# SO21 – AC – Data Exclusivity

## OV

#### **[1] Cx checks solves – the neg can read infinite interps which can easily be prevented by asking in cross. No abuse if I provide whatever necessary before their prep.**

#### **[2] 1AR theory paradigm –**

#### **a] grant me it else infinite abuse – neg won’t have any deterrence**

#### **b] drop the debater because the 1ar is too short to win theory and substance**

#### **c] no RVIs – the 2nr has enough time and the 2ar needs strategic flexibility**

#### **d] competing interps – 1ar interps aren’t bidirectional and Cis are best for normsetting**

#### **1ar theory first – Strat skew – short 2AR needs collapse to counter the long 2N collapse**

#### **[3] No omissions: All neg theory violations and kritik links must come from the text of the AC, not the absence of specification.**

#### **a] I have a limited time to speak so it’s an infinite aff burden**

#### **b] they can always make some sort of shell or link even if I don’t do anything which allows for infinite neg abuse.**

#### **[4] Presumption affirms –**

#### **a] you presume statements true until prove false -- if I said my name was Ayman you’d believe me till disproven**

#### **b] affirming is harder 7-4-6-3 time skew, and** Shah 2-13:

Sachin Shah, [LHP Debater, Attended TOC 2018 and TOC 2019, Broke at TOC 2019, 5 on AP Stats, Computer Science Major, Experience with side bias stats] February 13, 2020, “A Statistical Analysis of Side-Bias on the 2020 January-February Lincoln Douglas Debate Topic by Sachin Shah” <http://nsdupdate.com/2020/a-statistical-analysis-of-side-bias-on-the-2020-january-february-lincoln-douglas-debate-topic-by-sachin-shah/?fbclid=IwAR2P0AZqQtSiwMZlCpia-Fy1zFOdHn6JrGtcYgGulqeimd-V0a1xbaIMYYs> //LHP AV

It is also interesting to look at the trend over multiple topics. In the rounds **from** 142 TOC bid-distributing tournaments (September 20**17** – 20**20** YTD), **the neg**ative **won 52.75%** of ballots (p-value < 0.0001, 95% confidence interval [52.3%, 53.2%]). This suggests **the bias might be structural, and not topic specific, as this data spans nine different topics** [3]. Given a structural advantage for the negative, **the aff**irmative **may be justified** in being granted **a substantive advantage** **to compensate** for the structural skew. This could take various forms **such** **as** granting the affirmative **presumption** ground, tiny **plans**, **or** **framework choice**. Whatever form chosen should be tested to ensure the skew is not unintentionally reversed. Therefore, this analysis confirms that affirming is in fact harder again on the 2020 January-February topic. So, once again, don’t lose the flip!

#### **c] Freezes action – requiring pro-active justification for all our actions would make it impossible to make morally neutral claims like ‘I ought to drink water’ which means we always assume we can take an action absent a proactive reason not to.**

## FWK

#### **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 (Act Util). Prefer additionally.

#### [1] It’s a lexical pre-requisite. Threats to bodily security and life preclude the ability for moral actors to effectively act upon other moral theories since they are in a constant state of crisis, and if people are dead they can’t actualize any ethical theory.

#### [2] 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] Actor specificity comes first because different agents have different obligations. Takes out calc indicts because they’re empirically denied.

#### [3] Degrees of wrongness – only consequences can explain why some actions are better or worse than others – breaking a promise to take someone to lunch isn’t as bad as breaking a promise to take a dying person to the hospital but only the consequences of breaking it can explain why, so all ethical theories collapse to util & other ethical theories are irresolvable/unweighable.

#### [4] No intent-foresight distinction—if we foresee a consequence, then it becomes part of our deliberation which makes it intrinsic to our action since we intend it to happen.

#### [5] Topic lit – most articles are written through the lens of util since they’re crafted for policymakers and the general public to understand who take consequences to be important, not philosophy majors. Fairness bc you vote for better debater not better cheater. Education because that is the terminal impact of debate. These are framework warrants, not a reason to drop the debater.

