JUST THE TREATMENT WE NEED
A CLINICAL EXAMINATION OF THE GLOBAL PHARMACEUTICAL SYSTEM

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Our world is ravaged by a terrible health problem, with blatant symptoms manifested by the suffering of millions. In a modern installment of the chronic problem of inequality, inadequate access to essential medicines causes millions of unnecessary deaths each year. Inequality is nothing new—almost two millennia ago, the Greek historian Plutarch said, "an imbalance between rich and poor is the oldest and most fatal ailment of all republics".[1] Yet somehow as science prevailed over some of nature's deadliest diseases, and as the world became more interconnected through technology, economic interdependence, and the rapid exchange of ideas, this "fatal ailment" metastasized. Advancements in modern medicine have greatly improved the lives of the wealthy, while much of the world remains trapped in a self-perpetuating cycle of poor health and lack of economic opportunity. With a pharmaceutical industry worth over US$300 billion a year, the pressure to profit hinders the just distribution of the social goods it produces.[2] The reason this malady persists is not because it is incurable, but because we have failed to prescribe a proper treatment. It is time to put the pharmaceutical industry in the clinic to find out what ails it and how it can be restored to good health in order allow for human flourishing and social justice.

I: Medical History

Beginning with the so called "Great Divergence" of the Western world in the 19th century and continuing into the global age, inequality has expanded from a local ailment of republics to a global health catastrophe. Miraculous advances in Western medicine have brought an unprecedented capability to prevent and treat diseases, but the progress in efficacy is tarnished by a simultaneous decline in equity. Throughout recent history, the advanced economic standing of developed countries has allowed them to improve the health of their populations and the efficacy of their medicine, and economic inequality has reinforced health inequality as developing countries remain unable to fund these improvements.

It was in this context of rapid improvements for some and stagnation for others that an international system of intellectual property rights was born.As pharmaceutical companies developed new and effective drugs, they lost profits as competing companies produced generic copies of the drug and sold them at lower prices. In re-

sponse, governments in the developed world instituted strong patent protections in the pharmaceutical sector throughout the late twentieth century. The purpose was to incentivize innovation of new drugs by giving pharmaceutical firms a monopoly over their products for a set time period (usually twenty years), allowing them to recoup the high costs of biomedical research.[3]

At the same time, however, many developing countries weakened or eliminated patent protections in order to lower the cost of medicines and increase access to those who needed the drugs.[4] This threatened the profits of transnational pharmaceutical companies in developed countries, who then used political pressure and lobbying to convince their national policymakers to impose globally uniform patent laws.[5] In 1994, a pharmaceutical industry alliance drafted the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, and the alliance's powerful host countries made it a requirement for this agreement to be translated into the national law of any country seeking membership in the World Trade Organization.[6] This was a pivotal year in the history of the global pharmaceutical system as intellectual property rights for new pharmaceutical products became more regularized across the globe.

II: Symptoms

There is fervent debate on the relative merits of TRIPS compared to the pre-TRIPS era, but if the symptoms of the current state of global health can be any indication, the present system is undoubtedly ailing. There are 4.8 billion people living in developing countries, 2.7 billion of whom live on less than $2 a day.[7] The majority of these people lack access to life-saving medicines,[8] resulting in ten million deaths every year that are preventable by Western medical capabilities.[9] Peter Singer and Doris Schroeder (2010) distinguish between two failures of the global pharmaceutical system: the accessibility problem and the availability problem. These problems emerge when drugs are too expensive for those who need them or when no drug has been researched and developed for a particular disease, respectively.[10] By imaging an ideal pharmaceutical system that is equitable and allows for the fulfillment of the human right to health, it becomes clear how these two problems push lived reality further away from this ideal.

