# 1AC

#### 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] Structural violence outweighs, effects build up exponentially over time

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

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 insulins.

\*\*\*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 –

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

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

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//arjun!

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

#### 2] [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.

#### 4] [Cohen 21] Millions of people in the U.S. alone are affected by high Insulin prices

Cohen, Joshua. “Insulin’s Out-Of-Pocket Cost Burden to Diabetic Patients Continues to Rise despite Reduced Net Costs to PBMs.” Forbes, 5 Jan. 2021, www.forbes.com/sites/joshuacohen/2021/01/05/insulins-out-of-pocket-cost-burden-to-diabetic-patients-continues-to-rise-despite-reduced-net-costs-to-pbms/?sh=6eec458940b2. Accessed 7 Oct. 2021.

Of the approximately 35 million Americans who have diabetes (Types 1 and 2), about a third require insulin to manage their disease. For diabetic patients, [out-of-pocket costs](https://www.statnews.com/pharmalot/2020/10/06/insulin-diabetes-prices-oecd/?) for insulin can be a major expense, whether they are insured in the commercial market, enrolled in Medicare, or un- and underinsured. For decades, list prices of insulin products have been [soaring](https://time.com/5709241/open-insulin-project/). For the insured, out-of-pocket costs are usually calculated as a percentage - co-insurance - of the list price of insulin products. Increases in patient co-insurance therefore reflect rising list prices of insulin products. In addition, in the deductible phase of insurance insured patients face retail list prices. Despite the fact that net costs of insulin to pharmacy benefit managers (PBMs) and payers have decreased in recent years, owing to steep rebates, very often these savings have not been passed through to patients. Many varieties of insulin are now available, including rapid-acting and longer-acting agents. Ninety percent of commercially insured patients with Type 2 diabetes are prescribed the newer versions of insulin. These more effective and easier to administer formulations of insulin are costlier. Since 2012, list prices of many of these newer forms of insulin have risen particularly rapidly, with average annual increases of more than 15%. As a result, the U.S. is a global outlier on money spent on insulin products. The U.S. represents only 15% of the global insulin market, but [generates](https://www.ncbi.nlm.nih.gov/pubmed/26284715) nearly 50% of the industry’s insulin revenue. Newer versions of insulin retail for between $175 and $300 a vial. Most patients with diabetes need two to three vials per month, and some can require more. So, without direct assistance from drug manufacturers, this amounts to a substantial monthly cost burden. There have been multiple reports of patients who cannot afford insulin products. Roughly a quarter of diabetic patients dependent on insulin [skimp](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2717499) or even skip doses altogether. Fallout from the Covid-19 pandemic includes rising numbers of un- and underinsured. And, according to a [Commonwealth Fund](https://www.commonwealthfund.org/publications/issue-briefs/2020/sep/not-so-sweet-insulin-affordability-over-time) study, uninsured Americans with diabetes are more likely to be using older, less costly (and less effective) formulations of insulin compared to those with private insurance or Medicaid. Sixty-eight percent of uninsured patients pay the full list price for insulin, while 9% of privately insured and 3% of Medicaid beneficiaries do. Consequently, the uninsured are much more likely to report being unable to afford prescription medicines, by a 38% to 10% margin. There have been several initiatives carried