federal government to manufacture drugs or hire an outside contractor, and set fair prices for essential medicines, such as insulin. But the [bill didn’t go anywhere](https://www.govtrack.us/congress/bills/115/s3775). While these measures suggest the problem of insulin price gouging is finally being tackled, there are several catches to consider. Colorado is just one state, and people with diabetes live in every state in America. The cap also only applies to people who have health insurance coverage. As for Cigna’s plan, patients can only participate if their employers opt into the change in plan, [Stat](https://www.statnews.com/2019/04/03/cigna-reduce-insulin-cost/) reported. Cigna is just one of many insurance companies out there, covering less than 1 percent of the 23 million living with diabetes in America. And new federal laws haven’t passed. “As solutions to the insulin-cost crisis are being considered,” a new [New England Journal of Medicine](https://www.nejm.org/doi/full/10.1056/NEJMp1909402?query=TOC) editorial argues, “there is value in remembering that when the patent for insulin was first drafted in 1923, Banting and Macleod declined to be named on it. Both felt that insulin belonged to the public. Now, nearly 100 years later, insulin is inaccessible to thousands of Americans because of its high cost.” Most patients with diabetes remain vulnerable to the whims of drug company pricing, since companies can still set whatever prices they wish. And no drug is better for understanding how that happened than insulin.

How the companies justify their price increases

With Type 1 diabetes, which affects about 5 percent of people with diabetes in the US, the immune system attacks the insulin-producing cells in the pancreas, leaving the body with little or none of the hormone. In Type 2 diabetes, the pancreas still makes insulin, but the body has grown resistant to its effects. In both cases, patients rely on insulin medication to keep energy from food flowing into their bodies. The US is a global outlier on money spent on the drug, representing only 15 percent of the global insulin market and [generating](https://www.ncbi.nlm.nih.gov/pubmed/26284715) almost half of the pharmaceutical industry’s insulin revenue. According to a recent study in [JAMA Internal Medicine](http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2429536), in the 1990s Medicaid paid between $2.36 and $4.43 per unit of insulin; by 2014, those prices more than tripled, depending on the formulation. The doctors and researchers who study insulin say it is yet another example — along with [EpiPens](http://www.vox.com/2016/8/23/12608316/epipen-price-mylan) and [decades-old generic drugs](http://www.vox.com/2016/2/4/10915190/congressional-hearing-drug-prices-shkreli) — of companies raising the cost of their products because of the lax [regulatory environment](http://www.vox.com/2016/2/4/10915190/congressional-hearing-drug-prices-shkreli) around drug pricing. “They are doing it because they can,” [Jing Luo](https://connects.catalyst.harvard.edu/Profiles/display/Person/125144), a researcher at Brigham and Women’s Hospital, told Vox in 2017, “and it’s scary because it happens in all kinds of different drugs and drug classes.” In countries with single-payer health systems, governments exert much more influence over the entire health care process. In England, for example, the government has an agency that negotiates directly with pharmaceutical companies. The government sets a maximum price it will pay for a drug, and if companies don’t agree, they simply lose out on the entire market. This puts drugmakers at a disadvantage, driving down the price of drugs. The US doesn’t do that. Instead, America has long taken a free market approach to pharmaceuticals. Drug companies haggle separately over drug prices with a variety of private insurers across the country. Meanwhile, Medicare, the government health program for those over age 65 — it’s also the nation’s largest buyer of drugs — is barred from negotiating drug prices. That gives pharma more leverage, and it leads to the kind of price surges we’ve seen with EpiPens, recent opioid antidotes — and insulin. Insulin manufacturers say the increases are just the price tag that comes with innovation — creating more effective insulin formulations for patients. According to a [2017 Lancet paper](http://www.thelancet.com/journals/landia/article/PIIS2213-8587(17)30041-4/fulltext) on insulin price increases, “Older insulins have been successively replaced with newer, incrementally improved products covered by numerous additional patents.” The result is that more than 90 percent of privately insured patients with Type 2 diabetes in America are prescribed the latest and costliest versions of insulin. But soaring prices for these newer formulations is out of step with how much they improve treatment for patients, said Yale endocrinologist [Kasia Lipska](https://medicine.yale.edu/intmed/people/kasia_lipska.profile). For Type 1 diabetes, newer formulations appear to be more effective at controlling blood sugar than older formulations. “For Type 2 diabetes, it’s less clear — the benefits are not as strong.” So, Lipska asked, “Are [the new insulins] 20 times better? I’m not sure.” [Luo](https://connects.catalyst.harvard.edu/Profiles/display/Person/125144), the Lancet paper’s lead author, doesn’t find the “cost of innovation” argument very convincing. In his research, he’s come across many examples of the same insulin products that have been continuously available for years without improvements, yet their price tags have gone up at a much higher rate than inflation. “The list price of these products are already out of reach for most Americans living with diabetes — in some cases, over $300 a vial,” he said. “It is also strange to see Humulin still priced at over $150 a vial considering this product was first sold in the US in 1982.”