While an ideal pharmaceutical system would provide access to life-saving medicines to those who need them despite their nationality or income, much of Western medicine is distributed based on who can pay, leaving the poor without treatment. This is the accessibility problem: drugs exist and are available, but they can only be used by the wealthy minority that can afford them. Despite the Millennium Development Goal 6 target of universal access to antiretroviral treatment by 2010, 1.7 million deaths from AIDS-related illnesses in 2011 prove that the target was not attained.[11] There are effective treatments to prevent people living with HIV from dying due to AIDS-related illnesses, but they are too expensive for many individuals and health systems in developing countries. In 2001, only 30,000 of the 28.5 million Africans living with HIV/AIDS had access to life-prolonging drugs.[12] The "pills if you can pay" system is especially problematic for communicable diseases such as AIDS and tuberculosis precisely because leaving them untreated (or worse, partially treated) increases the likelihood of the infec-

tions spreading or becoming drug-resistant.

This lack of accessibility is also disastrous for noncommunicable diseases, which—contrary to the oft-misleading logic of "epidemiological transition"—are the cause for much more mortality in the developing world than in the developed world.[13] Rheumatic heart disease is an example of a noncommunicable disease that has been eliminated from developed countries through advanced prevention and treatment, but still looms large in low-income countries.[14] The accessibility problem begins with economic inequalities, but over time it translates into massive health inequalities as the inability to afford medicines increases the burden of disease.

The ideal pharmaceutical system would also provide adequate availability of treatments for the deadliest diseases, and research drugs that promise the largest health gains (e.g. lives saved). The gains targeted in our current system are not increased health, but rather increased profits. Because of this, the drug industry has focused on diseases that afflict people in rich countries; at the same time. the industry has remained cautious about researching drugs for diseases affecting developing countries due to the low potential for profits.[15] This exacerbates the availability problem, in which the drugs needed to treat a disease simply have not been created. For example, there are an estimated 1 billion people living with neglected tropical diseases. The three tropical diseases with the highest mortality rates (Chagas disease, human African trypanosomiasis, and visceral lieshmaniasis) have no effective treatment due to international neglect and low funding.[16] Diseases that add up to 90 percent of the global burden of disease only receive 10 percent of pharmaceutical research and development, a disparity known as the "90-10 gap".[16] Over the last two decades, a fivefold increase to about US$250 billion in pharmaceutical funding has wrought amazing results, but these advances have served the wealthy and left the poor without treatment; only 1-2% of this increased funding addresses infectious diseases in low-income countries.[17]

While Singer and Schroeder's (2010) accessibility and availability problems are telling symptoms of an ailing pharmaceutical system, the issues do not stop there.[18] Systematic inefficiencies also prevent the system from reaching its ideals; little of the money spent goes toward improving the health of human populations. As developing countries fight patents to provide drugs at cheaper prices, a significant portion of industry money is spent in lawsuits protecting patents. When South Africa adopted a National Drugs Policy to provide effective drugs at low cost in 1996, 39 pharmaceutical companies filed a suit to protect their patent pricing.[19] Large pharmaceutical firms spend about one sixth of their sales revenue on research and development, while spending twice that on marketing their products.[20] This spending disparity indicates the importance of informing consumers through public channels. With their exorbitant funds, these pharmaceutical firms are able to broadcast their messages to the public, no matter how biased the information may be.[20] These excess expenditures surpass the already high cost of research and innovation, requiring companies to set their patent-protected prices above what many health systems are able to pay. These higher drug prices contribute to cost escalation, which is a major problem afflicting health systems—both rich and poor—around the world.[21]

In lieu of scientific impact assessment, the profitability of a drug can be determined by how well it is marketed rather than its effectiveness. Even when impact assessment is used, data uncertainty provides space for manipulation to find configurations that favor commercial interests.[22] Interviews with company employees reveal that they are pressured by drug companies to produce favorable analyses by reconfiguring models.[23] When government funding of research declines, academic-industry partnerships become more common, resulting in more conflicts of interest.[24] Through advertising and manipulation of impact assessment, pharmaceutical companies can make a new product profitable even if it is truly no better than what was previously used. At the same time, companies are incentivized to develop maintenance drugs that reduce symptoms because they are more profitable than more cost-efficient, high-impact treatments such as vaccines and curative drugs.[24] Thus, the inefficiencies of the pharmaceutical system can be linked to increased spending that is unrelated to research and to the development of drugs with inconclusive positive impacts.

