# 1AC vs. Loveless Academy RR

## 1ac

### Plan

#### Plan Text: The member nations of the World Trade Organization ought to eliminate data exclusivity intellectual property protections for medicines, Diependaele 17

Diependaele, Lisa, et al. “Raising the Barriers to Access to Medicines in the Developing World - the Relentless Push for Data Exclusivity.” Developing World Bioethics, John Wiley and Sons Inc., Apr. 2017, [www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/). // LHP PS

**There seem to be few, if any, reasons left to accept data exclusivity in addition to the existing patent regime. Data exclusivity poses a considerable additional risk to the affordable access to medicines in developing countries.** In the absence of evidence that data exclusivity will support innovation and economic development, **there is no legitimate ground for developing countries to favour such a policy.** Moreover, **since current levels of revenue already generate copious profit margins for the pharmaceutical industry in US and EU markets, it is inequitable and highly problematic to require developing countries to implement data exclusivity**. For developed country markets, the key question remains whether society should pay the price for extended monopolies in return for merely ‘incremental’ innovations**. Even in the US and the EU, the implementation of data exclusivity, by undermining legitimate competition, seems incompatible with the long tradition of stringent competition and anti‐trust policies, which have always been vital components of the economic structure.** In its current form, **data exclusivity offers the pharmaceutical industry an ‘easy route’ to market exclusivity, without fear of challenges. Indeed, it seems that data exclusivity is meant to increase the (already significant) profitability of the pharmaceutical industry, rather than allowing them to have a legitimate demand fulfilled.**

**It’s topical and the aff solves – Data Exclusivity is a TRIPs Plus IP protection – Thrasher 21**

Thrasher, Rachel. “How Data Exclusivity Laws Impact Drug Prices:” *Global Development Policy Center Chart of the Week How Data Exclusivity Laws Impact Drug Prices Comments*, 25 May 2021, [www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data](http://www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data)-exclusivity-laws-impact-drug-prices/. // LHP AB

**Data exclusivity is a form of intellectual property protection that applies specifically to data from** pharmaceutical **clinical trials. While innovator firms run their own clinical trials to gain marketing approval, generic manufacturers typically rely on the innovator’s clinical trials for the same approval. Data exclusivity rules keep generic firms from relying on that data for 5 to 12 years, depending on the specific law.** Data exclusivity operates independently of patent protection and **can block generic manufacturers from gaining marketing approval even if the patent has expired or the original pharmaceutical product does not qualify for patent protection.** Although data exclusivity laws are matters of domestic legislation, the United States, the EU and others increasingly demand in their free trade agreement (FTA) negotiations that their trading partners protect clinical trial data in this way. **Data exclusivity is just one of a host of “TRIPS-plus” treaty provisions designed to raise the overall level of intellectual property protection for innovator firms**. Although the WTO’s Agreement on Trade-Related Intellectual Property Rights (TRIPS) does require Member states to protect clinical trial and other data from “unfair commercial use,” it does not require exclusivity rules that block the registration of generic products.

#### TRIPs Plus Provisions, namely data exclusivity, are being used in many bilateral trade agreements – Thrasher et al 21

Thrasher, Rachel, Veronika J. Wirtz, Warren Kaplan, Kevin P. Gallagher, Hattie Werk. “How Data Exclusivity Laws Impact Drug Prices:” *Global Development Policy Center Chart of the Week How Data Exclusivity Laws Impact Drug Prices Comments*, 25 May 2021, [www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data](http://www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data)

Despite these decisions at Doha (and post-Doha) there continue to be concerns about the extent to which the trading system is compatible with SDG 3. **Trading partners from high-income countries continue to pursue bilateral and regional trade agreements that seek intellectual property and investment protections beyond what is required by the TRIPS Agreement (TRIPS-plus).** Those same partners also tend to **limit the adoption and use of public health flexibilities in the TRIPS Agreement (TRIPS-flexibilities), including those clarified and extended by the Doha Declaration and its aftermath**. As a result, since 2001, the WTO has waned in importance with regards to the regulation of intellectual property rights, while **a proliferation of new regional and bilateral trade and investment treaties have increased in prominence in the global trade policy landscape**. Moreover, investment provisions in these treaties have the potential to expose governments looking to increase access to medicines to costly investor-state disputes (Baker & Geddes 2017). Overall, there is concern that, despite the flexibilities in multilateral arrangements, **trade and investment treaties can pose threats to access to some essential medicines**. Trade and investment policy is entering a new era of debate and (re)negotiation. The most recent proposed US trade agreement, the USMCA, has further raised the access bar by including new intellectual property protections exceeding those found in prior agreements. Furthermore, many least 1 “Essential medicines” is the term found in SDG 3.8. It is a term of art employed by the World Health Organization (WHO) for those medicines which satisfy the specific priority health needs of a cou\ntry’s population, recognizing that resources are limited in any context, even an affluent country such as the US. Over 130 countries have adopted this process of setting priorities for government medicines reimbursement and it is up to each nation to define its national priorities. Some activists, academics, and civil society organizations view this list as under-inclusive from the perspective of access to medicines, because many medicines are excluded because of cost, health system incapacity, and delayed government action. Indeed the **UN High Level Panel (UN 2016) suggested a broader concept of “access to medicines for all conditions for all people.”** In order to maintain our connection between access to medicines and SDG 3, we are using the term “essential medicines” as defined by the WHO, while acknowledging that other views exist. There is concern that, **despite the flexibilities in multilateral arrangements, trade and investment treaties can pose threats to access to some essential medicines.”** RETHINKING TRADE TREATIES & ACCESS TO MEDICINES: Toward a Policy-Oriented Agenda | bu.edu/gdp | October 2019 7 developed countries (LDCs) with current rights to exempt themselves from TRIPS will graduate and will have to adhere to the agreement when their transition periods end. Over the last two decades **many organizations and expert groups have issued policy recommendations to increase policy alignment between trade treaties and access to medicines in low- and middle-income countries**. **Two recent global landmark reports were published by The United Nations High Level Panel on Access to Medicines (UN 2016) and The Lancet Commission on Essential Medicines Policies (Wirtz et al. 2017).** However, despite the large number of policy recommendations, including those that encourage countries to adopt TRIPS flexibilities into national legislation and avoid TRIPS-plus provisions, there are large variations in their implementation between countries. Many important knowledge gaps remain about the processes and factors that influenced both the outcome and the implementation of trade treaties, which can explain the variation between countries. Furthermore, rigorous evaluation of the effects of trade treaties on access to medicines is restricted by limited availability of data, and a lack of uniformity in indicators and methods.

