# 1AC

## 1AC – Data Exclusivity

### 1AC – Solvency

#### Plan: Member nations of the World Trade Organization ought to reduce IP protections for medicines by significantly reducing data exclusivity

* Federal Insecticide, Fungicide, and  
  Rodenticide Act (FIFRA)
* In order to obtain marketing approval for some agricultural test  
  data, originators provide the U.S. Federal  
  Government with the data and the cost to generate the  
  data (similar to the U.S. Orange Book obligations  
  to submit patent information). If  
  the originators do not provide information on the cost of the data,  
  they can face a negative  
  presumption during the arbitration determination  
  of the actual cost.
* The originator gets ten years of market exclusivity, but for the  
  5 years afterward the  
  originator is granted a limited remuneration  
  right subject to procedures for  
  non-voluntary licenses by third  
  parties.
* During the 5 year period following the initial 10 years grant of  
  exclusivity, Generic/second applications have an automatic  
  right to use the data and can register products relying on the  
  data if they pay adequate remuneration to the test data  
  originator.

Sanjuan et al 06 [Judit Rius Sanjuan, James Love and Robert Weissman, Protection of Pharmaceutical Test Data: A Policy Proposal, KEI Research Paper 2006:1] simha

We propose that countries pressured in trade negotiations or other contexts to provide TRIPS-plus protection for pharmaceutical test data use a modified version of the FIFRA approach. Under this system: \*Originators should be required to disclose their real investment costs in generating the test data and provide documentary evidence. \*The generic/second applicants should have an automatic right to use/rely upon the originators’ test data from “day one” — the first registration by the originator anywhere in the world — and no data exclusivity periods should be applicable. \*The originator of the test data would get a remuneration right during a limited period of time of 3 to 5 years. The generic/second applicants would contribute to the cost of generating this data by paying the originator an adequate and reasonable remuneration. Again, determining the adequate remuneration is the key point. Two different approaches should be considered: a) A reseasonable royalty” model, where generics could pay a percentage representing a modest share of the revenues on sales of the generic product. b) A “pro-rata share of costs” model, where generics could pay a contribution based upon their share of the global market sales for the product. This second option is similar to the one that some FIFRA arbitrators have designed for agricultural test data. A possible adjustment could be introduced for risk of investments and cost of capital 79. The adoption of an arbitration system, similar to the one used for U.S. agricultural data, should also be considered for pharmaceutical data, in order to speed decision-making an avoid bogging down compensation determinations in the courts. For the second option, it is essential that implementing legislation make it clear that a generic producer in a country would only be obligated to pay for the fraction of the total costs of the test data that is appropriate for their (likely small) fraction of the total global market for the product. For example, if the costs80 of test data for a particularly drug were $50 million, amortized over five years in equal installments, and the generic producer had sales that were .1% of the global market for the product, the pro-rata share of the costs for one year would be as follows: $50,000,0000 x 1/5 x .001 = $10,000 (a year for 5 years) If the domestic generic firm’s share of the global market is smaller, the contribution will also be smaller. Country-level determination of costs of conducting trials and generating test data might be assisted by international organizations, such as the World Intellectual Property Organization (WIPO) or the World Health Organization (WHO). These organizations could create a public database that would centralize the collection of data on the costs of the clinical trials worldwide. Such information might be collected in connection with a larger, public database that would include clinical test medical information. As compared to the data exclusivity approach, the proposed cost-sharing model has several advantages: \*During the period of protection, the test data originators can benefit from reasonable contributions to the costs of the test data — without conferral of monopoly rents that overcompensate for the costs of generating data. \*Countries adopting this approach can resist demands to provide exclusive rights, because they are offering remuneration to drug developers based on their actual investment costs — and thereby directly addressing the “free riding” criticism of the nondisclosure approach. \*National regulators can avoid the creation of monopolistic situations, and foster competition within the pharmaceutical industry. \*Generic competitors who share costs can enter the market without delay because there is no exclusive marketing period. \*Developing country generic companies’ contributions will be affordable, because of their small share in worldwide sales. \*Generic competitors can enter the market during the period of data protection without unethically duplicating clinical trials by eliminating the need to duplicate clinical trials.

#### Data exclusivity only provides extra protection that can’t scale up – plan massively increases generics and fosters competition

* AI means plan utilizes emerging tech effectively and leads to massive increases in medicine
* Barriers extra and impede competition

Raghavan and Kimball 20 [Srividhya Ragavan, Professor of Law and Director of India Programs, Texas A&M University School of Law., Jonathan Kimball, Vice President of Trade and International Affairs, Association for Accessible Medicines (AAM), 7-8-2020, "TradeRx Report Is it Time to Do Away with Data Exclusivity?," TradeRx Report, https://www.traderxreport.com/data-exclusivities/is-it-time-to-do-away-with-data-exclusivity/] simha

If there is a lesson from COVID-19, it is the need to look at the nature of our health care systems with a keen eye towards dismantling the barriers to accessing health care. While there are several barriers to access health care, this blog particularly focuses on the impact of regulatory exclusivities on access to pharmaceuticals.