Drugmakers do this because they can

So insulin’s drug pricing problem is much bigger than anything one state — or drug company — alone can fix. But more changes in the market may be on the horizon. The three major insulin makers — Eli Lilly, Novo Nordisk, and Sanofi — [testified before the House Energy and Commerce’s oversight subcommittee](https://khn.org/morning-breakout/insulin-makers-to-be-called-in-front-of-congress-to-answer-for-price-hikes/) last April, focusing more attention on the issue. Lawmakers, including Sens. Chuck Grassley (R-IA) and Ron Wyden (D-OR), have also been investigating the problem and sending letters to drug companies asking them to account for their outrageous price hikes. But while the pressure around insulin may be mounting, we’re also seeing the terrible impact of rising insulin prices on patients: people being forced to taper off insulin so they can pay their medical bills, and winding up with kidney failure, blindness, or even death. Some are forced to head to Canada, where drug prices are more heavily regulated and, according to the new [NEJM](https://www.nejm.org/doi/full/10.1056/NEJMp1909402?query=TOC) editorial, where a carton of insulin costs $20 instead of the $300 patients often pay in the US. “Of course, there isn’t enough insulin in all of Canada to make large-scale importation feasible,” the editorial authors wrote. One real solution to the problem, however, would be to bring a generic version of insulin to the market. There are [currently no true generic options available](https://www.ncbi.nlm.nih.gov/pubmed/25785977?dopt=Abstract) (though there are several [rebranded and biosimilar insulins](https://www.t1international.com/blog/2014/11/20/whats-deal-generic-insulin/)). This is in part because companies have made those incremental improvements to insulin products, which has allowed them to keep their formulations under patent, and because older insulin formulations have fallen out of fashion. But not all insulins are patent-protected. For example, none of Eli Lilly’s insulins are, according to the drugmaker. In those cases, Luo said, potential manufacturers may be deterred by secondary patents on non-active ingredients in insulins or on associated devices (such as insulin delivery pens). There’s also “extreme regulatory complexity” around bringing follow-on generic insulins to market, Luo added. And that’s something regulators, such as the [Food and Drug Administration](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628121.htm), have been working to streamline. History has shown that their efforts are worthwhile: When[cheaper generic options are introduced](https://www.vox.com/2017/1/31/14453870/trump-pharmaceutical-lower-drug-prices) to the market, overall drug prices come down. A century after insulin was discovered, it’s about time we had one.

#### [Barker 20 - 2] Here are some stories of diabetics if you weren’t convinced that the insulin crisis is bad

Barker 20 [Erin M Barker, Executive Editor at the Campbell Law Review with a JD, 2020, "When Market Forces Fail: The Case for Federal Regulation of Insulin Prices," Campbell Law Review, [https://heinonline.org/HOL/P?h=hein.journals/camplr42&i=331]/Kankee//re-cut](https://heinonline.org/HOL/P?h=hein.journals/camplr42&i=331%5d/Kankee//re-cut)/edited Arjuwan