#### AND, they continue

**TRIPS-plus provisions impact access to medicines** in three key ways: (1) by increasing IP protection available to the patent holder under old TRIPS provisions, (2) by introducing new standards of IP rules and IP protection, and (3) by ramping up the enforcement requirements for intellectual property infringement. Traditional standards of patentability, disclosure in patent applications, revocation and opposition, and limited exceptions now contain new standards which provide increased protection for intellectual property holders. Rather than allow flexibility in patenting rules, these treaties tend to require patents on new uses and new methods of use on known substances. They set lower standards for “novelty” and “industrial applicability”, as well as disclosure in patent applications. They also limit the grounds for patent opposition or revocation, and weaken the limited exceptions (TRIPS Art. 30) to decrease access to early-working and government use exceptions (TRIPS Art. 31). Finally, many FTAs restrict the grounds on which a compulsory license may be granted, and some prohibit international exhaustion standards. New provisions likewise limit the policy options available to member states. These treaties introduce patent term extensions, which require countries to grant extensions for patent processing and regulatory delays. They contain patent registration linkage provisions which effectively halt a generic medicine’s registration in the event of any claim by the originator (however substantiated) that it would infringe on a patent. The treaties also demand that member states recognize patents on diagnostic, therapeutic and surgical methods for treatment. **One of the most commonly discussed new provisions in trade agreements is the protection of data exclusivity. Unlike “data protection” (TRIPS Article 39.3) which relates to “unfair commercial use”, data exclusivity provisions require that a country’s medicine regulatory authority protect the test data (i.e., typically a product’s clinical trial data) of a company wishing to be first on the market exclusively for a certain number of years (e.g. 5 to 12 years in most trade agreements).** This could delay the launch of generic competition if those generic companies must either generate their own data or wait until the data exclusivity period ends (Shadlen et al. 2019). Data exclusivity provisions have become more prevalent as the United States and the EU have pushed for these heightened standards in their agreements. China has proposed to include the most stringent data exclusivity rules in their domestic law – 6 years for innovative drugs and 12 for biologics (Wang 2018).

### Medicine Prices

#### Data exclusivity massively raises medicine prices.

#### 1] Statistically proven – multiple models agree that impacts are significant and consistent, range of empirical examples as well – Palmedo 21

Palmedo, Michael. “Evaluating the Impact of Data Exclusivity on the Price per Kilogram of Pharmaceutical Imports.” *Boston University Global Development Policy Center*, Apr. 2021,  [https://www.bu.edu/gdp/files/2021/04/GEGI\_WP\_048\_Palmedo\_FIN.pdf. //](http://www.bu.edu/gdp/files/2021/04/GEGI_WP__Bing_FIN.pdf.%20//) LHP AB

Michael Palmedo directs interdisciplinary research on intellectual property at American University (AU) Washington College of Law’s Program on Information Justice and Intellectual Property. His research focuses on the empirical evaluation of the impact of changes to patent and copyright laws. He recently completed the Shamnad Basheer IP/ Trade Fellowship at Texas A&M University, where he researched pharmaceutical industry influence into the U.S. government’s Special 301 Review.

Previous studies of **data exclusivity** have found that it **raises medicine prices and**/or **reduces access**. Data exclusivity requirements have **led to higher prices and $396 million additional expenses for Colombia’s public health system** (Cortés, et. al., 2012). **In the US, the price of one particular off-patent drug increased from nine cents to $4.85 per pill after data exclusivity** was applied (Kesselheim and Solomon, 2010). Two **studies of data exclusivity required by FTAs find a significant** impact – data exclusivity blocked **generic versions of off-patent medicines from the Guatemalan market** (Shaffer and Brenner, 2009) and **delayed the introduction of cheaper generics into the Jordanian market for 79 percent of medicines** (Malpani, 2009). Table 3 shows the **results of four regressions based on** the binary indicator of **data exclusivity**. **Each indicates that the relationship between data exclusivity and higher prices for pharmaceutical imports is statistically significant and robust to the inclusion of controls**. The coefficient on Year\*DataExclusivity is positive and significant in all specifications. The overall models fit the data well – all the right hand side variables have significant coefficients with the expected signs, the adjusted R-squared are all above 0.80 and the within-entity R-squareds range from 0.39 to 0.49. Column (1) shows the results with the overall time trend as a variable for the period 1996-2010. The **annual growth rate for pharmaceutical imports in countries without data exclusivity was 3.9 percent**, but the **corresponding growth rate in countries with data exclusivity was 7.6 percent**. Though the difference is small year to year, it compounds. **Over 15 years at these rates of growth, a price in a theoretical country without data exclusivity would increase 78 percent and the corresponding price in a theoretical country with data exclusivity would increase 200 percent**. GEGI@GDPCenter Pardee School of Global Studies/Boston University www.bu.edu/gdp 11 The control variables in this specification behave as expected. Logged GDP per capita in US dollars, taken from the World Bank, is positive, indicating the expected relationship between a country’s wealth and prices. Logged total kilograms is negative, supporting previous findings that larger pharmaceutical purchases are associated with lower prices (Helbe and Aizawa 2017).

#### 2] Exclusivity kills access to affordable medicine particularly in developing countries by granting market exclusivity without patents explicit to them – Guatemala proves – Diependaele, et al. 17

Diependaele, Lisa, et al. “Raising the Barriers to Access to Medicines in the Developing World - the Relentless Push for Data Exclusivity.” Developing World Bioethics, John Wiley and Sons Inc., Apr. 2017, [www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/). // LHP AB

**In** **many** **developing countries**, public health **institutions cannot provide essential medicines to patients**. Moreover, even if essential medicines are available, **they remain unaffordable for billions** of people. Especially **original brand medicines are ‘priced out of reach’**.[70](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/#dewb12105-note-0071) Although many factors can increase the accessibility and affordability of essential medicines, the United Nations (UN) and the World Health Organization (**WHO**) highly **recommend** that developing countries make full use of TRIPS flexibilities and **facilitate the production and importation of generics**.[71](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/#dewb12105-note-0072)

In many cases, **data exclusivity will delay the availability of new generics**. A **recent study showed that the implementation of a data exclusivity regime in Guatemala, mandated by DR‐CAFTA, resulted in generic competition being denied entry to the Guatemalan market**.[72](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/#dewb12105-note-0073) **In each case, the available originator drugs were priced substantially higher**.[73](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/#dewb12105-note-0074) **Especially in** those **countries which, pre‐TRIPS, did not grant patents for pharmaceuticals**, **data exclusivity** can be an efficient method to **ensure market exclusivity for originator drugs and prevent generic competition in that market**.