It is estimated that it takes at least six to seven years to go from initial discovery of a molecule to the marketplace, wherein drugs undergo extensive clinical trials. Exclusivity was introduced to compensate for the high cost of clinical trials and the fact that the end result of those trials is the data that demonstrates the relative safety and efficacy of a drug. During this monopoly period, when generic or biosimilar drug manufactures are unable to launch follow-on products clinical trial data is protected from competition, allowing an additional opportunity, on top of the patent term, during which time companies could recover the cost of the innovation. But, if the benefits of the end of that exclusivity period are to be realized as quickly as possible, it is critical for follow-on producers to use this data in order to enter the market as soon as the period of patent exclusivity ends. Obstacles to access this data have become a barrier that deserves to be reconsidered closely. For small-molecule drugs especially, the proprietary data developed by the original medicine producer is important for follow-on producers to file generic applications. Idhifa is an example of a small molecule drug used for the treatment of acute myeloid leukemia. It is currently priced at $28,000 for a month’s supply of the medication. The drug was approved in 2017 by the FDA for marketing and its patent is set to expire in 2034. Although the data exclusivity period for this drug will expire before the end of the patent term, the patent exclusivity monopoly in and of itself provides adequate incentive such that the data on the efficacy of the drug need not require an additional layer(s) of protection. Considering that small molecule drugs (like all inventions) already benefit from a 20-year period of patent monopoly, the question of whether we need clinical trial data to be protected separately and to achieve what goals remains critical. In a paper published in the University of Pacific L.J., we assert, specifically with reference to biologics, that technological innovations undermine the justifications for data exclusivity. Although our paper’s focus was on biologics, the same arguments fully apply to small molecules as well. First, technological advancement reduces the cost and the time for drug discovery per se, whether small molecule or biologics. New and emerging technologies (e.g., artificial intelligence, the use of biomarkers in drug discovery and clinical trials, mobile technology, etc.) are being deployed every day to enhance efficiencies and reduce the time taken to bring a drug to the market. As new technologies are adopted and advances in scientific understanding are leveraged, it results in shorter drug development timelines. BenchSci, the blog, highlights how about 230 plus start-ups exclusively use AI to discover relationships between diseases, targets, and drugs; to curate imaging, to create databases; to create genomic datasets and more using AI. The use of AI and related technologies as well as big data has shortened the period of clinical trials and has simultaneously strengthened it. Second, the COVID-19 pandemic has highlighted the need for not only innovating medications, but also the importance of making those innovations widely accessible. All diseases can result in loss of productivity – relatively simpler ones such as diabetes or, more aggressive ones, such as forms of cancer can all affect productivity of not only patients but also caregivers and others who are immediately impacted by it. COVID-19 highlights the important role that a healthy population plays in facilitating world trade. Given that technology has minimized the trial to table time for drugs, it is important to eliminate those barriers that are no longer necessary to incentivize innovation, but instead prevail as mechanisms that delay the use of the clinical trial test data, thus impeding competition, and forestalling lower prices that result in increased access. Reconsidering the importance of regulatory exclusivities is important at this time. A reduction in the period may contribute to the lower cost of medication, resulting from increased competition as soon as a patent monopoly expires. While technology has enabled a shorter time for innovators to get to the market by completing clinical trials faster, limiting regulatory exclusivities may allow generics to enter the market more quickly by having access to clinical trial data, and thus, leading to faster access of the medication to the public.

#### Generics are key to access and innovation

Raghavan 17 [Srividhya Ragavan, Professor of Law and Director of India Programs, Texas A&M University School of Law, “The Significance of the Data Exclusivity and Its Impact on Generic Drugs”, 1 J. Intell. Prop. Stud. 131 (2017), https://scholarship.law.tamu.edu/facscholar/816] simha

Q9. While it might be true that data exclusivity negatively impacts generic drugs, are generics really a long-term solution to the global healthcare crisis and the problem of access to medicines?

There are three reasons why generics have become a part of the global pharmaceutical industry. First, generics are a necessary part of the food-chain of global pharmaceuticals. They are required to not just cater to the health needs of the poorer countries but also to kick-start innovation in these nations.

Second, historically, copying has been the first step for innovation even in the developed world. Thus for innovation in pharmaceuticals to proliferate all over the world, generics will serve as the first step to kick-start the industry. Especially for least-developed countries, the leap to innovation in pharmaceuticals in the future will occur only when they take the first step of being able to establish generic drug manufacturing facilities locally.

Third, even in developed nations that are obsessed with patents, like the United States, the astronomical cost of medication has resulted in an increased appreciation for the role of generics. Thus generics are viewed as important components to enable market competition as well as to challenge bad patents. In all, the generic drug industry represents an important industry catering to the healthcare needs of a large segment of the global population.

### 1AC – Data Monopolies

#### The advantage is Data Monopolies

#### The US and EU norm data exclusivity in FTAs to cement pharma monopolies - stifles innovation and harms access to generics for developing countries

* FTAs = Free Trade agreements

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* followers can’t obtain market approval w/o originator data
* companies know that drugs work so its less risky

