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I affirm the plan: **The member nations of the WTO ought to eliminate intellectual property protections for medicines.**

## Advantage 1: Insulin

#### Increases in prices of Insulin make a medicine that’s essential for millions of Americans unaffordable which causes diabetics to skimp on other necessities.

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

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

#### In turn, increased drug prices lead to lower medicine use by POC

**Benavidez and Frankt 18** [Gilbert Benavidez is a policy analyst for the Partnered Evidence-based Policy Resource Center (PEPReC), Austin Frakt, PhD, is a health economist and director of the Partnered Evidence-based Policy Resource Center at the Boston, August 21 2018, “Racial Disparities, Prescription Medications, and Promoting Equity,”Public Health Post, [https://www.publichealthpost.org/viewpoints/racial-disparities-prescription-medications-equity/]/](https://www.publichealthpost.org/viewpoints/racial-disparities-prescription-medications-equity/%5d/) Triumph Debate

The United States has the highest drug prices in the world and it’s not even close. For millions in the country, the cost of prescription drugs is an ever-growing barrier to proper disease treatment. This is most often the case for minority groups, who have long experienced disproportionally adverse health access and outcomes. But high drug prices alone do not explain the inequity we see. Though cost is a major factor, Colon, et al. found that disparities are not simply a function of socioeconomic status—the story is more complicated. Minorities Face Many Barriers to Prescription Medicines Costs White Americans are, on average, much wealthier than Black and Hispanic Americans. The median net worth of White households in 2016 was 9.7 times higher than African-American households and 8.3 times higher than Hispanic households. Wealth disparities result in negative health consequences. Among insured adults with diabetes, Tseng, et al, found race and ethnicity to be a significant predictor of medication underuse—patients underusing their medication in order to prolong supply—due to cost. (Medication underuse is a somewhat common cost saving strategy, per the CDC.) The authors attribute this to lower incomes and higher out-of-pocket drug costs. Although study participants all had health insurance, disparities persisted. Lack of Insurance Affording medications is even harder for those without coverage. Though the Affordable Care Act (ACA) reduced the number of uninsured Americans, over 28 million remain without insurance. More than half (55%) of uninsured Americans under the age of 65 are people of color. For those with no insurance, paying retail prices for medications is often financially impossible. Implicit Racial Bias in Prescribing Practice Race can have an implicit effect on the prescribing practices of providers. For example, one study showed that White children treated at pediatric emergency departments inappropriately received antibiotics for respiratory infections more often than Black or Hispanic children, indicating that prescribing patterns can vary depending on the race of the patient. Terrell, et al., found that in their sample, ethnic and racial minorities were prescribed analgesics at a lower rate compared to White patients when discharged from the emergency department. Practical Policy Pursuits Here are four policy options for addressing racial disparities in access to prescription medication: Continue to Expand Medicaid One in five people of color have access to prescription drugs through Medicaid. Virginia recently expanded Medicaid (becoming the thirty-third state to do so). Medicaid expansion is on the November 2018 ballot in Utah and Idaho (Atkeson and Jones write more about the Idaho intiative here) while supporters in Nebraska are collecting signatures to get it on the ballot. A Maine state court has ruled that Governor LePage must submit the paperwork to expand. Promote the ACA and an Essential Benefits Package The ACA has played a key role in increasing health insurance among low-income people of color. Prescription drugs are one of ten essential health benefits the ACA requires insurers to cover. Interventions to increase coverage are needed, particularly in regard to medications. Research shows that promoting coverage gains through increased advertising is effective. Reduce Implicit Bias in Prescribing Parity in prescribing practices is possible. New research shows that reducing stigmatizing language in electronic health records can reduce implicit bias in physicians-in-training, influencing their attitudes about both patients and prescribing behavior.