#### [6] Extinction hijacks and side constrains the framework – it o/w and comes first

Pummer 15 [Theron, Junior Research Fellow in Philosophy at St. Anne's College, University of Oxford. “Moral Agreement on Saving the World” Practical Ethics, University of Oxford. May 18, 2015] AT

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But that is a huge mistake. Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; it is not the view that the latter don’t matter. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. We should also take into account moral uncertainty.What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters**, it** is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. It is enough for my claim that there is moral agreement in the relevant sense if, at least given certain empirical claims about what future lives would most likely be like, all minimally plausible moral views would converge on the conclusion that we should try to save the world. While there are some non-crazy views that place significantly greater moral weight on avoiding suffering than on promoting happiness, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless seem to be fairly implausible views. And even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve. Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast. We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period. Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.**”** (From chapter 36 of On What Matters)

## Plan

#### **Plan Text: The member nations of the World Trade Organization ought to reduce data exclusivity intellectual property protections for medicines through TRIPs – 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.

#### Data Exclusivity is uniquely bad when compared to patents, especially in developing countries, in the context of monopolies, WHO 17

“Data Exclusivity and Other ‘Trips-plus’ Measures.” *UHC Technical Brief*, WHO, 2017, apps.who.int/iris/rest/bitstreams/1140151/retrieve. // LHP AB

Yet, there are some questions as to whether **data exclusivity could prevent the registration of medicines produced under a compulsory license** (Fig. 1b). If so, data exclusivity would **effectively render the compulsory license inoperative**. Second, **if** a period of data exclusivity is also **granted when an existing medicine obtains** marketing **authorization (or registration) for a second or new indication or for a new form, as in the case of paediatric versions of already approved drugs, data exclusivity could (be used to) extend** the **period of exclusivity** of the originator product (Fig. 2). Fig. 2: Extension of data exclusivity for second indication Patent granted Registration market entry End patent term Data exclusitvity Data exclusitvity Registration 2nd indication Finally, data exclusivity **could prevent** the **registration of generic** versions of **medicines even when** there is no patenton a medicine, e.g. **when a pharmaceutical product does not meet the standards for patentability** (e.g. **because it is not new or an inventive step),** **the patent lapses, when a country has no patent law,** or **when patents are not being granted for pharmaceuticals**. The **latter** situation **can arise in least-developed countries that are World Trade Organization (WTO) Members**, which do not have to grant or enforce patents for pharmaceuticals until 2033.b

## ROTB

#### The role of the ballot should be a critical pedagogy of hope centering around formulating concrete alternatives to existing conditions.

Amsler, Sarah S. 2007 “Pedagogy against “dis-utopia”: From conscientization to the education of desire.”