The Enactment Of Data Exclusivity While the US and the EU have had a comprehensive legal framework for data exclusivity for three decades, international standards are more recent and more controversial. TRIPS is an important milestone, but it does not mandate data exclusivity. More recent US and EU FTAs, however, have introduced stringent data exclusivity obligations for several developing countries. Data exclusivity in the US The concept of data exclusivity originated in the US. In 1984, the Drug Competition and Patent Term Restoration Act (Hatch-Waxman) introduced the ‘Abbreviated New Drug Application’ (ANDA) for generic drugs, allowing regulatory approval to be based on evidence that a generic drug is bioequivalent to the original. To compensate, the Act introduced a period of five years of data exclusivity.4 Consequently, for five years, a follower cannot obtain marketing approval by relying on the originator's data. A generic competitor needs to submit independently generated clinical data or delay its application. Besides five years of data exclusivity for all new chemical entities, additional protection was granted for specific categories of drugs and clinical data. Where a new drug is recognized as an ‘orphan drug’ – for the treatment of rare conditions – a period of seven years of data exclusivity applies. For data that support changes to products already on the market (such as new indications, new dosages and new delivery methods), ‘clinical investigation exclusivity’ limits market authorizations for three years. The submission of data to support the pediatric use of an existing drug lengthens the period of data exclusivity by six months. Data exclusivity in the EU Following the US, the EU adopted a regulation in 1987, mandating a period of data exclusivity of at least six years. In 2004, the EU extended this to ten years. This delay can be extended for another year ‘if, during the first eight years of those ten years, the [originator] obtains an authorization for one or more new therapeutic indications which … bring a significant clinical benefit in comparison with existing therapies.’5 As in the US, the EU has introduced a separate regime of ten years of data exclusivity for orphan drugs. The TRIPS Agreement: the protection of undisclosed data against unfair commercial use It is argued that TRIPS set the first international standard regarding data exclusivity. However, TRIPS does not impose such an obligation – Art. 39(3) merely requires the protection of undisclosed data against ‘unfair commercial use’: Members, when requiring … the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. TRIPS does not define ‘unfair commercial use’. It is hard to see how the ‘reliance’ of a regulatory authority on the originator's data could constitute a ‘commercial use’. At one extreme, a follower may submit the originator's data – at the other it may just ask the regulator to rely on that data. In the latter case, the regulator may refer to the originator's data or it may rely on the fact that sufficient data has been presented to it or to another country's regulator. It is only in the first case that it can clearly be said that there is ‘commercial use’ of the data.6 Moreover, the Paris Convention – to which the first paragraph of Art. 39 TRIPS refers – defines ‘unfair competition’ as acts ‘contrary to honest practices in industrial or commercial matters’ such as false allegations and misleading.7 The granting of exclusive rights is not mentioned at all. Data exclusivity in bilateral agreements with the US and the EU While the US and the pharmaceutical industry continue to argue that TRIPS does require the adoption of data exclusivity,8 they have also sought more specific and stringent standards in bilateral and regional agreements. Since TRIPS, both the US and the EU have consistently urged their trade partners to undertake increased protection of all intellectual property rights in bilateral and regional FTAs.9 Especially regarding regulatory protection – including data exclusivity and patent linkage10 – these TRIPS-Plus agreements have significantly raised the standards. In 1994, the North American Free Trade Agreement (NAFTA) between the US, Canada and Mexico, was the first supranational agreement to include a specific obligation to adopt data exclusivity. In addition to an obligation to protect clinical test data against disclosure and unfair commercial use, Art. 1711(6) NAFTA specifies that, without permission, no one may rely on these data in support of an application for marketing approval for ‘a reasonable period of time, normally not less than five years.’11 In contrast, more recent agreements employ a stricter wording. The US-Chile FTA (2004) was the first to require ‘a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product’ (Art. 17(10)). This wording has been standard ever since. Several other US FTAs have raised the bar for data exclusivity further by expanding the scope of the obligations. Whereas some early agreements limited data exclusivity to ‘new chemical entities’ and for clinical data that involved ‘considerable effort’, Art. 16(8) of the US-Singapore FTA (2004) requires data exclusivity for all regulatory approvals. Moreover, since 2005, many US bilateral agreements introduced a separate regime of data exclusivity for new clinical information, bringing standards even closer to US regulations.12 Some FTAs also require data exclusivity even when the regulatory authority does not require the submission of data, but instead relies on regulatory approval in another country. For example, Art. 15(10) of the Dominican Republic-Central America Free Trade Agreement (2004; DR-CAFTA) forbids the marketing of pharmaceutical and agricultural chemical products ‘on the basis of (1) evidence of prior marketing approval in the other territory, or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory, for at least five years for pharmaceutical products and ten years for agricultural chemical products…’. As a consequence, if a drug is not marketed in a country by the originator, a follower cannot enter the market either, unless it independently generates the data. Moreover, most agreements specify that the term of data exclusivity is to be counted from the date of the initial approval in the approving country, which can be significantly later than the initial approval in the US.13 Since the revision of its initial FTA with Peru in 2007, waiving the obligation to grant data exclusivity when approval is based on prior approval in another country,14 more recent US agreements with Panama (2011; Art. 15(10)) and Colombia (2011; Art. 16(10)) also contain slightly ‘softened’ standards: the application of data exclusivity is limited to the approval of ‘new chemical entities’, for clinical data that involved ‘considerable effort’ and for a ‘reasonable period’, normally five years. The EU has also tabled proposals regarding data exclusivity as a TRIPS-Plus requirement during its trade negotiations, although less frequently than the US.15 In 2012, the EU concluded the EU-Peru-Colombia FTA, of which Art. 231(4)(a) requires five years of data exclusivity for pharmaceuticals and ten years for chemical agricultural products.16 Importantly, this FTA foresees the possibility to regulate ‘exceptions for reasons of public interest, situations of national emergency or extreme emergency’, indicating the possibility of granting market access for generic drugs to address health emergencies. The EU-South Korea FTA (2010; Art. 10(36)) also specifies a period of five years of data exclusivity, and the EU-Canada agreement forbids the marketing approval of generics relying on originator's data for eight years. (Chapter 22, Art. 10). While the total number of countries currently bound to enact data exclusivity regulations might seem limited, the impact of these TRIPS-Plus requirements should not be underestimated. The incorporation of data exclusivity provisions in FTAs has become the new standard. For example, the recently concluded Trans Pacific Partnership (TPP) provides for an elaborate data exclusivity regime. In addition to five years of data exclusivity for new chemical entities and three years for new clinical information, the TPP is the first treaty providing a specific data exclusivity regime for biologics, mandating eight years of data exclusivity, or five years combined with additional measures.17 If the TPP is ratified, a total of 12 countries, representing 40% of the global GDP, will be required to incorporate these measures.18 The Role of the Business Communities in Securing Data Exclusivity It is clear from the documents regarding the negotiation of TRIPS that the development of international intellectual property law has been significantly influenced by business communities. Both before and during the TRIPS negotiations, the United States Trade Representative (USTR), directly influenced by business interest groups, vigorously pursued the inclusion of substantial minimum standards for the protection and enforcement of intellectual property rights in the GATT, the precursor to the WTO.19 Especially in the first years of the Uruguay Round negotiations, significant efforts had to be made by the negotiating countries’ trade administrations to gather the necessary information and expertise, offering business lobby groups the opportunity to fill some of the space.20 Regarding data exclusivity, similar dynamics have occurred. Both in the US and the EU, business interest groups actively lobbied to secure data exclusivity. Although clinical data could be protected as trade secrets in the EU and followers could not enter the market without regulatory approval, member states’ regulatory authorities were more permissive about the reliance on originator's data to grant regulatory approval to generics. After data exclusivity was introduced in the US in 1984, the European pharmaceutical industry actively lobbied to obtain similar protection in the EU. They managed to persuade the European authorities that this would boost pharmaceutical research and innovation in Europe. They claimed that data protection in the US gave American counterparts a competitive advantage and that, in order to gain competitive edge, the EU should adopt longer data exclusivity periods than the US.21 The European Federation of Pharmaceutical Industries and Associations (EFPIA) requested a harmonized period of data exclusivity in the EU of ten years. Throughout the preparation of the ‘pharmaceutical review’ – a broad package of legislative proposals aimed at harmonizing the regulatory framework for pharmaceutical development – EFPIA managed to position itself as an indispensable expert to both the European Commission and