#### Lowering protections would increase the availability and decrease cost for POC

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

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 omain 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

#### **Solving for inequality is a prerequisite to solving for other problems in society**

Collins 17, Chuck Collins (senior scholar at the Institute for Policy Studies, where he directs the Program on Inequality and coedits Inequality.org), August 3, 2017, ‘Reversing Inequality: Unleashing the Transformative Potential of an Equitable Economy”, <https://thenextsystem.org/inequality>, sh3a

Inequality Matters While the data on inequality is hard to dispute, people do draw different meanings from it. Some argue that how wealthy the wealthy are is irrelevant as long as social mobility and opportunity for the rest of us are real. But are they? Damages Poverty’s indisputable toll aside, the growing gap between the very wealthy and everyone else has its own troubling dynamics. According to findings from any number of disciplines, the extreme disparities of wealth and power corrode our democratic system and public trust. They break down civic cohesion and social solidarity, which in turn worsens health outcomes. Inequality undercuts social mobility and undermines economic stability and growth. Economic historians now view inequality as a precondition for major economic upheavals and downturns, such as the Great Depression of 1929 and the Great Recession of 2008. A brief overview of why inequalities of income, assets, and opportunity matter confirms as much.

## Advantage 2: Developing World Access

#### 1.6 million Africans died of malaria, tuberculosis, and HIV in 2015, due to patent law preventing generic drug import

**Pheage 16** [Tefo Pheage- journalist for African Renewal, December 2016, “Dying from lack of medicines,” United Nations Africa Renewal, [https://www.un.org/africarenewal/magazine/december-2016-march-2017/dying-lack-medicines]/](https://www.un.org/africarenewal/magazine/december-2016-march-2017/dying-lack-medicines%5d/) Triumph Debate

Approximately 1.6 million Africans died of malaria, tuberculosis and HIV-related illnesses in 2015. These diseases can be prevented or treated with timely access to appropriate and affordable medicines, vaccines and other health services. But less than 2% of drugs consumed in Africa are produced on the continent, meaning that many sick patients do not have access to locally produced drugs and may not afford to buy the imported ones. Without access to medicines, Africans are susceptible to the three big killer diseases on the continent: malaria, tuberculosis and HIV/AIDS. Globally, 50% of children under five who die of pneumonia, diarrhoea, measles, HIV, tuberculosis and malaria are in Africa, according to the World Health Organisation (WHO). The organisation defines having access to medicine as having medicines continuously available and affordable at health facilities that are within one hour’s walk of the population. In some parts of Zimbabwe, for example, some nurses give painkillers to sick patients as a “treat-all drug,” says Charles Ndlovu, a Zimbabwean living in Botswana. Some of his family members have been treated in hospitals in Zimbabwe. With most medicines unavailable, the nurses have little choice. Dave Puo, from Mpumalanga in South Africa, says that in his country, “when you seek medical attention, you are often informed that there is no medication and advised to go to the big hospitals,” which the majority of the poor cannot afford. “The system does not care about your [empty] pockets.” Inhibiting factors About 80% of Africans, mostly those in the middle-income bracket and below, rely on public health facilities, reported the World Bank in 2013. With public health facilities suffering chronic shortages of critical drugs, many patients die of easily curable diseases. Several factors inhibit access to medicines, but the major ones, according to the WHO, are the shortage of resources and the lack of skilled personnel. “Low-income countries experience poor availability of essential medicines in health facilities, substandard-quality treatments, frequent