As the access to medicines in the developing world is a highly complex issue, simply not providing data exclusivity cannot by itself resolve the lack of basic healthcare infrastructure in many developing and least‐developed countries. However, for both governments and individuals, the **price of medicines can be a significant financial burden**. Although generics are not necessarily affordable for all, the **prices of original drugs tend to be at least ten times higher**.[74](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/#dewb12105-note-0075) Because most developing countries rely strongly on generics, the **consequences of implementing data exclusivity could be enormous**.[75](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/#dewb12105-note-0076)

Data **exclusivity** **also offers industry the opportunity to ‘optimize’ its global business strategy**. **Pharmaceutical companies do not file patent applications in all the countries where they will eventually market their products**. The **inclusion of data exclusivity in FTAs ensures market exclusivity without a patent**. Furthermore, **companies will first introduce new drugs in wealthy markets**, where they expect the best commercial opportunities. **Only at a later stage, are new drugs marketed in developing countries**. Consequently, **delaying marketing approval** ‐ by means of data exclusivity ‐ **can equally delay generic competition**.

#### 3] Data exclusivity destroys generic competition skyrocketing medicine prices – Malpani

Malpani, Rohit. “All Costs, No Benefits: How TRIPS-plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines.” Oxfam Library, Mar. 2007, oxfamilibrary.openrepository.com/bitstream/handle/10546/114080/bp102-all-costs-no-benefits-trips-210307-en.pdf%3Bjsessionid%3D089750820CF675173F0C3204C369D63F%3Fsequence%3D1. // LHP AB

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**Multinational** pharmaceutical **companies have prevented generic competition for** many **medicines by solely enforcing data exclusivity provisions in Jordan’s IP law**. This is **because companies can rely upon data exclusivity** more **easily than patent protection to deny generic competition**. **Patent offices apply rigorous standards** and impose safeguards **to ensure that only innovative medicines are granted a monopoly**. On the contrary, a pharmaceutical **company merely has to submit clinical trial data to obtain a five-year market monopoly**.30 According to Oxfam’s analysis **of 103 medicines registered and launched since 2001 that currently have no patent protection in Jordan**, at least **79 per cent have no competition** from a generic equivalent **as a consequence of data exclusivity** (see Appendix 1 for methodology). Jordanian generic manufacturers interviewed by Oxfam **expressed frustration at the data exclusivity law** because multinational pharmaceutical companies can rely upon data exclusivity to preclude generic competition.31 A **generic competitor could replicate these medicines, in the absence of a data exclusivity law, shortly after the medicine’s launch on the domestic market**. Although data exclusivity was imposed as a result of the US-Jordan FTA and WTO accession, the TRIPS-plus measures benefit many other countries’ multinational drug companies. **At least 21 US, European Union (EU), and Swiss drug companies have taken advantage of** the benefits of **data exclusivity**. TRIPS-plus rules, although imposed by the US FTA, benefit all drug companies because developing countries must alter their national intellectual property laws to fully implement TRIPS-plus rules. Thus, all pharmaceutical companies marketing medicines in a developing country, including European companies, benefit from these changes, and benefit from US efforts to impose TRIPS-plus rules elsewhere.32 Consequences of data exclusivity on public health **Generic competition drastically reduces medicine prices**. Multinational pharmaceutical companies that enforce data exclusivity for their clinical trial data in Jordan can prevent the onset of generic competition for five years, even without a patent on the medicine. In contrast, **nearby Egypt has not introduced data exclusivity and other TRIPS-plus rules, and multinational pharmaceutical companies have only received patent protection for medicines from 2005 onwards.** Thus, **most medicines currently sold on the Egyptian market have no form of monopoly protection** (and therefore may have multiple generic competitors). **All costs, no benefits**: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines, Oxfam Briefing Paper, March 2007 9 **Heart disease and diabetes are serious public health problems in both Jordan and Egypt. Jordan had approximately 195,000 cases of diabetes in 2000, while Egypt, a more populous country, had an estimated 2.6 million cases**. Similarly, according to 2002 WHO (World Health Organization) estimates, **heart disease is one of the leading causes of death in both countries**. A comparison of prices for five best-selling medicines that treat diabetes and cardiovascular disease in Jordan and Egypt illustrates the enormous disparity between the costs of the originator medicine in Jordan (with no generic competitor available solely because of data exclusivity) against the lowest-priced generic equivalent in Egypt (where price reductions due to generic competition are unrestricted). (See Table 1.) Table 1: **Relative prices between medicines with no generic competition in Jordan (due to enforcement of data exclusivity) and the price of the lowest-priced generic equivalent in Egypt Country** (company) Active Pharmaceutica l Ingredient (dosage) Medical use Price per Unit (in Jordanian dinars at prevailing exchange rate) **Jordan** price compared to Egyptian price Egypt (local generics manufacturer) Jordan (Merck) Metformin (850 mg) Metformin (500 mg) **Anti-diabetic** .02 .16 **800% Egypt** (local generics manufacturer) Jordan (Kleva) Atenolol (100 mg) Atenolol (100 mg) Antihypertensive .03 .11 367% Egypt (local generics manufacturer) Jordan (Glaxo SmithKline) Rosiglitazone maleate (4 mg) Rosiglitazone maleate (2 mg) Anti-diabetic .40 .67 167% Egypt (local generics manufacturer) Jordan (Merck) Simvastatin (20 mg) Simvastatin (20 mg) Antihyperlipidemic .452 2.25 498% Egypt (local generics Ramipril Antihypertensive .14 557% All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines, Oxfam Briefing Paper, March 2007 10 manufacturer) Jordan (SanofiAventis) Ramipril hypertensive .78 Source: Jordan and Egypt Ministries of Health (2006) These **new medicines are significantly more expensive in Jordan than in Egypt. If TRIPS-plus rules had been present in Egypt, local manufacturers could not have driven down prices for these medicines through generic competition**, and the prices for these medicines would have been much higher. The **result would have been increased health-care costs and less medical treatment**, especially for poor people.