the European Parliament.22 Multinational pharmaceutical companies continue to play a similar instrumental role in the propagation of global intellectual property rights.23 Regarding data exclusivity, initial efforts focused on ‘compliance’ with Art. 39 TRIPS. For example, in 2000, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) issued a report, describing clinical data as ‘proprietary registration data’ and data exclusivity as an ‘independent intellectual property right’ that had to be protected in order to be TRIPS-compliant.24 Although this is highly questionable,25 the USTR adopted the same approach: the TRIPS Agreement recognizes that the original applicant should be entitled to a period of exclusivity during which second-comers may not rely on the data that the innovative company has created to obtain approval for their copies of the product. During this period of exclusive use, the data cannot be relied upon by regulatory officials to approve similar products.26 Ever since, business interest groups and pharmaceutical companies have continuously urged the USTR to demand third countries to provide data exclusivity.27 Pharmaceutical Research and Manufacturers of America (PhRMA) – a key industry group – even suggests that the US should take ‘aggressive action’ – trade sanctions and international dispute settlement procedures – to remedy these alleged intellectual property violations.28 The USTR is at risk of ‘regulatory capture’, of being dominated ‘by private interest groups that the agency is responsible for regulating.’29 Therefore, it is critical to examine how private interest representation is organized. The USTR – advised by the Industry Trade Policy Advisory Committee on Intellectual Property Rights (ITAC 15), consisting of representatives of key industries30 – is exempt from federal regulatory mechanisms to ensure a balanced representation of interests and public access to information, leaving a giant loophole. In practice, ITAC 15 does not consult other industries, public interest groups or academic experts.31 Moreover, the USTR is not even required to make its communications with industry advisers public.32 An important tool in the formulation and implementation of US external trade policies are the ‘Special 301 Reports’. The USTR lists countries on ‘watch lists’ if they fail to adequately protect US commercial interests. In the last decade, ‘sufficient protection’ of clinical test data has become an important parameter in this context. For example, the 2015 report highlights ‘serious obstacles’ to the effective protection of pharmaceutical test data as important issues for 18 countries, all developing countries and emerging economies.33 Even though many NGO's and non-profit organizations such as Oxfam, Public Citizen and Knowledge Economy International have urged the USTR to reconsider its position on data exclusivity,34 their impact seems limited. The policy formulation process – which closely involves industry representatives but remains shielded from public scrutiny – as well as the policy outcomes – which clearly favour the industry's requests – suggest that the USTR is successfully influenced by the pharmaceutical industry. The Arguments Invoked for Data Exclusivity The arguments, invoked to legitimize the industry's pursuit of increased protection, can roughly be divided into three. First, data exclusivity is said to be an essential policy tool to promote innovation. According to the second argument, data exclusivity is a legitimate measure to protect property rights in clinical trial data. The third argument is one of ‘justice’ – that followers should not be free to use information generated by originators since ‘free-riding’ is unfair and thus wrong. The first, consequentialist, line of argument is that data exclusivity is necessary to allow pharmaceutical companies to recoup the costs of conducting clinical trials. Clinical trials require significant investment, and because there might be little or no patent protection left at the time of marketing, some additional years of data exclusivity are said to be essential financial incentives. Thus, according to the proponents, data exclusivity ‘helps to ensure a limited period during which an adequate return on … investment can be made.’35 Furthermore, it is claimed that incentivizing clinical trials will encourage the development and marketing of non-innovative drugs.36 If a country provides this incentive, R&D investments and innovation are promised to increase. Especially in a global pharmaceutical market, according to IFPMA, it would be unwise for countries not to adopt data exclusivity as: countries which offer data exclusivity are encouraging businesses to move their product, investment and potential manufacturing to their markets earlier. If other companies could immediately use these data to obtain their own marketing authorization … there would be less incentive for the innovator to invest ….37 PhRMA also seeks to legitimize its demand for the global recognition of data exclusivity by pointing out that not all countries grant patent protection for new biological drugs, which are more difficult and costly to produce than traditional pharmaceuticals. ‘In these countries, data protection may provide one of the few incentives for regionally specific innovation and may provide an important incentive to launch new innovative products in the country.’38 For example, BIO – the Biotechnology Industry Organization – advocated the adoption of a twelve year data exclusivity period for biologicals in the Trans-Pacific Partnership (TPP).39 The second line of argument is that data exclusivity is a legitimate measure to protect the property rights of the pharmaceutical industry over the clinical trial data they generate. Essentially, because the pharmaceutical industry financed and generated the clinical data, they own the data: ‘The results obtained are as much the property of the company that produced them as is the plant used to manufacture the product.’40 Indeed, pharmaceutical industry associations frequently employ terms such as ‘proprietary test data’.41 Third, data exclusivity is often described by the pharmaceutical industry as a necessary means, in addition to patent protection, to prevent the generic industry from ‘free-riding’.42 Since the originator needs to make a significant financial investment to generate the clinical data, direct or indirect reliance on the original clinical data by others is seen as an unjust competitive advantage, ‘unjust enrichment’ or ‘unfair commercial use’, even in the absence of fraud or dishonesty.43 Finally, another (mostly unmentioned) reason for the pharmaceutical industry to strive for the adoption of data exclusivity is the increased tendency towards clinical trial data transparency. After extensive lobbying by public interest groups, the new EU clinical trials legislation, which will enter into force by May 2016, will require the registration of all clinical trials in an EU database, making clinical trial results publicly available.44 A similar trend can be witnessed in the US.45 From the perspective of the pharmaceutical industry, this is an increasingly worrying trend for, if the results of clinical trials become publicly available, clinical trial data are no longer ‘undisclosed data’, and, absent data exclusivity, can thus be used by followers in support of their applications for marketing approval. Clearly, the continuous push by the pharmaceutical industry for stringent data exclusivity standards seeks to neutralise the effects of this trend of increasing transparency regarding clinical trial data. Assessing the Arguments In order to assess the legitimacy of the pharmaceutical industry's quest for increased protection of clinical data, we will take a closer look at the arguments mentioned in the previous Section. Considering the enduring lack of availability and affordability of essential medicines, we will pay particular attention to the potential impact of data exclusivity in developing countries. The innovation argument The cost of drug development The argument that data exclusivity is necessary to incentivize innovation is based on particular claims regarding the cost of pharmaceutical research and development. However, the actual costs of drug development are highly debated. Estimates vary significantly, but most figures cannot be independently verified because the industry systematically refuses to disclose the underlying data for independent review.46 Industry associations usually refer to the Tufts Center for the Study of Drug Development (CSDD) – an institute established as a result of a conference held at the Chicago School of Economics with funding from the pharmaceutical industry.47 The CSDD's most recent estimates report drug development costs of up to 2.6 billion USD.48 Obviously, it is in industry's interests to portray R&D costs as being as high as possible, and thus only to report aggregate data which include failures and the cost of capital, and without crediting government subsidies. Consequently, according to some commentators, the actual costs of drug development may be as low as a quarter of the reported costs.49 Nevertheless, it is clear that drug R&D requires significant investment, and thus that originators need an opportunity to at least recoup their expenses. However, is data exclusivity necessary to achieve this? The industry claims that costs have increased significantly, particularly due to the costs of clinical development. However, the costs looks meagre compared to total revenues: PhRMA itself reports an increase of 34.2 billion USD in costs between 1995 and 2010 but a six-fold increase in revenues of 200.4 billion USD for the same period.50 Furthermore, a look at the top 100 US drug sales for 2013 shows that 55 ‘blockbusters’ each generated over 1 billion USD.51 Even if a drug would only have a couple of years of effective patent protection, this should suffice to cover the costs. Overall, the pharmaceutical industry remains hugely profitable. For 2013, the top 20 pharmaceutical companies each reported profit margins of 22.3-59.7%, and incomes of 2.5-15.9 billion USD.52 Clearly, these figures question the necessity of providing data exclusivity to enable recoupment of drug development costs. At the very least, requiring developing countries to implement data exclusivity is totally unnecessary. Data exclusivity and pharmaceutical innovation Data exclusivity can increase the profits of the pharmaceutical industry. Industry claims that, by offering this financial incentive, data exclusivity also increases innovation. Unfortunately, hardly any empirical research is available. However, because data exclusivity de facto confers or