III: Case Study: Brazil

It is important not only to see these symptoms in the global context, but also to understand the concrete effects they have on developing countries. Without the financial means to afford drugs or fund innovation, low-income countries suffer most acutely from these problems of access, availability, and efficiency. Yet even middle-income countries in the midst of substantial economic growth, such as Brazil, find their efforts to improve their quality of life hindered by the high cost of medicine. Despite being recognized as one of the BRIC countries enjoying rapid economic growth and newfound global influence, Brazil is still a nation with great disparities of wealth and a long history of oppression by race and gender that continues to have an impact on population health.[25] In the late 1980s, a massive wave of social mobilization led to the removal of a military dictatorship and the creation of the Constituição da República Federativa do Brasil.[26] The new constitution declared a right to health for all, establishing the universal Unified Health System (SUS).[27]

The SUS immediately faced funding shortages due to structural adjustment policies promulgated by the International Monetary Fund in the early 1990s.[28] One decade after its creation, AIDS activists used human rights language to argue that the SUS was not maintaining its constitutional promise to fulfill the right to health, as expensive antiretroviral treatments were inaccessible for many.[29] Since prices were then protected by TRIPS, the health system was confronted with the accessibility problem. To address this, the Brazilian Ministry of Health breached the rules of TRIPS by developing generics and bargaining down prices, drawing condemnation from the U.S. government and pharmaceutical companies.[30] While it received criticism, the National AIDS Program (NAP) saved $1.1 billion[31] and was named by UNAIDS as the best AIDS program in the developing world.[32]

In a pharmaceutical system as troubled as ours, however, even success stories can be problematic. Rather than withdrawing from Brazil, pharmaceutical companies took the NAP as a chance to become more involved in the future of Brazilian health care. As older antiretroviral treatments lost their efficacy, the SUS needed newer and more expensive treatments that were cov-

ered by patents.[33] Furthermore, the understanding of the constitutional right to health expanded to include access to more and more drugs, and the public hospitals in less affluent states could not provide them.[34] The pharmaceutical companies were complicit in this process, and were even caught rallying Brazilian citizens to demand their products as part of their right to health.[35] Now, since patients have a constitutional right to health and their cash-strapped health system is failing to provide the medications they need, they are suing more frequently the Brazilian government in order to obtain medications.[36] The judiciary continues to make the growing number of drug-related decisions on a case-by-case basis, but access is granted in nearly every case.[37]

Since the Brazilian constitution promises an ideal health system that provides the right to health at no cost, it is a perfect case to illustrate just how far this ideal is from the current reality. The high price of patented medicines drains the limited funds available and detracts from the capabilities of the SUS to reach rural areas and urban slums.[38] This accessibility problem leaves the poor without drugs and without primary care, forcing them to file suit as a last resort. Proponents of TRIPS argue that it alleviates problems of availability by incentivizing innovation in developing countries. But rather than increasing Brazil's domestic innovative capabilities, TRIPS led to a greater reliance on importing innovations from foreign pharmaceutical companies.[39] The inefficiency problem has also been catastrophic in Brazil. A large portion of the money allocated for the SUS is now used to provide specialty medications to patients who have demanded them in court. Due to public demand, new drugs that are questionably effective but undoubtedly expensive have to be purchased en masse by the SUS.[40] The alarming inefficiency of the SUS was summed up by health secretary Dr. Osmar Terra, who said, "We try to guarantee the availability of medicines. But it is extremely perverse that we have to guarantee the most expensive medicines, which have no effect whatsoever. The laboratories use patients to increase profits".[41]

While this case study focuses on Brazil, every country in the world is adversely affected by the failings of the global pharmaceutical system. Venezuela faces a crisis similar to Brazil, in which drugs that are supposed to be cost-free in a universalized health system are too expensive for the government to provide.[42] Even the United States faces access issues that prevent drugs from reaching those who need them. The first hepatitis C treatment was developed in 2014, but the patent-protected price is an "astronomical" $84,000, which few people with the disease could afford.[43] While these Western-hemisphere populations are suffering from the lack of medicines, Africa and Southeast Asia have been hit much harder by the failings of the global system.[44] Diagnosing these problems of accessibility, availability, and inefficiency demonstrates how the state of the global pharmaceutical system is morally unacceptable.