stock-outs and suboptimal prescription and use of medicines,” says the world health body. Africa’s inefficient and bureaucratic public sector supply system is often plagued by poor procurement practices that make drugs very costly or unavailable. Added to these are the poor transportation system, a lack of storage facilities for pharmaceutical products and a weak manufacturing capacity. Africa’s capacity for pharmaceutical research and development (R & D) and local drug production still has a long way to go, say experts. Only 37 out of 54 African states have some level of pharmaceutical production. Except South Africa, which boasts some active local pharmaceutical ingredients, most countries rely on imported ingredients. The result is that Africa imports 70% of its pharmaceutical products, with India alone accounting for nearly 18% of imports in 2011. Pharmaceutical imports in Africa include up to 80% of the antiretroviral drugs (ARVs) used to treat HIV/AIDS, according to trade data. “Many African governments spend a disproportionate amount of their scarce resources on procuring medicines,” writes Carlos Lopes, former executive secretary of the United Nations Economic Commission for Africa. To produce medicines, a country must abide by Current Good Manufacturing Practices (CGMP), which are enforced by the United States and other governments to ensure the quality of manufacturing processes and facilities. Many African countries do not have the technical, financial or human resources required for high-scale drug production. But Egypt, Morocco, South Africa and Tunisia have made progress in local pharmaceutical productions. Morocco is Africa’s second-largest pharmaceutical producer (after South Africa), and has 40 pharmaceutical manufacturing companies that supply 70% of products for local consumption and also exports to neighbouring countries. Countries such as Ghana, Kenya, Nigeria and Tanzania are currently developing production capacity. Suspicions Many African political leaders and development experts believe that the world’s biggest pharmaceutical companies are reluctant to offer technical support to African manufacturers. For example, in 2001, 39 international pharmaceutical companies dragged the South African government to court to challenge its plans to manufacture and import cheap, generic HIV/AIDS drugs. The companies claimed that South Africa’s plans breached their patent rights. Although they later withdrew the matter from court following pressure from groups that advocate for international access to medicines, South Africa’s late president Nelson Mandela accused the companies of exploiting the developing world by charging exorbitant fees for HIV/AIDS drugs. “That is completely wrong and must be condemned,” he said at the time. There is evidence, however, that local production improves access and brings down the cost of medicines. “Ever since the high-tech generic drug production [facility], Cinpharm-Cameroon, was set up, it is relatively easier for Cameroonians to have access to medicines,” says Mr. Lopes. “Now a low-wage earner can access a course of antibiotics at a lower price than a Kenyan counterpart.” Worth $24 million, Cinpharm-Cameroon produces 40 different drugs. The Trade Related Aspects of Intellectual Property Rights (TRIPS) regulation of the World Trade Organization (WTO), in force since 1986, curtails the right of companies to manufacture generic drugs, forcing countries to rely on brand-name products. However, the WTO in 2006 granted developing countries a 10-year waiver to manufacture generic drugs using the intellectual property rights of big pharmaceutical companies overseas. Despite US objections, the waiver, which expired this year, was extended until two-thirds of WTO members decide to remove it. Experts believe that is unlikely to happen, as the US appears to be the only big country insisting on its removal. WHO director-general Dr. Margaret Chan remarked in 2010 that the debate on access to medicine is often clouded by suspicions: “Suspicions that the rules governing international trade in pharmaceutical products are rigged to favour the rich and powerful; that economic interests will trump health concerns.”

