# SO21 – AC – Data Exclusivity

## OV

#### Interpretation: Debaters at the 2021 Greenhill Invitation must cite or open source their cases on the NDCA Wiki within 30 minutes after reading them.

#### Violation – screenshots – they don’t put anything on their wiki:

Graphical user interface, text, application, Word

Description automatically generatedGraphical user interface, text, application, email

Description automatically generatedGraphical user interface, text, application, Word

Description automatically generatedGraphical user interface, text, application, Word

Description automatically generated

#### This is an expectation of debaters at the Greenhill Tournament

Greenhill Tournament Invite 2021. [https://docs.google.com/document/d/12zeUPREmBufE5N3c80zt1CYNnzZyy6ZPaCVI2KBkgL8/edit#](https://docs.google.com/document/d/12zeUPREmBufE5N3c80zt1CYNnzZyy6ZPaCVI2KBkgL8/edit)

As mentioned in the opening letter, those attending the Greenhill Fall Classic are guests of Greenhill School and its coaching staff. While we value different pedagogical perspectives, at this event, we are unwavering in our perspective on the value of openness. **We have required disclosure as a condition of competing at Greenhill** for over a decade. We know some people disagree with that expectation. We respect that area of disagreement, we **just ask that you compete elsewhere**. Openness promotes comprehension and preparation, which are critical components for effective clash, and better debates. As the host of an early season tournament, we feel particularly compelled to promote an environment that facilitates better debates for the students involved. Case lists enhance the pedagogical and competitive goals of openness by allowing students to better understand their opponents’ arguments which is an essential component to quality clash and better debates. \*If you cannot agree with the stipulation below, we respectfully ask that you explore other competitive opportunities this weekend. **Those that DO attend, yet attempt to evade/ignore our requests, will be asked to leave**. **Participation in the Greenhill Fall Classic, and its benefits like mutual preference judging, is a privilege, not a right.\*** **It is** also our belief that teams/**debaters have an affirmative obligation to update the wiki as new arguments are run throughout the tournament**. **To clarify, this is a requirement/expectation to compete**. To provide clarification about the expectation of the timeliness of disclosure; **we ask that the information be placed online as soon as possible.** Aaron Timmons, Dr. Alexandra Chase, and Demarcus Powell will be the final determiners of what “timely” posting means. If we have to ask you to comply, that means, to be clear, you are not submitting in a timely manner. If we have to ask, MPJ will likely be removed from that school. Links to a Drop box are not acceptable. **All information must be placed directly into the wiki.** *You may ask – “Why are you doing this?”* 1. We are of the belief that a culture of openness in the sharing of academic information and believe that a case list is one vehicle to maximize that objective. 2. A case list that is required of all participants helps to “democratize” the collection of information for all schools in attendance. Without an official case list, schools with plenty of resources, coaches, etc., and are in the “inner circle” acquire a disproportionate amount of information relative to others. 3. A case list that is required of all participants, and clarifies the expectations for submission, helps to avoid “freeloading” by those that access the information, yet don’t contribute the same level (or any amount) of information. *You may ask – “What are you requiring us to do?”* 1. The community norm that has developed in policy debate is that no one should have to disclose a position that they haven’t run yet. We feel this norm is applicable to Lincoln Douglas as well. We are not asking you to disclose information BEFORE you run it. Specifically, if this is your first event of the year you do not have to disclose your positions until you run them. For example, if you run a case round one, only then does it become public information. 2. **The expectation is that all debaters are required to disclose positions (affirmative and negative) and full citations (including page numbers of the evidence), and a few words from the beginning and end of the card, that are read in any debate on the National Debate Coaches Association wiki. The URL for the case list is** [**http://www.debatecoaches.org/resources/wikis**](http://www.debatecoaches.org/resources/wikis/)**. It is our expectation of judges to evaluate (and adjudicate) perceived violations of our expectations regarding disclosure.**

#### Vote on jurisdiction – the tournament invitation says that disclosure on the NDCA wiki is required to compete in the tournament. It is very explicit. It says they expect judges to adjudicate violations of their expectations regarding disclosure. It is a tournament rule to disclose on the wiki.

#### That means you should drop them on it.

#### **I adopt a comparative worlds ROTB.**

## 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.

#### [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.

## 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

## 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] Data Exclusivity does not increase innovation & has greatly risen drug prices in India – Bing 21**

Bing, Han. “TRIPS-plus Rules in International Trade Agreements and Access to Medicines Chinese Perspectives and Practices.” *Boston University Global Development Policy Center*, Apr. 2021, [www.bu.edu/gdp/files/2021/04/GEGI\_WP\_\_Bing\_FIN.pdf. //](http://www.bu.edu/gdp/files/2021/04/GEGI_WP__Bing_FIN.pdf.%20//) LHP AB

[Dr. Han Bing is a senior research fellow at the Institute of World Economics and Politics (IWEP) of Chinese Academy of Social Sciences (CASS). Han Bing’s research interests are in international investment law, international trade law and China’s business environment]

First, **data exclusivity has not played the role of “incentive innovation”. After more than a decade of practice since the introduction of data exclusivity in China**, China’s **pharmaceutical industry has not significantly improved its innovation capacity and is still challenged by the “gap between the quality of marketed products and the international advanced level**”. According to the statistics, **during 2000-2004, pharmaceutical companies outside the U**nited **S**tates**, Europe**, and **Japan marketed** 10 innovative drugs, accounting for only **six percent of the global market**. In contrast, **from 2015 to 2019, pharmaceutical companies** outside the United States, Europe, and Japan launched 41 innovative drugs, accounting for **only 16 percent of the global market**. The share of innovative drugs marketed by pharmaceutical companies outside the United States, Europe, and Japan increased by only 10 percent (see Figure 1) (European Federation of Pharmaceutical Industries and Associations 2020). Secondly, **data exclusivity is a policy factor that delays the marketing of generic drugs in China thereby affecting access to medicines**. For example, the **hepatitis C medicine Sovaldi produced by Gilead is priced about $1,000 a tablet in the US while it costs about $10 for a generic one in India** (Sun 2015). The main reason India is able to manufacture a generic version of Sovaldi is that the **Indian Patent Office refuses to grant patent rights, including patents of pro-drug and base chemical compounds, for Sovaldi** (Na and Jing 2014). After that, Gilead signed a non-exclusive license agreement with Indian generic medicine manufacturers. According to the agreement, **Indian pharmaceutical manufacturers obtain the complete technology transfer from Gilead to produce Sovaldi and fix their own prices** (Sun 2015). The patent application of Sovaldi in China has also been rejected. However, **although not granted a patent, according to the current provisions on the exclusive right of protection for undisclosed test or other data in China, it will still be protected for 6 years** after it is approved for listing. **During this period, a generic version produced by Chinese pharmaceutical enterprises is unable to be sold** on the market. Hence, China’s protection on undisclosed test or other data for a period of six years delayed the entry of generic drugs into the market, which inevitably **led to exorbitant prices and limited patient access to medicines in China**.

#### **[2] 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 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).

**[3] Guatemala + other empirics further prove – & data exclusivity especially affects developing countries through late med introduction – 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**.

#### 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."

#### [2] 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 – 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

## Pre-Empts

#### **[4] Data Exclusivity reduces innovation and all of their “studies” are incorrect – 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.