lengthens market exclusivity, it must have similar effects to those of patents, hence findings regarding the effects of patent protection on innovation can reveal important trends. Intense debate exists among economists, policy experts and industry, as to whether or not (strengthening) the patent system stimulates innovation. Much research is based on theoretical economic models, assuming that investments in R&D will automatically increase when the expected financial incentives adequately compensate the risks and costs of R&D.53 However, this ‘Schumpeterian model’ of innovation has its flaws. Indeed, there seems to be a point beyond which increased protection will no longer benefit innovation.54 Moreover, strong patent protection can hinder innovation, for example by delaying sequential innovations.55 Data exclusivity might not prevent, but instead discourage innovation, by incentivizing low-risk investment. Especially for non-innovative drugs, data exclusivity offers industry a lucrative opportunity since the development of such drugs costs significantly less and, despite the lack of patent protection, a market monopoly for several years can be obtained through data exclusivity. The assumption that increased protection will automatically encourage innovation is thus questionable. Most empirical data show a much more nuanced picture. Key to a correct interpretation is what exactly is measured, and in which countries. Cross-country data indicate that the positive correlation of patents with innovation – measured by R&D investments and patent applications – is only consistently positive in developed and higher-income emerging economies. For developing countries, empirical results do not systematically indicate a positive correlation.56 Moreover, when compared to the global increase of patent applications, applications by domestic applicants have declined.57 Clearly, the argument that adopting data exclusivity could generate an advantage for domestic industry is false. Foreign companies equally enjoy the benefits of data exclusivity.58 It is often assumed that a rise in patent applications by foreign firms in a country that increases patent protection will lead to an increased transfer of technology and innovation. Yet the positive effects of patent protection on technology transfer also seem limited to large- to middle-income countries.59 Equally, the effects of increased patent protection on R&D investments by foreign firms mostly occur in developed and emerging economies.60 In developing countries, positive effects are scarce.61 In Jordan, for example, the implementation of ‘TRIPS Plus’ levels of patent protection and adoption of a data exclusivity regime following the conclusion of an FTA with the US, did not result in any additional foreign investment in pharmaceutical manufacturing or R&D, nor did it encourage domestic innovation.62 In sum, there is little evidence that increasing protection has had a positive impact on economic development and innovation in countries in the developing world, which remain net importers of technology.63 In addition to this problem, there is no systematic evidence of a causal relationship between increased patent protection and innovation.64 Although many studies find a positive correlation between strong patent protection and innovation, this can mostly be explained by other factors such as educational attainment and economic freedom.65 As most studies recognize, the positive effects of intellectual property rights mainly depend on a country's innovative ability.66 The argument that adopting data exclusivity would support the development of drugs for the diseases that mainly affect poorer populations in developing countries, is also feeble. The current business model relies on wealthy markets and public and private insurers paying the bills. In the absence of solvent ‘consumers’, market exclusivity may not provide a sufficient incentive for R&D investment.67 Interestingly, empirical data also indicate that the acceptance of stronger patent protection by its foreign trade partners does not have a significant impact on innovation in the US: It probably implies that the patent-protected US market is sufficiently large for innovators to recoup the costs of R&D investments and further strengthening IPR protection by individual foreign countries merely adds pure rent to the proceeds that US innovators earn.68 While innovation can be a legitimate goal, market exclusivity may not be the best way to encourage it, especially in developing countries. In the best case, data exclusivity can encourage some innovation and benefit some actors, but not necessarily the ‘innovation’ that patients need. Data exclusivity does not compensate the financial ‘risk’ of R&D, as the highest costs come at a time when the risks of failure are lowest and the time to market short.69 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 many developing countries, there is no market for high-priced pharmaceuticals. In the absence of other factors encouraging innovation, data exclusivity does not encourage innovation. Data exclusivity and (affordable) access to medicines in developing countries 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 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 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 In each case, the available originator drugs were priced substantially higher.73 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 Because most developing countries rely strongly on generics, the consequences of implementing data exclusivity could be enormous.75 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. In sum, data exclusivity poses an additional hurdle to affordable access to medicines in developing countries. In the absence of evidence that data exclusivity supports innovation and countries’ economic development, there seems to be no legitimate ground for developing countries to adopt it, let alone strengthen it. The property rights argument An entirely different argument invoked by the pharmaceutical industry is that data exclusivity is a legitimate measure to protect their property rights over the clinical trial data they generate. This gives rise to the question as to whether anyone can legitimately claim a property right to data. Data exclusivity limits reliance on the knowledge that clinical data brings us – that a drug is safe and effective and can be allowed on the market. As mentioned earlier, knowledge is traditionally considered to be incapable of being property, in contrast to the forms in which knowledge can be presented. It is the very nature of knowledge to be a public good. When clinical data prove that a drug is safe and effective, everyone knows that equivalent drugs will be safe and effective as well. Assuming for a moment that industry's investment in clinical trials would legitimate a property claim, why should this necessitate an unalienable exclusive user right? Having a property right does not imply an exclusive user right, especially when the interests of society as a whole are at stake. Indeed, most patent laws allow exceptions to the exclusive rights of patent holders. For example, the TRIPS Agreement maintained the possibility of issuing compulsory licences76 to address public health emergencies. In contrast, most data exclusivity regimes do not allow any public interest exceptions. Data exclusivity could even undermine the flexibilities allowed by TRIPS, by preventing compulsory licensed generics from obtaining marketing approval. The free-riding argument The third argument invoked by industry portrays the reliance of generic followers on originators’ clinical data as ‘free-riding’, giving the generic industry an ‘unjust’ competitive advantage. However, this argument from ‘justice’ faces severe problems and does not imply an absolute right to exclude others, as mandated by data exclusivity. Generally speaking, our lives as socialised humans are founded on free-riding. In all aspects of life – economic, cultural, and scientific – people rely on earlier efforts made by others. One cannot dispute that the reliance of the generic competitor on the originator's efforts to produce clinical data constitutes an advantage. However, that does not mean the advantage is ‘unfair’ or ‘unjust’. For innovative drugs, the patent system already makes an exception to free competition to account for the originator's investment. Adding a further temporary monopoly under the guise of data exclusivity does nothing to stop free-riding; it is merely delayed. Moreover, even without data exclusivity, the originator's investment in clinical data is not without benefit; it provides a ticket to being the first mover on the market, entitled to make a profit until others arrive on that market. Furthermore, whereas patents are often challenged and revoked, data exclusivity cannot be challenged. Considering that market exclusivity can bring about significant societal costs and impacts, this is unfair. Even if a generic competitor would successfully challenge a patent on a drug currently on the market, this drug could maintain its market exclusivity relying on data exclusivity. The pharmaceutical industry, on the other hand, can take full advantage of the possibility to use litigation. Even if proceedings are unsuccessful, they can delay the access of generics to the market. Consultations organized by the European Commission indicate that, between 2000 and 2007, over 700 lawsuits for patent and data exclusivity infringements were initiated by the pharmaceutical industry, but only 2% of the claims were recognized.1 Additionally, demanding that the generic industry duplicates clinical trials in order to avoid ‘free-riding’ is unethical, not least because Phase I clinical trials require testing of drugs (which almost inevitably have some undesirable side-effects) on healthy ‘volunteers’ and Phase II trials require dosage optimisation on patients for whom knowingly incorrect dosages may be detrimental, if not fatal. Finally, even if the reliance of the generic competitor on the originator's efforts to produce clinical data would be an ‘unfair’ advantage – this does not legitimize granting exclusive rights, as is the case with data exclusivity. Fair competition could also be established by asking generic competitors to pay a contribution for their ‘use’ of the clinical data. Given the adverse consequences of excluding generic competition, this would undoubtedly be a more legitimate option. However, the mere fact that an argument from justice would not entirely preclude any system of compensation, does not mean that compensations should be paid. Concluding Remarks 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.