IV: Diagnosis

These symptoms are substantiated by a heap of global health research. Given the same evidence, however, arguments have been made for varying diagnoses of the problem. United States policy and the pharmaceutical industry create a barrier to reform by arguing for the

false diagnosis that poverty is the only significant cause for limited treatment. By overstating the effect of poverty on access to medicines, the blame for the 10 million deaths and countless additional costs of human suffering is shifted from any human-controlled factors to "simply the way the world is".[45] This restricts any potential action for improvement by covering up the insidious structural violence that contributes to the problem.

Instead of being considered as a potential factor in reducing access to essential medicines, patents are often thought of as part of the solution. It can cost hundreds of millions of dollars to research and develop a new drug, and patents are the only way to recoup the price of innovation.[46] Without innovation, there will be fewer life-saving drugs in the future, and the result will be just as bad as the lack of access now.[47] As a result of stronger patents, the TRIPS era has improved the availability problem by giving pharmaceutical firms a financial reason to develop drugs that help the poor.[48] However, the situation of Brazil and many other developing countries proves that TRIPS does not live up to its promises on the availability problem. Also, there is no doubting that patents are an important contributor to the accessibility problem, because they raise the prices of drugs beyond what is affordable for developing countries. Singer and Schroeder (2010) argue that rather than judging TRIPS against the worst-case scenario or the pre-TRIPS era, we should compare it to the ideal to reveal how the system could be improved.[47] It is not enough to settle for TRIPS just because it improves the situation a little, while ten million humans die preventable deaths every year.

This continuing tragedy cannot be attributed to individual moral failings, but rather to a misalignment of the system. Despite their mission statements, the primary aims of drug companies do not align with public health and the public good.[49] As economist Milton Friedman wrote, "the social responsibility of business is to increase its profits." The solution to this problem cannot be reached by vilifying the pharmaceutical companies, who create the life-saving drugs. If a virtuous pharmaceutical company developed a cure for human African trypanosomiasis in the current system, it would be unable to recoup the costs of the research and would subsequently go bankrupt. The methods required for companies to fulfill their responsibility to shareholders and stay afloat do not align with human health needs.

The reason the pharmaceutical industry faces so much criticism is that the unjust distribution of pharmaceuticals is perpetuated by human-controlled factors, such as TRIPS. The agreement has "had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfil the right to health".[50] It has also widened the health gap between the developed and the developing countries.[51] Finally, it unjustly entrenches low income countries in a position of need because they do not have the economic capabilities to develop their own production and innovation.[52] As I see the diagnosis, the global pharmaceutical system has significant problems stemming from the incentive structures that are maintained by TRIPS. The power of strong patent protection over the most vulnerable populations is structural violence, favoring profits over human lives and human dignity.[53] Without this understanding of the group processes and incentive

structures at the root of the illness, it is impossible to prescribe a proper treatment that alleviates the suffering caused by an unjust pharmaceutical system.

V: Treatment

By realigning the incentive structures of pharmaceutical development and distribution, it is possible to create a global pharmaceutical system that allows for human flourishing. There are ways to incentivize innovating for the future without causing so much suffering in the present. A number of philanthropic measures have been used to increase access to medicines in impoverished locations, but these interventions do not change the nature of the unjust system. Sometimes, philanthropy is even used to defend the TRIPS system and perpetuate the larger-scale injustice.[54] A more sustainable intervention is tiered pricing for pharmaceuticals in low income countries based on the ability to pay. It is economically irrational to keep patent-protected prices high in low-income settings, because few people can afford to buy the product and profits are miniscule.[55] By lowering prices in developing countries, the accessibility problem would be reduced without sacrificing much profit. However, any loss of profit in the pharmaceutical industry will face steep resistance, especially with the political influence of lobbies.