#### Three Impacts:

#### **1] Quality Treatment – American Hospital Association 19’**

“New Report Shows Impact of Rising Drug Prices and Drug Shortages on Patients and Hospitals: Aha.” American Hospital Association, AHA, 15 Jan. 2019, www.aha.org/press-releases/2019-01-15-new-report-shows-impact-rising-drug-prices-and-drug-shortages-patients. //LHP DP

This report confirms that **we are in the midst of a prescription drug spending crisis that threatens patient access to care and hospitals’ and health systems’ ability to provide the highest quality of care,”** said AHA president and CEO Rick Pollack. “**Solutions must be worked on to rein in out-of-control drug prices and ease the drug shortages that are putting a strain on patient care.**” “We see a developing crisis. **Relentless drug price increases and all too frequent shortages of critical medications are eroding the capacity of hospitals to provide our patients needed care,”** said FAH president and CEO Chip Kahn. “We believe **policymakers should act now to protect patients**.” “ASHP is at the forefront of efforts to combat the systemic impact of ongoing drug shortages and rapidly rising drug prices,” said ASHP CEO Paul W. Abramowitz, Pharm.D., Sc.D. (Hon.), FASHP. “By working with government agencies and partners such as AHA and FAH, we will continue to offer policy solutions and a roadmap for the changes necessary to ensure optimal care for patients.” Today’s report updates and expands on a previous AHA/FAH report from 2016 on skyrocketing inpatient hospital drug cost increases by also analyzing outpatient drug costs and the impact of drug shortages. The report found that **hospital budget pressures resulting from the continued dramatic increases in drug prices have negative impacts on patient care**, **with hospitals being forced to delay infrastructure investments, reduce staffing, and identify alternative therapies. Hospitals also struggle with drug shortages, which can disrupt typical work patterns and patient care, and often require significant staff time to address.**

#### 2] They force people into poverty

Hoban 10 Rose Hoban 9-13-2010 "High Cost of Medicine Pushes More People into Poverty" <https://www.voanews.com/science-health/high-cost-medicine-pushes-more-people-poverty> (spent more than six years as the health reporter for North Carolina Public Radio – WUNC, where she covered health care, state health policy, science and research with a focus on public health issues. She left to start North Carolina Health News after watching many of her professional peers leave or be laid off of their jobs, leaving NC with few people to cover this complicated and important topic. ALSO cites Laurens Niens who is a Health Researcher at Erasmus University Rotterdam)//Elmer

Health economist Laurens Niëns found that **drugs needed to treat chronic diseases could be considered unaffordable for many people in poor countries. Medicines can be expensive** and often make up a large portion of any family's health care budget. And the burden can be even greater for people in poor countries, where the **cost of vital medicines** can **push them into poverty**. **The problem is growing as more people around the world are diagnosed with chronic diseases such as high blood pressure and diabetes.** Being diagnosed with a chronic disease usually **compells patients to seek treatment for a prolonged period of time.** That **increases the eventual price tag for health**, says health economist Laurens Niëns at Erasmus University in the Netherlands. **Niëns examined medication pricing data from the World Health Organization** **and also looked at data from the World Bank on household income in many countries.** Using the data, he calculated how much people need to spend on necessities such as food, housing, education and medicines. "**The medicines we looked at are medicines for patients who suffer from asthma, diabetes, hypertension and we looked at an adult respiratory infection**," Niëns says. "Three conditions are for chronic diseases, which basically means that people need to procure those medicines each and every day." Niëns focused on the cost of medicine for those conditions. He found the **essential drugs could be considered unaffordable for many people in poor countries** - so much so that their cost often pushes people into abject poverty. "**The proportion of the population** that is living **below the poverty line, plus the people that are being pushed below the poverty line, can reach up to 80 percent in some countries for** some **medicines," Niëns says. He points out that generic medicines - which are more affordable than brand-name medications - are often** **not available in the marketplace**. And, according to Niëns, poor government policies can drive up the cost of medications. "For instance, a lot of governments actually tax medicines when they come into the country," he says. "[They] have no standard for the markups on medicines through the distribution chain. So often, governments think they pay a good price for the medicines when they procure them from the producer. However, before such a medicine reaches a patient, markups are sometimes up to 1,000 percent."

#### 3] High drug prices force patients to go underground for drugs.

Bryant 11 Clifton Bryant 2011 “The Routledge Handbook of Deviant Behaviour” (former professor of sociology at VA Tech)//Elmer // Recut LHP AB

Now, the field of medicine is able to achieve seemingly miraculous results, through organ transplantation, reviving patients who have been "clinically" dead, and curing supposedly "incurable diseases." Medical miracles are not cheap, however, and the costs of **medical care and** drugs **have risen (and** continue to rise**)** at a near-astronomical rate**.** Consequently, neither private medical insurance plans nor Medicare will now cover certain procedures, treatments, and medicines. In the future, with continuing reform of the US healthcare system, even fewer procedures, treatments, and medications might will be covered. Certainly, some medical treatment will be "rationed," and **particular categories of people (such as the elderly) may be systematically denied the coverage they need**. As a result of all this, medical**- and health-related** crime **and deviance** will inevitably rise. Medical insurance, Medicare, and Medicaid **fraud**, which is already prevalent today, **will increase exponentially**. Smugglers will "bootleg" ever more pharmaceuticals into the US, and a large, thriving, nationwide black market will develop for those who cannot afford to buy uncovered medications**.** More **medicines and diagnostic equipment will be stolen, and back- street medical procedures using such stolen equipment may well be offered for cash with no questions asked**. **Armed robberies of valuable pharmaceuticals from drug stores and super- markets will increase, too**. **Bribery to obtain insurance-uncovered or rationed medical care** (or, indeed, any kind of medical care where demand exceeds supply) will likely mushroom. **This is actually common in some countries around the world.** Counterfeiting expensive pharmaceuticals will be prevalent**, and medical frauds of all kinds will be very widespread**. Many of these frauds will be directed at the elderly population as it continues to increase in size. The elderly will be particularly vulnerable because they are most likely to be denied coverage for certain medical procedures or treatments. For instance, **private health insurance and Medicare will both refuse to cover a woman in her mid-80s for potentially life-saving heart-bypass surgery. As a result, she will be a prime candidate for victimization by medical fraud that offers her affordable, but bogus, treatment.** There is already a **thriving international black market in human organs** (Schepper-Hughes 2009). Kidneys are obtained from poor individuals in impoverished countries for relatively modest sums of money. This cash allows the donors to purchase luxuries, such as a small automobile, educate their children, or simply sustain their families for a few months. The organs are sometimes **transferred** quickly **to a hospital in the donor's own country** for transplant surgery. But on other occasions they are **transported to the US or another Western country**. In the US, obtaining an organ for transplantation in this fashion is illegal. Nevertheless, the practice will undoubtedly increase greatly in the future. Where medical care and medicines become exorbitantly expensive, cheaper ways to obtain them, even when these are illicit, will be sought. Where there are shortages of medical care or medicines, perhaps because of rationing, other means of obtaining them, even if deviant, will surely be employed. As the cost **and the difficulty** ofobtaining **medical care and** medicines increase, the implications for increased crime and deviance become almost limitless**.**

#### Counterfeit drugs kill millions –

Greenberger 20 Phyllis E. Greenberger 12-3-2020 "Counterfeit Medicines Kill People" <https://www.healthywomen.org/health-care-policy/counterfeit-medicines-kill-people/who-suffers-because-of-counterfeit-drugs> (HealthWomen’s Senior Vice President of Science & Health Policy)//Elmer // Recut LHP AB