INTRODUCTION Today, a single vial of insulin can cost more than $250 in the United States, and most patients use between two and four vials each month.' Consequently, if a diabetic patient is without insurance, or if insurance does not cover a specific brand of insulin, that person could pay upwards of $500 to $1,000 per month out-of-pocket for an essential medication.2 These costs are astronomical and unacceptable-the federal government must step in to regulate pricing. On January 11, 1922, fourteen-year-old Leonard Thompson faced the end stages of a terminal illness: diabetes mellitus, otherwise known as type 1 diabetes.3 Thompson weighed only sixty-five pounds after living with diabetes for three years.' His attempt to control his diabetes with a starvation diet failed to keep him from slipping in and out of a diabetic coma.5 Desperate for any chance to save his son, Thompson's father agreed to let the hospital inject the boy with a recently-discovered drug-insulin.6 Thompson would be the first human subject to receive the injection,' and the results were nothing short of miraculous.' His blood sugar lowered to a normal level, and the glucose and ketones' present in his urine also lowered to a tolerable level.10 Four men discovered this "wonder drug"": Frederick Banting, Charles Best, James Collip, and John Macleod.12 Following Banting's and Best's initial publication of their results,13 the discovery of insulin and its successful application to human subjects landed on the covers of newspapers worldwide.14 Insulin provided life-saving treatment for people who previously faced a death sentence; the drug brought diabetic patients out of comas, allowing them to end their starvation diets and eat carbohydrates." For their discovery, Banting and Macleod won the 1923 Nobel Prize in Physiology or Medicine and split their winnings with Best and Collip.16 Banting, Best, and Collip acquired an American patent on insulin and its method of creation on January 23, 1923.17 When applying for their patent, the trio maintained that "their goal was not profit, but ensuring the speedy and safe availability of their discovery to the public.""8 They then sold their patent rights to the Board of Governors of the University of Toronto for $1.00 each.1 9 In a letter to the University's president, the trio wrote, "The patent would not be used for any other purpose than to prevent the taking out of a patent by other persons. When the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."20 Banting, Best, and Collip stated a clear goal: their lifesaving invention was to remain available to all. That goal has failed. This Comment analyzes how federal regulation of insulin prices will correct failed market forces, leading to a stabilized market for the indispensable medication. Part I of this Comment will provide a brief overview of the current state of the insulin market in the United States. Part II of this Comment will explain economics-based justifications for adopting federal legislation to regulate the insulin market. It will also provide an overview of the types of regulatory schemes that the government could utilize in this market. Part III of this Comment will describe and critique legislation that two states-Nevada and Colorado-have already acted to regulate the cost of insulin and will then examine currently proposed federal legislation that aims to lower insulin prices. Lastly, Part IV of this Comment offers a solution: the addition of language to the proposed federal legislation, incentivizing competition and positively affecting market prices through the nationalization of patents. I. THE STATE OF THE INSULIN MARKET IN THE UNITED STATES TODAY A. Economic Impact ofRising Insulin Prices From 2002 to 2013, the cost of insulin nearly tripled.21 Then, from 2012 to 2016, the cost of insulin rose dramatically again, nearly doubling. 22 In the first month of 2019 alone, insulin manufacturers Sanofi and Novo Nordisk raised some of their insulin product prices as much as 4.9% and 5.2%, respectively. 23 As of 2017, diabetes treatment and complications cost the United States ("U.S.") more than $327 billion per year, making it the most expensive chronic illness in the country.24 This cost is a combination of $237 billion in direct medical costs, including $15 billion for insulin, and $90 billion in indirect costs. 25 The American Diabetes Association reports: While much of the cost of diabetes appears to fall on insurers (especially Medicare) and employers (in the form of reduced productivity at work, missed work days, and higher employer expenditures for health care), in reality such costs are passed along to all of society in the form of higher insurance premiums and taxes, reduced earnings, and reduced standard of living.26 Government insurance, including Medicare, Medicaid, and insurance through the military, provide for a majority (67.3%) of the cost of diabetes care in this country.27 Private insurance pays for 30.7%, and the uninsured pay for 2% of the cost of diabetes care. 28 Uninsured diabetics visit the doctor 60% less and receive 52% fewer prescriptions than insured diabetics, yet uninsured diabetics account for 168% more emergency department visits than insured diabetics.2 9 Accordingly, because of both the direct and indirect costs of diabetes care, it is not just diabetics who are paying-all of society shoulders the financial burden of the increasing cost of diabetes. 30 B. Social Impact ofRising Insulin Prices Rising insulin prices induce "negative health and financial burdens on the population." 3 1 Of the 30 million diabetic Americans, approximately 7.4 million require daily doses of insulin to survive.32 Rising insulin prices have forced some to cut back on or skip doses of insulin. 3 Others elect to forgo other necessities such as food or rent in order to afford insulin. 3 A 2018 study found that almost 26% of diabetics in the U.S. had rationed their insulin the previous year.35 Recently, poignant stories have emerged detailing the tragic societal consequences of these negative health and financial burdens, including deaths due to an inability to afford insulin. 6 One such story is that of Alec Smith, a twenty-six-year-old who died less than a month after his mother's health insurance plan removed him as a beneficiary.3 7 Smith, who worked a full-time job and earned more than minimum wage, could afford neither new insurance nor the monthly $1,000 out-of-pocket cost of his insulin. 38 Another story is that of Meaghan Carter, a forty-seven-year-old woman who died alone on her sofa on Christmas night because she could not afford insulin.3 9 Carter, a nurse, was between jobs.4 0 She planned to start a new nursing position with health insurance benefits only a week after her death.4 1 Carter's family found empty vials of insulin among Carter's nursing supplies in her home.42 According to Carter's sister-in-law Mindi Patterson, "[s]he had gauze, bandages and all her nursing supplies"-"plenty to take care of others but not enough to take care of herself." 4 3 The stories of Alec Smith and Meaghan Carter demonstrate that there is more than just money at stake here-people's lives are on the line because of insulin prices in the U.S. Almost a hundred years after the discovery of insulin, diabetics should not be forced to ration an essential drug or face death due to excessive costs. Banting, Best, and Collip's goal was to make insulin affordable for all," but that is not the case today. The current price of insulin in the U.S. is unacceptable and must be addressed. II. THE FEDERAL GOVERNMENT SHOULD REGULATE THE INSULIN MARKET BECAUSE OF THE FAILURE OF TYPICAL MARKET FORCES

## Underview:

#### 1] Aff gets 1AR theory, otherwise neg can spam aprioris and tricks and insta win, kills edu & fairness. 1AR theory is DTD, CI and no RVIs, DTD disincentivizes friv theory, reasonability hard to warrant and only applies for friv shells, CI makes the most sense and has no judge intervention.

#### 2] T has RVIs, a] same timeskew that heavily favors neg, makes sure neg can’t blipstorm shells and drop them all to go for substance because the aff underresponded in the 1AR, b] actually deters friv theory like nebel and keep the debate to substance, increasing education, c] increases fairness, aff objectively has less time for shells so they need something to fight back