#### Incentive theory doesn’t apply - data exclusivity diverts investment

Shaikh 16 [Shaikh O.H., Ludwig-Maximilians-Universität München Doctor of Philosophy – PhD. Max Planck Institute for Competition and Innovation, Munich, Germany, (2016) Intellectual Property Law, Educational Consulting, Legal Consulting, Business Consulting, Copyright Law, Consumer Law, IT Law, Trademark Law, Business Law, and Startup Law, Test Data Exclusivity: Raison d’être. In: Access to Medicine Versus Test Data Exclusivity. Munich Studies on Innovation and Competition, vol 4. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-662-49655-8\_2] simha

\*figures omitted

- “Standard IMDs” and “Other drugs” are the least innovative

2.1.1 Test Data as Public Good: Is the Incentive Theory Applicable?

Test data is essentially information or knowledge, or both, about the safety and efficacy of the product and thus qualifies as a public good. Therefore, in theory, it will be under-produced without appropriate incentives. But is it right to assume that test data would not be produced if not specifically incentivized? Moreover, is it necessary to confer an exclusive right as an incentive to produce such data? Though the assumption about the undersupply of public goods as provided by the private sector may generally hold true, economists acknowledge certain cases where such goods are successfully provided by the private sector.11 One way to achieve that is to bundle the public good, in this case, the test data, with an exclusive good, the pharmaceutical product.12 In fact in the present case, test data is a public good that is, at best, an intermediate product, necessary for the production of the end product, the pharmaceuticals. This is by virtue of the legal requirement to provide proof for safety and efficacy of the pharmaceutical product. The production of this end product is already incentivized through another exclusionary right, the right conferred by the patent law13 (as well as patent term extensions and compensation for regulatory delays in certain jurisdictions).14 Hence, generation of test data should be considered an input cost that has to be incorporated when making the decision to invest in pharmaceutical R&D with the aim of creating a new pharmaceutical product for which incentives are already provided through patent law.15 Even in the absence of patent incentives, there is hardly a justification for test data exclusivity. Alternate incentives such as rewards, prizes, public-private partnerships in R&D, purchase commitments for the final output of the pharmaceutical R&D, tax benefits etc are more direct and targeted as compared to test data exclusivity.16

2.1.2 Test Data Exclusivity: An Incentive for New Pharmaceutical Products?

In the light of the discussion so far, one may consider this question redundant. Nonetheless, an answer to this question is worthwhile to analyze whether test data exclusivity has any separate impact, from patent protection, for spurring R&D for new pharmaceutical products. As mentioned above, where a pharmaceutical product does not merit patent protection test data exclusivity may be considered useful for dynamic competition by some.17 Society may have an interest in incentivizing certain sub-patentable pharmaceutical products that may have some economic or social benefit. However, test data exclusivity protection fails to provide the right incentives for such inventions. Test data exclusivity is available as a result of generation of test data. Novelty18 or societal benefits, in terms of therapeutic advancement,19 of the pharmaceutical product are not relevant considerations.20 Test data exclusivity is available for all pharmaceutical products as long as requisite safety and efficacy data is generated. There is no mechanism to filter out those products that the society does not need or that may be produced even under the normal competitive conditions.21 As is true for patents, the case against test data exclusivity is further bolstered by its negative impact on availability of affordable generics and resultant competition, in the absence of patent protection. Test data exclusivity’s role in the second case also runs counter to the societal decision for a minimum term of patent protection (including patent term extensions and compensation for regulatory delays) as substantial incentive for stimulating desirable pharmaceutical R&D.22 From the perspective of the incentive theory, extending such protection would not promote dynamic competition any more, and would affect static competition negatively.