#### Few people in the developing world were able to access HIV drugs due to unaffordability concerns

**Satyanarayana 05** [Kusuma Satyanarayana, associate professor in the Department of Cultural Studies, English and Foreign Languages University, April 2005, “TRIPS, patents & HIV/AIDS drugs,” *Indian Journal of Medical Research; New Delhi Vol. 121*, Iss. 4, 211-4. [https://www.researchgate.net/publication/7918705\_TRIPS\_patents\_HIVAIDS\_drugs]/](https://www.researchgate.net/publication/7918705_TRIPS_patents_HIVAIDS_drugs%5d/) Triumph Debate

Why the focus on drugs? According to Barry Bloom, Harvard School of Public Health, highly active retroviral therapy cuts down death rates in HIV/AIDS patients by 73 per cent2. These drugs are unaffordable to the poor patients and there are far too many of them. In December 2004, only about 12 per cent (700,000 of 5,800,000) HIV/AIDS patients from all developing and transnational countries were receiving anti-retroviral (ARV) treatment1. The relative coverage says it all - about 8-9 per cent in Sub-Saharan Africa and South East Asia and 65 per cent in the Americas. What is more, just 34 high-burden countries in Africa and Asia account for over 90 per cent of these. Almost 15 yr since antiretroviral drugs became available, just one of ten pregnant women receives the ART. The ARVs don't come cheap. Cost estimates vary from US $ 150 to US$ 250 per person per year (ppy), if sourced from generic manufacturers. An estimated US $5.1 billion to US$ 5.9 billion will be needed by the end 2005 toward ART and support cost for the 3 by 5 goal of WHO and UNAIDS1. And this will cover only 3 million people in the low and middle income countries3. The 'low-cost option' estimate of US$ 5.1 billion is based on the US$ 140 ppy negotiated by the Clinton Foundation from a generic manufacturer from India3. It appears that Abbott offers an ARV combination for $500 ppy to all African countries and less developed countries (LDCs), but charges $4336 for the same drug to ten Latin American countries4. Patients in developed countries like the US pay $10,000 to $15,000 annually for the same medication2. The high cost of drugs is due to patent protection. Most of the R&D is done in the private sector and pharma companies hold almost all the patents for the ARVs. It takes an estimated US$ 500 million and 12 to 15 yr to bring a new drug to market5, and the industry needs to recoup the cost. Many commentators consider the TRIPS agreement to be responsible for the current global crisis in the HIV/AIDS drugs. 'TRIPS' stands for Trade-Related aspects of Intellectual Property Rights, a global treaty to ensure intellectual property rights within international trade. During 1986-94, industrialized countries led by the US pushed for a global intellectual property rights (IPR) protection system. Earlier, IP regimes were mostly left to national discretion in both developed and developing countries. Countries like India did not have 'product' patent protection for drugs and the total period of patent protection was five years from the date of sealing or 7 years from the date of filling. The objective was to harmonize the way IP is protected around the world by establishing a set of common minimum international rules designed to protect inventors (primarily from the pharma industry). After prolonged and acrimonious negotiations, TRIPS came into force in 1995. As TRIPS rules prohibit 'copying' a drug under patent protection (so called generics), during these negotiations, countries like India, Brazil and other poor countries continuously expressed their misgivings about the potential adverse impact of the treaty on the price of medicines, including life saving drugs, a concern shared by several international non-governmental organizations (NGOs) like Medicines Sans Frontieres (MSF), Oxfam, Third World Network (TWN), etc. The simmering debate surfaced in 1997 when the Republic of South Africa modified IP laws to provide cheaper medicines for the alarming HIV/AIDS infected population by invoking what is known as compulsory licensing provisions for patented drugs. The US and the EU threatened trade sanctions against South Africa besides initiating a protracted legal battle. In the light of severe international criticism, the US withdrew the case. About the same time, the US took on Brazil when the Brazilian govt threatened invoking compulsory licence provisionson two patented drugs. The Lancet predicted6 that "...if the USA does not withdraw its case, the wrath of the international community will be as furious as in South Africa and make Brazil the moral winner what ever happens". The prediction proved right and on June 25, 2001, the US withdrew its complaint against Brazil. Some concerns on the TRIPS, patent protection and their impact on global health thus continue to be in the forefront of a global debate since 1985. Some of these include (i) strong patent protection leads to higher drug prices eventually out of reach of people in developing countries; (ii) enforcement of TRIPS provisions will have a serious negative effect on the local manufacturing capacity; (iii) TRIPS discourages R&D to produce a cheaper source of generic, innovative, quality drugs for poor countries; (iv) TRIPS provisions will not encourage adequate R&D for developing drugs and vaccines for diseases of the poor such as malaria, tuberculosis and HIV/ AIDS. Developed countries led by the US consistently opposed any dilution to the TRIPS provisions. Yet, developing countries like Zimbabwe, India and Brazil supported by international NGOs like the MSF, Oxfam, etc., pushed for discussion on the TRIPS rules and public health. Finally, in 2001 the TRIPS Council agreed to hold a special session on access to medicines. The US primarily took the US Pharmaceutical Research and Manufacturers of America (PhRMA) position7 that patents really are not the issue in access to medicines in poor countries. While these discussions were on, the tragic event of 11 September 2001 of the terrorist attack of World Trade Centre and Pentagon occurred which, some commentators, consider played a crucial role in the final outcome of the TRIPS Council debate in Geneva and the eventual outcome at Doha. Following this attack, the US and Canada perceived bio-terror (anthrax virus) threat and thus a large scale public health emergency which necessitated large supply of ciprofloxacin, a patented drug from Bayer. To bring the price down, Canada granted a compulsory license to a local manufacturer in October 2001 while the Secretary HHS, US threatened Bayer with a grant of compulsory license to a US firm if the company did not meet the demand for price reductions. Bayer was forced reduce the price to half at which it initially offered to supply the drug (See 7 for details). The action of the US was widely criticized: "It is time ..US Government recognized ... that public health needs may have to override trade profits, and that putting money into a fund while doing its utmost to prevent life-saving treatments reaching those who need them is duplicitous. The US .. should apply the same standards in defining what is, or not, a public health emergency"8.