In other words, **critical pedagogy is often assumed to be an inherent source of hope because it disrupts and denounces the illusion of historical fate** and liberates emergent utopian impulses through which self-determination is announced (da Veiga Coutinho 1974: 11). **But** critical educators are now asking **what relevance this understanding of pedagogy might have in a society where desires for individual transcendence and social change are or appear to be absent, devalued or denied. What are the possible consequences of conscientization in conditions where exposing complex power relations and dominant social forces emboldens fatalistic emotions rather than transforming them into hope; where, to paraphrase a well-worn theory, we see through ideologies and yet still buy into them?** Or as Henry Giroux more poignantly asks – and here what appears as hyperbole must be understood in the context of contemporary American political culture and the moral indignities of Abu Ghraib – ‘**what resources and visions does hope offer…when most attempts to interrupt the operations of an incipient fascism appear to fuel a growing cynicism rather than promote widespread individual and collective acts of resistance?’** (Giroux 2002: 38) What become of efforts to democratize knowledge when consuming publics democratically demand authoritarian teaching, or when self-realization is defined as the skilful adaptation to an existing order of things? In such circumstances, **‘critical hope’ becomes a paradoxical problematic rather than an assumed outcome of critical education**. **If the need or desire for personal transcendence or social change is not taken for granted as pre-existing or immanent, then the object of critical pedagogy must either be to create them, or to create the conditions for their emergence**. The aim of educating against the ideological forces of post-modern capitalism is therefore neither simply to recognize the social world, nor to create conditions of emancipatory communication. Instead, it is to produce the value orientations that make both of these activities meaningful in the first place. Hence, **the new movement in critical pedagogy prioritizes the ideational production of ‘critical hope’ as a motivational basis for transformative social action prior to and outside of concrete political or economic struggle, rather than beginning from it. Institutionalized critical education has become a project less in the service of particular political struggles and more an attempt to resist the closure, privatization, apathy, and psycho-emotional ‘coldness’ that is presumed to abort political struggle at its immediate roots of subjective experience.** Writing in defence of higher education as a key site of cultural resistance, **Giroux argued that critical pedagogy is no longer simply a matter of ‘raising consciousness’ about the possibilities for realistic opposition, but a question of educating people to believe that these possibilities are worthwhile in the first place** (1997: 28). This type of educational practice moves beyond cognitive rationality and towards the psychological, emotional and ethical experiences through which it is mediated. **The question here is not only what makes it possible for people to rationally formulate alternatives to existing conditions, but also what makes it possible for them to want to do so**. This reflects a turn away from the duality of ‘reason and freedom’ towards a more complex theory of social agency that includes its ‘morethan-rational’ and ‘less-than-rational’ dimensions (or in other words, the ‘pretheoretical’ and ‘extramundane’ elements) of human action, as well as the social and emotional foundations of inter-subjective ethics (Ahmed 2004; Anderson 2006; Anderson and Harrison 2006). In other words, contemporary critical educators are trying to produce through pedagogy a condition which, according to Honneth, is presumed to have been lost in the mid-twentieth century and yet which critical theory requires for its own justification: an innate, essential and indomitable need for personal and social transformation. This presents a familiar dilemma: ‘how can we imagine these new concepts even arising here and now in living beings if the entire society is against such an emergence of new needs?’ (Marcuse 1970: 76). Or, in the words of C. Wright Mills, we seem to have two choices when theorizing need and desire. On the one hand, he wrote, ‘if we take the simple democratic view that what men [sic] are interested in is all that concerns us, then we are accepting the values that have been inculcated, often accidentally and often deliberately’. On the other hand, ‘if we take the dogmatic view that what is to men’s interests, whether they are interested in it or not, is all that need concern us morally, then we run the risk of violating democratic values’ (Mills 1959: 194). In his habitually accessible way, Mills expressed the stubborn tension between socially constituted need asit-appears or is experienced, on the one hand, and universal norms of need that may be abstracted from or alien to lived experience, on the other. **It is this unhappy no-choice between the reification of immediate particular experience and the authoritarian imposition of abstract generality that critical theory must aim to transcend.**

## Offense

### Advantage – Medicine Access

#### 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**

**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).

#### **Links:**

#### **[1] In depth analysis – data exclusivity raises medicine 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.

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 **Guatemala**nmarket (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).

#### Impacts:

#### [1] They directly push 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] They 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 of obtaining 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.

### Advantage – Innovation

#### The Advantage is Innovation

#### 1] We are in an innovation crisis – new drugs are not being developed in favor of re-purposing old drugs to infinitely extend patent expiration.

Feldman 1 Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//SidK + Elmer

Drug companies **have brought great innovations** to market. Society rewards innovation with patents, or with non-patent exclusivities that can be obtained for activities such as testing drugs in children, undertaking new clinical studies, or developing orphan drugs. The rights provided by patents or non-patent exclusivities provide a defined time period of protection so companies can recoup their investments by charging monopoly prices. When patents end, lower-priced competitors should be able to jump into the market and drive down the price. **But that’s not happening**. Instead, drug companies build massive patent walls around their products, extending the protection **over and over again**. Some modern drugs have an avalanche of U.S. patents, with expiration dates **staggered across time**. For example, the rheumatoid arthritis drug Humira is **protected by more than 100 patents**. Walls like that **are insurmountable**. Rather than rewarding innovation, our patent system is now largely repurposing drugs. Between 2005 and 2015, **more than three-quarters** of the drugs associated with new patents **were not new ones** coming on the market but existing ones. In other words, we are mostly churning and recycling. Particularly troubling, new patents can be **obtained on minor tweaks** such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit.