A relatively new proposal that has the potential to realign the profit motive toward a more just system is the Health Impact Fund (HIF). Briefly, pharmaceutical companies that sign up for the HIF would agree to sell their products at much lower prices, forgoing all profits from sales. In return, the company would receive profits from the Fund proportional to the health impact of their product.[56] This would almost eliminate the accessibility problem, as prices of medicines would fall to the miniscule marginal cost of production. It would also significantly improve problems of availability because there is much more potential for health impact when drugs are developed for neglected diseases that affect the developing world. Finally, the system would be much more cost-effective because drugs would only be profitable if they have an impact, and firms would no longer need to spend so much money on lobbying, court cases, or salvaging their public image. Pharmaceutical companies would willingly register for the HIF because it would give them the chance to make more profit.[57] This new system would solve the problems faced by Brazil and so many other health systems around the world, giving governments a chance to provide the human right to health to all their citizens.

VI: Conclusion

A reformed incentive structure in the global pharmaceutical system is just the treatment we need to ensure that all humans receive the treatments they need. However, curing this ailment will be possible only if the failures of the current system are properly diagnosed. Here I have pointed to the structural deprivation of essential medicines in developing countries which results from the patents and incentives of the TRIPS regime. If the United States has been instrumental in forming the global pharmaceutical system system that puts patients and profits at odds, we must consider accepted and embraced the responsibility of healing the ailing pharmaceutical system. For this reason, we must dare to envision a system that respects human life and

promotes a world in which every person has access to the medicines they need to survive and flourish.

ENDNOTES

1 As cited in P. Farmer, *To Repair the World: Paul Farmer Speaks to the Next Generation*, ed. J. Weigel (Berkeley and Los Angeles, CA: University of Califor nia Press: 2013a). 54.

2 World Health Organization (WHO), "Pharmaceutical Indus try" (2014), Retrieved 18 June 2014, from http://www.who.int/trade/glossary/story073/en/

3 P. Farmer, M. Basilico, V. Kerry, M. Ballard, A. Becker, G. Bukhman, … A. Yamamoto, "Global Health Priorities for the Early Twenty-First Century," *Reimagining Global Health: An Introduction* (Berkeley and Los Angeles, CA: University of California Press: 303 – 339, 2013b). 326.

4 S. Thach and S.J. Marsnik, "Patient Standards Under TRIPS and the Pharmaceutical Industries in Brazil and India," *Latin American Business Review* (10: 237-261, 2009). 241.

5 A. Banerjee, A. Hollis, & T. Pogge,"The Health Impact Fund: Incentives for Improving Access to Medicines," *The Lancet* (375: 166-169, 2010). 166.

6 Thach and Marsnik, 240.

7 United Nations, "The Millennium Development Goals Report" (2012).

8 C.W.L. Ho, and K.M. Leisinger, "Intellectual Property and Access to Essential Medicines: A Tenuous Link?", *Asian Bioethics Review* (5.4: 376-382, 2013). 376.

9 United Nations Human Rights Council (UNHRC), "Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" (2009), 7.

10 D. Schroeder and P. Singer, "Access to Life-Saving Medicines and Intellectual Property Rights: An Ethical Assessment," *Cambridge Quarterly of Healthcare Ethics* (20:1, 1-11, 2010).

11 Farmer et al., 311.

12 J.T. Gathii, "Third World Perspectives on Global Pharma ceutical Access," *Ethics and the Pharmaceutical Industry* (New York: Cambridge University Press: 336 – 351 2005). 339.

13 Farmer et al. 2013b, 320.

14 Ibid., 321.

15 "Quagmire to Goldmine?" *The Economist* (2008), Retrieved 1 June 2014 from http://www.economist.com/node/11376895.