**Over 1 million people die each year from fake drugs**. COVID-19 Have you ever had a hard time getting a prescription filled? Or maybe you've had to wrestle with your insurance provider to get them to pay for a medication vital for your health? Worse, maybe you're one of the 27.5 million uninsured Americans who find it difficult to get health care, let alone obtain the prescription drugs you may need. If you've had any of these experiences, then perhaps you've turned to the internet to buy medications that would require a prescription. While legal online pharmacies do exist, many **online pharmacies are fraudulent, selling counterfeit medications, and millions of people have fallen victim to these scammers**. Make no mistake: Counterfeit medicine is not real. The active ingredients that help you stay healthy may be missing or diluted to levels that are no longer potent. This **can be dangerous and even life-threatening**, as people rely on their medications to keep them well, and sometimes even alive. Many **counterfeit medicines aren't even drugs at all, but rather snake oil cures that make people sick — they may even contain dangerous ingredients such as heavy metals, highway paint or even rat poison**. The World Health Organization (**WHO) estimates that over 1 million people die each year from these substandard drugs**. It's estimated that more than 10% of all pharmaceuticals in the global supply chain are counterfeit in normal times, and during COVID-19, the increased use of telehealth and the appearance of fraudulent doctors has led to a surge in drug fraud. In October of this year, Peter Pitts, president of the Center for Medicine in the Public Interest, a nonpartisan research organization, said pharmaceutical fakery was a "spreading cancer." Counterfeiting is a major problem that requires the federal government to step up to slow — and eventually prevent — its spread. It's also vital that consumers know exactly what's at stake when taking these fake drugs. Who suffers because of counterfeit drugs? Expensive prescription medications and generic drugs in nearly every therapeutic class may be counterfeited. **Out of $4.3 billion worth of counterfeit medications seized between 2014 and 2016**, 35% were marked as antibiotics. Some of the other most common culprits in counterfeit medicine are used to "treat" HIV/AIDS, erectile dysfunction and weight loss. No matter what condition or disease the counterfeit medication is intending to treat, the outcome can be disastrous. Counterfeit medications **exacerbate other existing health crises**. The United States, for example, is in the midst of an **opioid epidemic that is killing 130 people per day**. As of 2018, counterfeit drugs containing **illegally** **imported fentanyl** (a powerful opioid) had contributed to this tragedy by causing deaths in 26 states. The U.S. Department of Justice found that, in at least one case, these counterfeit drugs had been sold through a fraudulent online pharmacy.

### Insulin

#### Data Exclusivity skyrockets insulin prices – Palmedo 21

Palmedo, Michael. “Evaluating the Impact of Data Exclusivity on the Price per Kilogram of Pharmaceutical Imports.” *Boston University Global Development Policy Center*, Apr. 2021,  [https://www.bu.edu/gdp/files/2021/04/GEGI\_WP\_048\_Palmedo\_FIN.pdf. //](http://www.bu.edu/gdp/files/2021/04/GEGI_WP__Bing_FIN.pdf.%20//) LHP AB

Michael Palmedo directs interdisciplinary research on intellectual property at American University (AU) Washington College of Law’s Program on Information Justice and Intellectual Property. His research focuses on the empirical evaluation of the impact of changes to patent and copyright laws. He recently completed the Shamnad Basheer IP/ Trade Fellowship at Texas A&M University, where he researched pharmaceutical industry influence into the U.S. government’s Special 301 Review.

This study’s pricing indicator is the **annual price per kilogram paid by each country for each sixdigit HS class of drug imports** from 1996 through 2010. This covers the period when most of the countries in my set adopted data exclusivity. During this time, Comtrade has data on imports of eight different classes of retail medicines classified at the 6-digit HS level, which are shown in Table 2. All of these are shipments of packaged medicines for human consumption, rather than active pharmaceutical ingredients or other unmixed pharmaceutical products, which fall under a different HS classification. **Table 2 also shows descriptive statistics for the price per kilogram in each of the HS classes in the dataset**. The mean varied significantly over the period from one class to the next, ranging from $29.70 for imports in HS 300450 (medicines containing vitamins) to $268.49 for those classified as HS 300439 (medicines containing certain types of hormones and antibiotics). There was also a lot of variation within each class, with the standard deviation exceeding the mean for half of the HS groups. Though skewed when taken as a whole and when disaggregated by HS class, the **data on price per kilogram logs normal**. Figure 2 compares the annual average price per kilogram paid by importing countries each year by countries with and without data exclusivity from 1996 to 2010. The price increased at a higher rate in the countries that had enacted data exclusivity. Average prices in each group tended to be similar until the early 2000s, and began to diverge after 2004. **Figure 3 compares the average price per kilogram separately for each HS classification**. While import price inflation was higher in countries with data exclusivity for all of the HS groups, the **difference was most pronounced in HS 300431** (medicines containing **insulin**) and HS 300439. The following section tests the significance of the difference in pharmaceutical import price inflation in countries with and without data exclusivity. GEGI@GDPCenter Pardee School of Global Studies/Boston University 8 www.bu.edu/gdp Figure 2. Average Price per Kilogram of Pharmaceutical Imports (USD) 0 40 80 120 160 200 1995 1997 1999 2001 2003 2005 2007 2009 2011 Data Exclusivity No Data Exclusivity Linear (Data Exclusivity) Linear (No Data Exclusivity) Table 2. HS Classifications and Descriptive Statistics HS Code Product Description Mean St. Dev. N 300410 Medicaments, containing penicillins, streptomycins or their derivatives 43.92 27.26 549 300420 Medicaments; containing antibiotics (other than penicillins, streptomycins or their derivatives) 86.74 119.20 515 300431 Medicaments; containing insulin 231.55 178.69 524 300432 Medicaments; containing corticosteroid hormones, their derivatives or structural analogues (but not containing antibiotics) 119.68 285.54 529 300439 Medicaments; containing hormones (but not insulin), adrenal cortex hormones or antibiotics 268.49 558.99 521 300440 Medicaments; containing alkaloids or their derivatives, containing ephedrine or its salts 107.45 148.18 524 300450 Medicaments; containing vitamins or their derivatives 29.70 46.38 543 300490 Medicaments; consisting of mixed or unmixed products n.e.c. in heading no. 3004 51.33 50.38 524

Chart, scatter chart

Description automatically generated

#### The graph shows how insulin prices have hugely increased in a short span b/c of data exclusivity – will further increase with more exclusivity.

#### Insulin price gouging makes an essential medicine unaffordable – that causes diabetics to skip/ration doses, skimp on necessities, or die trying.