out in the commercial sector to address insulin affordability. Last year, for example, the insurer Cigna and its pharmacy benefit management division Express Scripts announced a program designed to [cap](https://www.statnews.com/2019/04/03/cigna-reduce-insulin-cost/) out-of-pocket costs for diabetic patients at $25 a month. Moreover, the recent advent of [biosimilar](https://www.forbes.com/sites/joshuacohen/2020/12/03/will-2021-be-another-break-through-year-for-biosimilars/?sh=cb3859635d8c) insulin products may help reduce out-of-pocket costs, as could the possibility of automatic interchangeability of biosimilar insulin and originator products. Nevertheless, for a comprehensive approach to improving insulin affordability that reaches a larger number of diabetic patients the federal government would need to get involved, and it has to a certain extent. Trump Administration has lowered out-of-pocket insulin costs for some President Trump has made some dubious claims on insulin prices, including one he uttered during a September presidential debate. There, he boasted that he had helped lower the price of insulin to the point that it’s “so cheap,” it’s “like water.” In fairness, however, the Trump Administration has cut out-of-pocket costs insulin costs for seniors. In March, the administration announced a plan to impose an upper limit on what seniors pay at the pharmacy counter; $35 a month. Starting in January 2021 Medicare beneficiaries will have more than 1,600 Medicare Advantage and Part D prescription drug plans to choose from that will provide a range of insulin products at a maximum of a $35 monthly co-payment. This is lower than the typical $47 co-payment plans impose in 2020. Trump also signed an [executive order](https://www.statnews.com/2020/09/29/trump-insulin-fact-check/) in July that would require federally qualified health centers to share the steep savings they receive through the 340B program with indigent patients, specifically for epinephrine and insulin products. But, this only applies to a very small portion hospitals participating in the 340B program. And, it doesn’t resolve the much larger issue that the 340B program [discounts](https://www.drugchannels.net/2020/09/my-wall-street-journal-op-ed-on-340b.html) aren’t generally winding up where they’re supposed to. In fact, as Adam Fein, CEO of the Drug Channels Institute, has eloquently [explained](http://drugchannelsinstitute.com/files/AdamFein-DrugChannels-340B-30Oct2020.pdf) the 340B program is driving up out-of-pocket costs of insulin for most patients. In effect, patients are subsidizing 340B program entities. A patient with a high-deductible health plan pays the full list price of an insulin product, and after the deductible pays a co-insurance that is calculated on the basis of the full list price. So, an “insured patient could pay thousands of dollars out of pocket, even as the 340B hospital and its contract pharmacy generate substantial profits.” In the end, affordability of insulin for diabetic patients is going to require a multi-pronged approach. First, increase access to comprehensive health insurance coverage that includes affordable co-payments, or a tie-in, through value-based insurance design, of low or even zero co-payments for high value products. Alternatively, passing through rebates to patients at the point of sale will protect people with diabetes from high out-of-pocket costs. Second, establishing a system in which list prices of insulin products, particularly premium prices of newer products, are based in part on value. Insulin manufacturers say the increases in list prices are justified, though these claims are disputed by some [health economists](https://www.thelancet.com/journals/landia/article/PIIS2213-8587(17)30041-4/fulltext)and policymakers. Certainly, some newer and costlier products may be worth it, but others might not be. A value-based pricing system could help contain list prices of products that produce only marginal added value.