#### **[2] Data Exclusivity reduces innovation– Diapendaele, Sterckz**

Diependaele, Lisa, Sigrid Sterckx, “Mandating Data Exclusivity for Pharmaceuticals Through International Agreements: A Fair Idea?” *Chap A,* 9 October 2018, DO - 10.1007/978-3-319-93907-0\_44

First, **empirical** evidence indicates there is a point beyond which increased patent protection no longer results in additional innovation, as measured by number **of patent applications**.67 **Hence, it is doubtful whether the possibility of a monopoly extension through data exclusivity will eventually result in additional R&D investments or patent applications**. What is more, **data exclusivity might discourage innovation by making the development and marketing of non-innovative drugs—not eligible for patent protection—more lucrative. The development of such drugs costs less, is significantly less risky, and can also be rewarded with a market monopoly for several years.** Furthermore, data exclusivity might not be the best mechanisms to compensate for the risks associated with R&D, as the **highest costs of development come at a time when the risks of failure are at the lowest and the time to the market short**.68 Second, cross-country studies show that there is only a consistently positive correlation between patent protection and innovation (as measured by R&D investments and patent applications) in developed and emerging economies.69 **In developing countries, (increasing) patent protection has not systematically resulted in increased innovation**. When compared to the global increase of patent applications, the **number of patent applications by domestic applicants** even **declined for** some **developing countries**.70 Hence, the **biggest advantages of stronger patents will not necessarily go to domestic industries but to foreign companies**.71 Even for incoming technology transfers and foreign R&D investments, MANDATING DATA EXCLUSIVITY FOR PHARMACEUTICALS… 582 often assumed to rise as a result of increased patent protection, the **beneficial effects are limited to developed and emerging economies**.72 For data exclusivity, the **available empirical evidence suggests there is no relationship at all between whether or not a country offers data exclusivity and the amount of investment in the country by the pharmaceutical industry**.73 Likewise, there is **no indication that the adoption of data exclusivity by developing countries could encourage the development of drugs for diseases that mainly affect poorer populations**, as a **market incentive can only incentivize market-driven innovation, dependent on solvent consumers**.74 In sum, for developing countries, there is little evidence that (increased) patent protection or data exclusivity will deliver on its promises. On the contrary, **various studies report that the adoption of data exclusivity delays the availability of generic drugs**.75 In light of the fact that for billions of people, **drugs are simply ‘priced out of reach,’76 the adverse consequences of implementing data exclusivity could be enormous**.77 Encouraging innovation can be a legitimate pursuit. However, the assumption that increased protection will automatically encourage innovation is questionable. Most empirical data show a more nuanced picture. Furthermore, there is no evidence of a causal relationship between market exclusivity and innovation.78 The positive correlations found by many studies can be explained by confounding factors such as educational attainment and economic freedom.79 Hence, the argument that data exclusivity is necessary to encourage innovation is insufficiently supported by empirical evidence. With regard to developing countries, this conclusion is even more pertinent. In light of the inconclusive evidence and the persisting problems regarding the lack of access to affordable drugs (which is not limited to the developing world), there seems to be **no legitimate ground to demand that countries adopt data exclusivity, let alone strengthen it.** Hence, the inclusion of binding standards on the protection of clinical test data through data exclusivity in FTAs cannot be justified with the innovation argument.

#### 3] Pharma Innovation prevents Extinction – checks new diseases.

Engelhardt 8, H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine)

Many are suspicious of, or indeed jealous of, the good fortune of others. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceutical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge. Profit in the market for the pharmaceutical and medical-device industries is to be celebrated. This is the case, in that if one is of the view (1) thatthe presence of additional resources for research and development spurs innovation in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of profit is one of the most effective ways not only to acquire resources but productively to direct human energies in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such innovation is both necessary to maintain the human species in an ever-changing and always dangerous environment in which new microbial and other threats may at any time emerge to threaten human well-being, if not survival (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the