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

#### Reducing IP protection for insulin increases innovation – it stops redundant research and competition

Emily 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

### Framework

#### Pain and pleasure are intrinsically valuable – to justify beyond that runs into moral incoherence. Moen 16,

Moen 16 [Ole Martin Moen, Research Fellow in Philosophy at University of Oslo “An Argument for Hedonism” Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281] SJDI // RCT by JPark

Let us start by observing, empirically, that a widely shared judgment about intrinsic value and disvalue is that pleasure is intrinsically valuable and pain is intrinsically disvaluable. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative.2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values. If you tell me that you are heading for the convenience store, I might ask: “What for?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good.3 As Aristotle observes: “We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that if something is painful, we have a sufficient explanation of why it is bad. If we are onto something in our everyday reasoning about values, it seems that pleasure and pain are both places where we reach the end of the line in matters of value.

#### Thus, the standard is maximizing expected well-being. It’s hedonistic act util. Prefer it.

#### 1] Actor specificity A] governments must aggregate because their policies benefit some and harm others so the only non-arbitrary way to prioritize is by helping the most amount of people B] No act-omission distinction – governments have to yes/no policies which means that choosing to omit is an act itself so side constraints freeze action C] Actor specificity comes first because different agents have different obligations. Takes out calc indicts because they’re empirically denied.

#### 2] Death is the worst impact and outweighs, A] internal link turn – it fundamentally destroys the subject which makes alternative value and resistance impossible, B] its irreversible so any chance life is good means it comes first

### Underview

#### 1] 1ar theory – the aff gets it because otherwise the neg can get away with infinite abuse. It’s drop the debater because the 1ar and 2ar are both too short to win theory and substance.

#### 2] Fairness is a voter – it’s key to objective evaluation of who the better debater is which is the judge’s obligation. Absent fairness, it’s impossible to test which arguments are true because they weren’t subject to rigorous contestation.

#### 3] Use comparative worlds –

#### A] reciprocity – other frameworks impose an absolute proof on us – gives them functionally infinite ground through skeptical arguments and logical tautologies – comparative worlds is a 1:1 burden structure that makes debate better and reciprocal.

#### B] Advocacy skills – anything else leads to defensive offense so they never have an active advocacy – voter since we need to be advocate for solutions to messed up things in the world – comparative worlds forces defense of advocacies

### Method

#### Scenario analysis hijacks fixed notions of truth – by imagining alternative worlds and possibilities, boundaries of ‘reality’ and knowledge are continuously reshaped. This has concrete effects on our relationship to the present. Kenter 98

“The Art of the Possible The scenario method and the ‘Third Debate’ in international relations theory” By Renate Kenter 1998

“It is important to emphasise that **scenarios are *not* predictions about the future.** Rather, **scenarios help to perceive different futures in the present.** Schwartz defines ‘scenario’ as: **“a tool for ordering one’s perceptions about alternative future environments, in which one’s decisions might be played out.”** Or, in other words: “a set of organised ways for us to dream effectively about our own future.” (P. Schwartz, 1991, p. 4) **The scenario method is based on the assumption that the future is unpredictable. Therefore, it is necessary to accept uncertainty**, to understand it and make it part of reasoning. **Through the creation of a few consistent pathways into the future, which take the form of** stories **(scenarios), the complexity of uncertainty is reduced to manageable proportions and it is structurally incorporated in thinking.** (P. Wack in GBN, 1996, p. 96) Kees van der Heijden16 and Pierre Wack relate that in the beginning, scenarios were only an extension of the traditional ‘predict-andcontrol’ approach to planning used by corporations. The only difference with singleline forecasting was that scenarios provided a ‘most likely’ projection through the assessment of different futures. (K. van der Heijden, 1996, p.15) Single line forecasts work reasonably well during relatively stable periods. **What makes forecasts so dangerous is that they are constructed on the assumption that tomorrow’s world will be much the same as today’s. Consequently, forecasts fail when they are needed most, namely as major changes suddenly occur. Instead of trying to perfect forecasting techniques, which aims at getting ‘the right’ forecast, a new assumption was adopted that led to the use of scenarios. This assumption is that the future is no longer stable; it is a moving target for which no single ‘right’ projection can be deduced from past behaviour.** (P. Wack in GBN, 1996, p. 28) Therefore, **the scenario method - as it is used by corporations today - is no longer based on probability, but on qualitative causal thinking. It provides a method with which decision makers can work out their intuitive needs and enhance their understanding of current changes in society.** (K. van der Heijden, 1996, p. 15) Wack distinguishes two kinds of scenarios: first generation scenarios, also known as learning scenarios, and decision scenarios. **The purpose of learning scenarios is not action, but gaining understanding**