16 Farmer et al., 315, 319.

17 Ibid., 315.

18 D.T. Jamison et al., "Global Health 2035: A World Con verging Within a Generation," *The Lancet* (382.9908: 1898 – 1955). 1907,

19 UNHRC, 18.

20 WHO.

21 Jamison et al., 1936-1939.

22 A. Gertner, "Science of Uncertainty: Making Cases for Drug Incorporation in Brazil," *Anthropological Quarterly* (83.1: 97-122, 2010). 107.

23 Ibid., 103 – 104.

24 L. Cosgrove and E.E. Wheeler, "Drug Firms, the Codifica tion of Diagnostic Categories, and Bias in Clinical Guide lines," *Journal of Law, Medicine & Ethics* (43.3: 644-653, 2013). 647 –649.

25 Banerjee et al., 167.

26 A. Berkman, J. Garcia, M. Muñoz-Labov, V. Paiva, & R. Parker, "A Critical Analysis of the Brazilian Response to HIV/AIDS: Lessons Learned for Controlling and Mitigat ing the Epidemic in Developing Countries," *American Journal of Public Health* (93(7): 1162-1172, 2005). 1165.

27 Ibid., 1163.

28 J. Biehl (2013), "The Judicialization of Biopolitics: Clai ming the Right to Pharmaceuticals in Brazilian Courts," *American Ethnologist* (40(3): 419-436). 420.

29 P.E. Elias and A. Cohn, "Health Reform in Brazil: Lessons to Consider," *American Journal of Public Health* (93.1, 44-47, 2003). 44 – 45.

30 Biehl, 2013, 424.

31 N. Homedes, and A. Ugalde, "Improving Access to Pharma ceuticals in Brazil and Argentina," *Health Policy Plan* (21.2:123 – 130, 2006).

32 Berkman et al., 1162.

33 J. Biehl, "Pharmaceuticalization: AIDS Treatment and Global Health Politics," *Anthropological Quarterly* (80.4: 1083-1126, 2007). 1088.

34 Ibid., 1099 – 1100.

35 Biehl, 2013, 421.

36 A. Petryna, "Pharmaceuticals and the Right to Health: Reclaiming Patients and the Evidence Base of New Drugs," *Anthropological Quarterly* (84.2: 305-329, 2011). 313.

37 Biehl (2013), 420.

38 Ibid., 427 – 429.

39 "An Injection of Reality," *The Economist* (2011), Retrieved 1 June 2014 from http://www.economist.com/node/21524879.

40 M.S.G. Rosina and L. Shaver, "Why Are Generic Drugs Being Held Up in Transit? Intellectual Property Rights, International Trade, and the Right to Health in Brazil and Beyond," *Journal of Law, Medicine & Ethics* (40.2: 197-204, 2012), 199.
Thach and Marsnik, 254.

41 Biehl (2013), 423.

42 Ibid.

43 P. Wilson, "Anti-HIV Drugs Dry Up in Venezuela," USA To day (2014), Retrieved 22 June 2014 from http://www.usatoday.com/story/news/world/2014/05/09/venezuela-drug-shortage-hiv/8897051/.

44 Reuters, "U.S. health insurers say Gilead hepatitis C drug too costly," Retrieved 23 June 2014 from http://www.reuters.com/article/2014/05/20/us-insurance-gilead-sciences-drug costs-idUSKBN0E029U20140520.

45 UNHRC, 7.

46 Gathii, 336 – 338.

47 Banerjee et al., 166.

48 "Quagmire to Goldmine?" *The Economist* (2008).

49 Schroeder and Singer, 8.

50 Ibid.

51 Cosgrove and Wheeler, 648.

52 UNHRC, 28.

53 Banerjee et al., 166.

54 Ho and Leisinger, 377.

55 Gathii, 350.

56 Ibid., 351.

57 Farmer et al., 326-327.

58 Singer and Schroeder, 11.

59 Ibid.