#### **The major barrier for a lack of access to medicine in developing countries is unaffordability due to patents**

**Crook 05** [Jamie Crook- director of litigation for the Center for Gender and Refugee Studies, 2005, “Balancing Intellectual Property Protection with the Human Right to Health,” *Berkeley Journal of International Law 23*(3), 524-550, [https://lawcat.berkeley.edu/record/1119803?ln=en]/](https://lawcat.berkeley.edu/record/1119803?ln=en%5d/) Triumph Debate

With as little as $8 to spend on health care per person annually, the governments of most sub-Saharan states cannot afford the $10,000 price tag for a year's supply of name-brand anti-retrovirals. 3 3 Some patent supporters point to the limited public health resources of these countries to argue that domestic poverty levels alone explain the lack of access to treatment. 3 " Surely poverty and under-resourced public health infrastructure are major barriers to access to costly medications. But it is also true that prices remain high, and therefore out of reach, because of patent protection. In pitting poverty as the sole culprit for the crisis, this "poverty, not patents" argument simultaneously, and paradoxically, urges continued patent protection to ensure further research that will somehow increase availability through the discovery of new treatments. 35 However, the logic of this argument does not add up; these new treatments will likely also enjoy strong patent protection and remain out of reach for the world's poor, making this an empty bargain for the millions of HIV/AIDS patients who cannot even afford existing treatment. Advocates of the "poverty, not patents" perspective point to skeletal public health programs in many AIDS-ravaged countries to argue that even if access to affordable generics, increased, no infrastructure exists for proper disbursement and monitoring. 36 The argument goes as follows: without substantial public health infrastructure, patients will not be able to adhere to the treatment cycle, rendering the drugs ineffective and facilitating drug-resistant viral strains.37 Yet recent studies have concluded otherwise. Patients in Brazil, Kenya, Senegal, and India have adhered to treatment programs as strictly as patients in wealthy western states.3 8 Research has also attested to the quality and efficacy of generically manufactured anti-retrovirals. 39 James Thuo Gathii argues that western governments, in cohort with pharmaceutical corporations, have over-emphasized the role of poverty in restricting access to anti-retrovirals.4 0 The Executive Vice President of Bristol Myers-Squib, which produces the AIDS drug Zerit, for example, denied the impact of patent-based profits on the AIDS crisis, claiming that "[AIDS] is about poverty." 4 1 Such arguments should come as no surprise, as pharmaceutical corporations have a financial interest in framing this humanitarian crisis as one of poverty rather than affordability. They also cast AIDS as a strictly social condition rather than an infectious disease, a notion not unique to pharmaceutical conglomerates. South African President, Thabo Mbeki, for example, misguidedly asserted that "extreme poverty" is the4rimary culprit of sub-Saharan Africa's public health ravages, not the HIV virus. The circular "poverty, not patents" argument assumes that high prices are a given and that poverty is synonymous with an inability to afford medication. But high prices are not a given; based on the examples of India and Brazil, relaxing patent standards for developing countries by condoning generic manufacture and parallel imports4 3 dramatically lowers prices and increases access to anti-retroviral treatment. 44 Instead of poverty, the true barrier to access is unaffordability. This idea should empower those who are truly concerned with combating the AIDS epidemic because, while poverty is a multidimensional problem with no immediate solution, current technology already allows for the manufacture of affordable generic treatment. Yet patent protections presently suppress the production of effective generic antiretrovirals, to the detriment of the world's poorest HIV/AIDS patients.

### FW:

#### The standard is reducing structural violence. Prefer:

#### Centralizing our “academic” insights about structural violence is k2 resisting neoimperial dominance of political institutions.

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(Raul, Professor and activist, this essay was peer reviewed in *The South Atlantic Quarterly* Winter “Counterhegemonies and Emancipations: Notes for a Debate”)

The discussion of the horizons of social struggle is neither an academic issue nor, in the end, a theoretical one. The historical experience of social struggle, and especially the history of revolutionary processes, demonstrates that the points of reference that provide the strength and ideas that orient struggle and social transformation are of primary importance. While it is the workers and their organizations that through struggle constitute the subject of social transformation, what we call points of reference (organizations, but also newspapers, clubs, and more recently, groups of intellectuals) have been able to make important contributions in formulating analysis and strategies adequate to the historical moment insofar as they take into account the realities of the transformational subject. In this sense, we think it is very important to intensify the debate concerning the horizons of social struggle. This becomes even more relevant if, following Perry Anderson’s characterization of the Latin American social reality, “Here and only here, the resistance to neoliberalism and to neo-imperialism conjugates the cultural with the social and national. That is to say, it entails an emerging vision of another type of organization of society and another model of relations among states on the basis of these three different dimensions.”1