**and insight. They are exploratory and map out the future context. They aim at perceiving more clearly the connections between various forces and events driving the system.** But good learning scenarios are not enough: Scenarios can be successful in structuring uncertainty only when (1) they are based on a sound analysis of reality, and (2) they change the decision maker’s assumptions about how the world works and compel him to change his image of reality. (P. Wack, 1996, p. 32) The realisation that changing the ‘mental models’ of decision makers was necessary for the scenario method to be effective led to the development of decision scenarios. Mental models are based on past experiences and information which have been internalised. Wack calls this mental model or internal map the decision maker’s ‘microcosm’. Where learning scenarios just deal with the ‘outside world’, decision scenarios deal with two worlds: they explore the world of facts and they aim at the world of perceptions, existing in the microcosm of decision makers and companies. (P. Wack in GBN, 1996, p. 94) **Wack’s concern from then on was not so much predicting the future, but enhancing people’s ability to gain new insights through reperception.** I believe, that Wack’s approach towards and development of the scenario method paved the way for its usage in other fields than the military and corporate world. Not only corporate executives perceive the world through their own ‘mental models’, but so do scientists and as a matter of fact, all individuals. Especially scientists and perhaps all individuals have an interest in gaining new insights through reperception.” **<continued>** “**I believe, the scenario method qualifies as a post-positivist method**. It meets most of the above made requirements. It is a discursive method, which involves storytelling**. It moves beyond modernist ‘prediction and control’, because scenarios do not try to predict the future. If they did, the future would be presented as a certainty over which there is total control. Instead they try to structure our perceptions and interpretations of it, therewith aiming at a broader understanding of the present, but leaving it open at the same time. The future remains uncertain and one can only try to think through possibilities, without having total control. There is an element of control, though. By using scenarios you try to get prepared for and to get some grip on uncertainties. So, while the future unfolds you will be able to respond adequately. Especially focused and decision scenario’s provide ways to determine a concrete course of action.**” **<continued>** “**The scenario method is set up to structure uncertainties and make them an integral part of thinking.** Again stories provide the perfect framework to do this in. **Multiple options can be assessed, interpreted and intersected. The perceived certainties and uncertainties involved can be combined in multiple ways, which enables people to structurally explore and think them through. Scenarios leave plenty of room for imagination, personal experience etc. They also leave room for the incorporation of empirical data or results acquired with other (scientific) methods. All can be addressed in the stories. Thus, the scenario method can easily be combined with other research. Added to this is the scenario method’s adaptability to scale. You can make scenarios on your own or with a small/large group of people.** You can use them for all sorts of topics ranging from very broad to very specific. Depending on the combination of the above mentioned variables you can determine in what part(s) of a larger (research) process scenarios are useful or what kind of conclusions/actions can be drawn from them. Pierre Wack tried to do so by distinguishing learning and decision scenarios. (see p. 29)” **<continued>** “Despite the elements of Critical Theory which, as I maintained, can be found in the scenario method, I would classify scenarios as a postmodern method. The main reasons to do so is because **the scenario method is not based on a metanarrative or foundationalist theory - it does not involve a theory of truth** – and because it is a pragmatic method in which change or emancipation are not a primary goal in themselves. In scenarios ‘change’ is a given. It will always occur, no matter what we do or not do. **Ultimately, nothing is fixed. Scenarios explore and evaluate practical and/or theoretical boundaries. At a certain point in space in time constraints imposed by current ‘reality’ are accepted, but the continuous exploration/evaluation of boundaries goes on. You can imagine them changing, which might contribute to their actual change. At the same time boundaries will change anyway because of a continuous complex of developments. At a certain point in space and time it will always remain partly uncertain what changes will occur and, perhaps more importantly, how they will be perceived. From this perspective what *is* true or possible, is not what matters so much, but what is *perceived* to be true or possible.** Language and the creation of language play a vital role in the scenario method. **The creation of language is equated with learning and with the production of knowledge. Through the usage of language and the creation of new language the boundaries of ‘reality’ are continuously (re)perceived and simultaneously ‘reality’ is (re)shaped.** The above reflects a postmodern attitude.”

#### Targeted demands on the state are *critical*

King ‘16 (has been active in campaigning for refugee rights and against border controls for over a decade, has taught at the University of Nottingham and worked as a caseworker with the British Refugee Council, Natasha, No Borders: The Politics of Immigration Control and Resistance pg 39-42, dml)

But to what extent are these experiments in autonomy ever entirely autonomous? In response to Richard Day’s book on the newest social movements, Richard Thompson argues that it’s unrealistic to talk about creating wholly autonomous social structures because ‘[t]he second they’re consequential is the second they’ll be noticed [by the state]. At that point, it becomes impossible to break the cycle of antagonism by will alone. They will come after us’ (Thompson n.d., emphasis added). In other words, experiments in autonomy are rarely (if ever) entirely free from a relation to the state, or from state antagonism, and we are rarely able to ignore that antagonism. We may antagonize the state, but we are forced also to respond to the state, as a form of self-defence. This has happened time and time again, from the steady illegalization of squatting in Europe, and the tightening of laws around private property, to the infiltration by the CIA of the Black Panther movement, to the struggle between the Zapatistas and the Mexican state. We see this in the struggle for the freedom of movement when, continuing with the examples above, the EU employs Frontex special missions on the Turkish/Greek borders, or when the living spaces of people without papers are raided or destroyed. Whether people have been forced to, or they have seen it as the best strategy, the history of struggles for liberation has been one that included demands on the state. Often this has taken the form of engagement in a politics of rights and/or recognition. From the movement of the Sans Papiers in France, to ‘a Day without Migrants’ in the USA; from campaigns that fight against the detention and deportation of people without papers, to struggles against police violence, resistance through forms of visible collective action have been central to struggles against the border. In most cases such struggles have made demands on the state, particularly through seeking recognition as a group, and through making claims to rights. But to what extent are demands for rights and/or recognition part of a no borders politics? Demands for rights and recognition have played a big part in the struggle for the freedom of movement. Yet there has been a long history of criticism over the politics of citizenship. Rights claims, for example, have been seen as essentially reinforcing the role of the state as the benefactor and grantor of rights, and reinforcing the notion that rights represent entitlements applicable to those who fit certain descriptions of being a human (cf. Arendt 1973 [1951]; Barbagallo and Beuret 2008; Bojadžijev and Karakayali 2010; Elam 1994). From this perspective, demands for rights and representation amount to disputes over the allocation of equality and therefore can only ever achieve a redistribution of that equality, rather than undermining the idea that equality is somehow qualified in the first place. As Imogen Tyler says, ‘[c]itizenship is a famously exclusionary concept, and its exclusionary force is there by design. The exclusions of citizenship are immanent to its logic, and not at all accidental. Citizenship is meant to produce successful and unsuccessful subjects. Citizenship, in other words, is “designed to fail”’ (Tyler, quoted in Nyers 2015: 31). Similar variations of this critique have appeared in the autonomy of migration debate. Representation can also be thought of as a bordering technology that seeks to pacify and discipline expressions of autonomy (or attempts at escape) (Papadopoulos et al. 2008). In other words, the politics of citizenship is problematic because it only ever brings people into the state. ‘Of course migrants become stronger when they become visible by obtaining rights, but the demands of migrants and the dynamics of migration cannot be exhausted in the quest for visibility and rights’ (ibid.: 219). I have a lot of sympathy with these arguments, and because of them am extremely suspicious of a politics of citizenship. But when it comes to actual practices of struggle against the border, a resolute stand against such strategies seems naïve, and insulting to those who have taken part. Migrant-led struggles have often been claims for rights, and ultimately I don’t want to dismiss such practices because they are philosophically problematic. In fact, sometimes to appeal to rights or recognition is the only available strategy in situations of extreme vulnerability, where people’s options are highly limited. Recognizing that we are in relations of power right now means also recognizing that our situation is imperfect and that we have to struggle in our (imperfect) reality. Youssef, a long-time activist for the freedom of movement in Greece, himself of North African descent, talked about the need for pragmatism in tactics; that sometimes we must engage with the state in order to bring about greater freedoms now. ‘Today, in Creta, in Chania, they will catch five people. How can I take them from the jail? I have something in the police station, OK. I have to talk with them today. OK? But tomorrow I can fuck him. He’s not my friend. He’s not my comrade. OK. We are talking today. Tomorrow we are fucking’ (interview, Youssef). His statement reflects how many practices that refuse the border often come out of necessity. In other words they’re rarely part of some intentional or ‘noble’ act to become a rights-bearer, say, and more often pragmatic decisions based on the need to alleviate immediate situations of oppression. A no borders politics seeks to go beyond claims to representation and rights that ultimately stand to reinforce the state. But claims to representation and rights can sometimes do this too. Building on Foucault’s idea that power can be both positive and empowering or negative and dominating, Biddy Martin and Chandra Mohanty suggest that fighting oppression involves seeing power in a way that refuses totalizing visions of it and can therefore account for the possibility of resistance, as in creating something new, within existing power relations (Martin and Mohanty 2003: 104). Suggesting that representation only ever brings people into power therefore means rejecting a vast range of moments when the oppressed have voiced their refusal to be reduced to non-beings outside of politics (Sharma 2009: 475). In other words, resistance is not only or always a reaction to the constraining effects of dominating power, but can also express power as something positive and liberating. From the Black Panthers to the Sans Papiers, demands for representation, when carried out by minority groups for themselves, can challenge the role of dominant power over that group and create new, emancipated subjectivities (Goldberg 1996; Malik 1996). Depending on who it is that acts, then, in some cases demands for recognition/rights can be a radical and transformative political act (Nyers 2015. See also Butler and Spivak 2007; Isin 2008; Nyers and Rygiel 2012). As Nandita Sharma suggests, in response to Papadopoulos et al.’s book Escape Routes, we must recognise that making life and fashioning our subjectivities are intimately intertwined and making ‘new social bodies’ … is not the same as bringing people back into power through identity politics (or identity policing). It is important to recognise that there are significant qualitative differences between subjectivities. There are those that Papadopoulos et al. rightly discuss as bringing us directly back into power – and which account for most of the subjectivities that people hold today (‘race’, ‘nation’, ‘heterosexual’, ‘homosexual’, ‘native’ and so on) – but there are also those that are born of practices of escape. (Sharma 2009: 473, emphasis in original)