2.2 Trends in Pharmaceutical Innovation

The historical patterns of innovation in the pharmaceutical industry also support the apprehension that test data exclusivity (as well as follow-on patents) may have a diversionary effect on R&D investment away from research on new and substantially improved medicines. In this regard, the following two studies on US Food and Drugs Agency’s new approval data are instructive. According to the first study of US FDA’s new drug approvals (NDAs), containing new molecular entities (NMEs)23 from 1950 to 2008,24 the efficiency of pharmaceutical R&D has substantially decreased.25 Pharmaceutical products containing NMEs were produced at a constant rate over the last 70 years though the industry’s R&D expenditure touched $50 billion/year in 2008 increasing exponentially at a rate of 13.4 % every year since the 1950s.26 One of the reasons for this outcome was the industry’s focus on marginal innovation or imitative research.27 In light of the above assertion, test data exclusivity may have a role to play, providing incentive for engaging in imitative research by protecting investment in generation of test data even when the products are not innovative. This is true, where imitative and marginal research is less risky and more profitable than investing in more complex R&D. Another study conducted by the Research and Education Foundation of the National Institute for Health Care Management (NIHCM)28 provides a more comprehensive analysis of pharmaceutical innovation. It analyzed FDA approvals from 1989 to 2000.29 The innovativeness of a pharmaceutical product is determined on two accounts: novelty of the molecular entity (chemical type) and improvement over available therapies (therapeutic potential).30 Accordingly, the Report distributed new drugs into five categories,31 as illustrated in Table 2.1. Priority NMEs (new molecular entities) are considered most innovative32 and are assigned priority review by the FDA.33 An NME qualifies for this status if it is new, i.e., its active ingredients have never been approved in the US,34 and shows ‘even moderate’ clinical improvement over existing therapies.35 Pharmaceutical products that are identical to those already available on the market are considered ‘other drugs’. Rest of the pharmaceutical products fall between two extremes on a continuum of innovation. The study found that out of a total of 1035 new pharmaceutical products under study, two-thirds contained previously approved molecular entity.36 As for the therapeutic potential, three out of every four new products failed to show any clinical improvement over existing therapies and were rated as ‘standard’. 37 The distribution of these pharmaceutical products on the continuum of innovation reflects the R&D focus of the originator industry. Only 15 % of all the products were rated as Priority NMEs. Standard NMEs and priority IMDs, pharmaceuticals with moderate innovation,38 were 20 % and 28 % of the total, respectively. However, a staggering 46 % were standard IMDs i.e., neither innovative in terms of the molecular entity nor as to therapeutic potential. Moreover, 11 % were treated as other drugs.39 Hence, close to 60 % of all the pharmaceutical products approved from 1989 to 2000, were no better than what already existed! Furthermore, to assess the changing patterns of FDA approvals over time, the report divided the 12-year period (from 1989 to 2000) into two periods of six years each.40 Accordingly, there were additional 219 new pharmaceuticals approved in the second period out of which only 3 % were regarded as Priority NMEs.41 Priority IMDs comprised 9 % and standard NMEs were 26 % of the increase. The bulk of the new increase, around 62 % was constituted by standard IMDs, containing already available molecular entities and lacking any clinical improvement over existing therapies.42 The standard-rated NMEs and IMDs accounted for 88 % of the total increase over the first period.43 The Report found that the increase in the number of standard-rated products was because the pharmaceutical companies could easily sell them to the consumers. In the period from 1989 to 1994, consumers spent $64.7 billion on prescription pharmaceuticals, which increased by $67.3 billion to almost $132 billion in the second period.44 Two-thirds of this increase was spent on new products approved in 1995 or later and almost 67 % of the amount spent on new products was spent on standard-rated products. In addition to the increase in spending, the average prescription prices of standard-rated products doubled in the year 2000 as compared to the level in 1995.45 Therefore, consumers paid almost twice the amount for the same therapies that were already available in the market. The NIHCM Report found that investing in product modifications is less expensive and time-consuming and thus preferable than investing in finding a new molecular entity.46 Moreover, pharmaceutical companies have a guaranteed 3-year period of test data exclusivity protection, just on the basis of new clinical studies.47 In summary, whereas the patent system potentially incentivizes the priority and standard NMEs and to some extent priority IMDs, though the latter two are not really innovative, there is no evidence that test data exclusivity also makes a convincing case in providing utilitarian benefits as argued in the discussion above.48 On the contrary, the evidence suggests that it may have a role to play in incentivizing investment in standard IMDs that had the lion’s share in FDA’s approval between 1989 and 2000 and accounting for the largest share in retail prescription spending. Possibly, it may only be an incentive to direct the society’s finite financial and human resources to activities that add no benefit to the society and affect access to affordable medicine. However, there is a need of further empirical investigation to identify what role did test data exclusivity play in the increase in standard-rated products.

#### Empirics prove the impact on developing countries – only studies conducted

Shaikh 16 [Shaikh O.H., Ludwig-Maximilians-Universität München Doctor of Philosophy – PhD. Max Planck Institute for Competition and Innovation, Munich, Germany, (2016) Intellectual Property Law, Educational Consulting, Legal Consulting, Business Consulting, Copyright Law, Consumer Law, IT Law, Trademark Law, Business Law, and Startup Law, Test Data Exclusivity: Raison d’être. In: Access to Medicine Versus Test Data Exclusivity. Munich Studies on Innovation and Competition, vol 4. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-662-49655-8\_2] simha

2.3 Impact of Test Data Exclusivity in Selected Developing Countries

There have not been many studies assessing the impact of test data exclusivity provisions in developing countries. There could be several reasons for this: firstly, some developing countries may still be benefitting from a transitory period allowed in the FTA with respect to implementation of certain provisions. Secondly, sufficient time has not passed since the coming into effect of many FTAs. For example, in case of FTAs where US is a party, full impact of data exclusivity cannot be assessed before 5 years of the coming in to force of the FTA. This time increases to between 8 and 10 years in the FTAs where EU or the EFTA countries are parties. Thirdly, it may also not be very easy to isolate the impact of data exclusivity on access to medicine from other exclusivities. Most importantly, countries have not yet realized the need to analyze the impact of test data exclusivity on access to medicine, as it may be clouded by patent protection. In the following, one study each from Jordan, Guatemala and Colombia will be summarized, presenting secondary evidence that test data exclusivity negatively affects access to not only generic pharmaceutical products but also to originator pharmaceuticals.

2.3.1 Jordan

Oxfam undertook an impact assessment study of the TRIPS-plus rules in Jordan-US FTA on access to medicine in Jordan.49 This was the first US FTA concluded with a country of the Middle East and also the first US FTA after the conclusion of the TRIPS Agreement that included provisions on test data exclusivity.50 According to the study, out of 103 medicines registered and launched in Jordan between 2001 and 2006, 79 % did not face any generic competition solely due to test data exclusivity.51 As a consequence, Jordanians paid an additional sum between $6.3 million to $22.04 million.52 Focusing on the prices of pharmaceutical products for diabetes and heart diseases, the report revealed that Jordanians paid as much as eight times more for the same product in Egypt, which had not introduced test data exclusivity protection at that time.53 Similarly, it was also found that there had been no considerable inflow of foreign direct investment (FDI) in Jordan, increase in licensing activity or any positive effect on technology transfer.54 Additionally, no originator company had a local subsidiary to produce originator products in Jordan.55 Many new pharmaceutical products available in the US were not registered and launched in Jordan, which is one of the promises of introducing test data exclusivity. The study found that of the top 26 products by sales in the United States only nine were available in Jordan.56 The report asserted that only 33 out of 82 pharmaceutical products from the complete portfolio of Pfizer, BMS, Merck, Genzyme, Roche and Genentech, were available in Jordan.