#### 5] [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](http://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive.%20Accessed%206%20Sept.%202021).//arjun!

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.

#### 6] [Lendener 21] Diabetes is NOT just an American issue though, hundreds of millions of people have the disease

Lendner, Paul. “WHO: Diabetes No Longer a Rich-Country Problem - Managedcaremag.com.” Managedcaremag.com, 30 Mar. 2021, www.managedcaremag.com/archives/2016/5/who-diabetes-no-longer-rich-country-problem/. Accessed 5 Oct. 2021.//arjun!

WHO: Diabetes No Longer A Rich-Country Problem Eating more doesn’t mean you eat better, might be one lesson taken from a study by the World Health Organization that tracks a dramatic worldwide rise in diabetes. That goes hand-in-hand with this shocker: The number of people living in extreme poverty (less than the equivalent of $1.90 a day) dipped to 10% last year for the first time in human history, according to the World Bank. And—get this—poverty might actually end by 2030. Yet every silver lining has its cloud, and the quarter-century march that just might end world hunger not only spreads the wealth but also ill health, in this case in the form of problems that come from eating more poorly. Diabetes, a once-near exclusive first world problem, now disproportionately affects poorer parts of the planet, according to WHO in its Global Report on Diabetes published in April. That this is the organization’s first such study of the problem can be taken as an indicator of just how much diabetes has grown as a worldwide problem. The unrelenting march of diabetes % prevalence and number of adults with diabetes by WHO region in 1980 and 2014\* \* Millions of people and % of total regional population Source: World Health Organization, Global Report on Diabetes, April 2016 Map of world with countries, multicolor, by FreeVectorMaps.com Prevalence of the disease nearly doubled since 1980, from 4.7% to 8.5% of the world’s adult population. “The percentage of deaths attributable to high blood glucose or diabetes that occurs prior to age 70 is higher in low- and middle-income countries than in high-income countries,” the WHO report states. WHO estimates that most of the 422 million adults with diabetes now live in low-income countries. Prevalence rose from just over 5% to about 7% in high-income countries. Rates in low-income countries rose from just over 3% to more than 7%, a rate of growth that overtook high-income countries for the first time. The WHO report says that diabetes has become a problem in poor countries because of the growing number of people who are overweight and obese. Around the world, children are getting heavier, so type 2 diabetes, once exclusively an adult disease, is affecting children, noted WHO. That diabetes caused 1.5 million deaths in 2012 tells only part of the story, because diabetes is a causal factor in heart disease, stroke, and kidney disease. In WHO’s reckoning, higher-than-optimal blood glucose was culpable in an additional 2.2 million deaths. So, who you gonna call? Well, WHO wants those at risk to depend on primary care physicians and their basic diagnostic tools, such as blood glucose tests. Good luck with that. “In general, primary health care practitioners in low-income countries do not have access to the basic technologies to help people with diabetes properly manage their disease,” the report states. In addition, low-income countries face a lack of access to insulin and oral hypoglycemics because they are priced too high for their budgets. Preventing diabetes often comes down to lifestyle, and the WHO urges countries to do all they can to help prevent people from becoming overweight or obese by making healthy foods available. Margaret Chan, the WHO’s director general, said the findings show an urgent need to address unhealthy diets and lifestyles around the world. “If we are to make any headway in halting the rise in diabetes, we need to rethink our daily lives: to eat healthily, be physically active, and avoid excessive weight gain,” Chan said in a prepared statement. “Even in the poorest settings, governments must ensure that people are able to make these healthy choices and that health systems are able to diagnose and treat people with diabetes.”

## Disclosure:

#### Interpretation: At all TOC bid distributing tournaments, debaters must have themselves on the wiki and provide contact info along with previously read positions OR reach out to their opponent and provide contact info 30 minutes before the round OR provide

#### Violation – check below

Text

Description automatically generated

#### Also before the round at 9:36 – 9:38 I asked them if they were fine with sharing/disclosing what they read round 1 but they said that since they were reading same NC they would only disclose to me/send me the doc and cards after the 1AC, there is no I meet or pre round checks to this shell since I gave them a chance to meet.

#### Standards:

#### 1] Supercharge - you don’t even have a wiki nor contact info and you didn’t disclose the negative means I have no clue what kind of debater you are so I have no way of tailoring my aff to have an underview that could engage with your neg well

#### 2] Prep skew – I disclosed all my affs on the wiki a while back so they can easily be prepped out but I literally have nothing to work with so there is no infinite prep arg cuz aff has been open while neg has shown nothing

#### This prep skew kills predictability, and predictability is highly important for education, since never having any idea what your opponent will read, especially as the aff, means you have to pull up all your backfiles and spam generics in the 1AR rather than doing a specific line by line that will actually contest the ideas and help both debaters learn about said ideas and good/bad responses to them.

#### Voters:

#### Education is a voter because schools, educational institutions, pay for it. Nobody remembers the fairness that a round has but they do remember everything that they learned from it.

#### Theory comes first, it critiques the actions that you took in this debate and sets up norms and rules for the debate space, so post-fiat impacts don’t matter.

#### Paradigms:

#### No RVIs because its illogical – you wouldn’t win chess for playing properly – Prefer logic for it’s a litmus test for other arguments

#### Prefer competing interps because a) reasonability is a race to the bottom pushing the limits on how much abuse is justifiable b) reasonability is subjective and invites judge intervention

#### Drop the debater to deter future abuse