#### Methodological pluralism is a necessary aspect of critique.

Bleiker ’14 (Roland, professor of international relations at the University of Queensland. “International Theory between Reification and Self-Reflective Critique” International Studies Review, Volume 16, Issue 2. June 17, 2014.)

This book is part of an increasing trend of scholarly works that have embraced poststructural critique but want to ground it in more positive political foundations, while retaining a reluctance to return to the positivist tendencies that implicitly underpin much of constructivist research. The path that Daniel Levine has carved out is innovative, sophisticated, and convincing. A superb scholarly achievement. For Levine, the key challenge in international relations (IR) scholarship is what he calls “unchecked reification”: the widespread and dangerous process of forgetting “the distinction between theoretical concepts and the real-world things they mean to describe or to which they refer” (p. 15). The dangers are real, Levine stresses, because IR deals with some of the most difficult issues, from genocides to war. Upholding one subjective position without critical scrutiny can thus have far-reaching consequences. Following Theodor Adorno—who is the key theoretical influence on this book—Levine takes a post-positive position and assumes that the world cannot be known outside of our human perceptions and the values that are inevitably intertwined with them. His ultimate goal is to overcome reification, or, to be more precise, to recognize it as an inevitable aspect of thought so that its dangerous consequences can be mitigated. Levine proceeds in three stages: First he reviews several decades of IR theories to resurrect critical moments when scholars displayed an acute awareness of the dangers of reification. He refreshingly breaks down distinctions between conventional and progressive scholarship, for he detects self-reflective and critical moments in scholars that are usually associated with straightforward positivist positions (such as E.H. Carr, Hans Morgenthau, or Graham Allison). But Levine also shows how these moments of self-reflexivity never lasted long and were driven out by the compulsion to offer systematic and scientific knowledge. The second stage of Levine's inquiry outlines why IR scholars regularly closed down critique. Here, he points to a range of factors and phenomena, from peer review processes to the speed at which academics are meant to publish. And here too, he eschews conventional wisdom, showing that work conducted in the wake of the third debate, while explicitly post-positivist and critiquing the reifying tendencies of existing IR scholarship, often lacked critical self-awareness. As a result, Levine believes that many of the respective authors failed to appreciate sufficiently that “reification is a consequence of all thinking—including itself” (p. 68). The third objective of Levine's book is also the most interesting one. Here, he outlines the path toward what he calls “sustainable critique”: a form of self-reflection that can counter the dangers of reification. Critique, for him, is not just something that is directed outwards, against particular theories or theorists. It is also inward-oriented, ongoing, and sensitive to the “limitations of thought itself” (p. 12). The challenges that such a sustainable critique faces are formidable. Two stand out: First, if the natural tendency to forget the origins and values of our concepts are as strong as Levine and other Adorno-inspired theorists believe they are, then how can we actually recognize our own reifying tendencies? Are we not all inevitably and subconsciously caught in a web of meanings from which we cannot escape? Second, if one constantly questions one's own perspective, does one not fall into a relativism that loses the ability to establish the kind of stable foundations that are necessary for political action? Adorno has, of course, been critiqued as relentlessly negative, even by his second-generation Frankfurt School successors (from Jürgen Habermas to his IR interpreters, such as Andrew Linklater and Ken Booth). The response that Levine has to these two sets of legitimate criticisms are, in my view, both convincing and useful at a practical level. He starts off with depicting reification not as a flaw that is meant to be expunged, but as an a priori condition for scholarship. The challenge then is not to let it go unchecked. Methodological pluralism lies at the heart of Levine's sustainable critique. He borrows from what Adorno calls a “constellation”: an attempt to juxtapose, rather than integrate, different perspectives. It is in this spirit that Levine advocates multiple methods to understand the same event or phenomena. He writes of the need to validate “multiple and mutually incompatible ways of seeing” (p. 63, see also pp. 101–102). In this model, a scholar oscillates back and forth between different methods and paradigms, trying to understand the event in question from multiple perspectives. No single method can ever adequately represent the event or should gain the upper hand. But each should, in a way, recognize and capture details or perspectives that the others cannot (p. 102). In practical terms, this means combining a range of methods even when—or, rather, precisely when—they are deemed incompatible. They can range from poststructual deconstruction to the tools pioneered and championed by positivist social sciences. The benefit of such a methodological polyphony is not just the opportunity to bring out nuances and new perspectives. Once the false hope of a smooth synthesis has been abandoned, the very incompatibility of the respective perspectives can then be used to identify the reifying tendencies in each of them. For Levine, this is how reification may be “checked at the source” and this is how a “critically reflexive moment might thus be rendered sustainable” (p. 103). It is in this sense that Levine's approach is not really post-foundational but, rather, an attempt to “balance foundationalisms against one another” (p. 14). There are strong parallels here with arguments advanced by assemblage thinking and complexity theory—links that could have been explored in more detail.