2.3.2 Guatemala

In 2009 the Center for Policy Analysis on Trade and Health (CPATH) conducted a study to analyze the impact of CAFTA-DR rules on access to generic pharmaceutical products in Guatemala.57 According to the study, the TRIPS-plus rules of CAFTA-DR relating to data exclusivity and patents resulted not only in restricting market entry for generics products but also in removal of already marketed generic products.58 Some of the pharmaceutical products protected in Guatemala through test data exclusivity rules, would face generic competition in the US earlier than in Guatemala.59 The study also presented price comparison of a sample of pharmaceutical products with test data exclusivity with non-data protected products made available by the Ministry of Health. Some of these protected products were priced between 1.6 to over 800 times higher than the non-protected products.60

2.3.3 Colombia

For assessing the impact of 10 years of test data exclusivity protection in Colombia, the LAC-Global Alliance for Access to Medicines, Misio´n Salad and IFARMA conducted a study in 2011.61 The study suggested that due to test data exclusivity protection, Colombians paid an additional $412 million in the last 10 years.62 The study casted doubts on the impact of test data exclusivity on availability of new originator pharmaceutical products. According to the study, out of a total of 10,873 registrations only 122 products containing new chemical entities were launched in Colombia during this period. The products classified as containing new chemical entities included many modifications of known products. The study also deplored the fact that test data exclusivity protection has not resulted in investment in pharmaceutical R&D and innovation by Colombian pharmaceutical companies, as foreign companies owned 100 % of the products qualifying for test data exclusivity protection. Similar to the Jordanian study, this study also found that market factors might have greater role in launch of new products than provision of test data exclusivity, based on the comparison with Venezuela and Argentina, two countries that do not provide for similar protection.

2.4 Conclusion

The above examples show that test data exclusivity can delay entry of generics as well as originator products, keep prices higher, delay entry of generics as compared to other countries’ markets and remove generic products from the market as well. Most importantly, test data exclusivity has been found to have no positive effect on the level of pharmaceutical investment in the protecting country. A recent study assessed whether presence or absence of test data exclusivity has any impact on pharmaceutical investment in 45 countries. It found out that out of several variables, including gross national income, population and ease of doing business, test data exclusivity was the only independent variable that did not have a statistically significant relationship with the level of pharmaceutical investment. The study concluded: ‘The data presented here suggests there is no relationship between whether or not a country offers [test] data exclusivity, and the amount of investment in the country by the pharmaceutical industry’. 63 Hence, countries that intend to introduce test data exclusivity protection, or that have already done so, must undertake the assessment of its impact on access to medicine both pre- and postimplementation.

#### Pandemics hit first in developing countries – establishing local countermeasures is key to solving future pandemics

Oppenheim and Yamey 17 [Ben Oppenheim, Senior Scientific Consultant - Metabiota Senior Fellow and Visiting Scholar - New York University Center on International Cooperation and Gavin Yamey, Director, Center for Policy Impact in Global Health and Professor of Global Health - Duke Global Health Institute, Duke University, 6-19-2017, "Pandemics and the poor," Brookings, https://www.brookings.edu/blog/future-development/2017/06/19/pandemics-and-the-poor/] rct simha

When epidemics or pandemics hit, they usually hit the poor first and worst. We have known this for a while. The German pathologist Rudolf Virchow described this link between poverty and vulnerability to outbreaks in his 1848 study of a typhus epidemic in Upper Silesia: For there can now no longer be any doubt that such an epidemic dissemination of typhus had only been possible under the wretched conditions of life that poverty and lack of culture had created in Upper Silesia. What we have not known, until recently, is how best to help the poor protect themselves from pandemics. To understand why the poor are more vulnerable to epidemics and pandemics and what protections are required, we need to consider how outbreaks first start, how they spread, and how they affect individuals and societies. Recently, we’ve been studying pandemics—outbreaks that spread across international boundaries, potentially wreaking enormous health, social, and economic damage. Pandemics are becoming more frequent, not less: Emily Chan and colleagues have shown that the likelihood of pandemics has risen over the last century due to environmental, ecological, and social factors. HOW PANDEMICS START—AND WHY THEY SMOLDER AND SPREAD Most pandemics begin with a pathogen leaping from wild or domesticated animals to humans, what is called a “zoonotic spark.” Kate Jones and colleagues have found high levels of spark risk in West and Central Africa, and South and Southeast Asia. These regions are experiencing rapid expansions in human settlements, intensifying agricultural and livestock production, and increasing exploitation of natural resources. Such factors drive contact between humans and animals, amplifying pandemic risks. These regions are also home to most of the global poor. The first line of defense against pandemics is surveillance: monitoring human and animal populations to spot outbreaks and contain them quickly. Despite growing international attention, disease surveillance remains weakest in impoverished countries at greatest risk. Such countries are short on labs, infrastructure, and trained epidemiologists. Underinvestment in preparedness reflects the painful choice facing poor countries with high disease burdens: attend to today’s health burdens or to the potentially far-off (yet inevitable) risk of a pandemic. These weaknesses mean that in poor countries, isolated outbreaks are likely to go undetected longer and, thus, to smolder and spread. HOW THEY IMPACT HEALTH—AND THE POCKETBOOKS OF THE POOR Regardless of where a pandemic starts, once underway, the poor tend to bear the brunt. Low- and middle-income countries (LMICs) have weaker health systems and limited capacity to handle surges in cases. Christopher Murray and colleagues estimate that if a flu pandemic similar in severity to the 1918 Spanish flu pandemic were to hit today, there could be 62 million deaths, of which 96 percent would be in LMICs. We can curtail pandemics if we quickly develop vaccines and make them widely accessible. However, without vigorous efforts to secure equitable access, vaccine distribution will follow the logic of the market. During the 2009 swine flu pandemic, wealthy countries secured large advance orders for vaccines, but, despite the efforts of the World Health Organization to negotiate donations, poor countries were crowded out—receiving vaccines more slowly than rich countries and unable to cover as many of their citizens. These same distributional inequalities are also likely to play out within poor countries. The poorest regions in a country are often the most vulnerable since they have fewer pandemic response resources—fewer health workers and clinics and less medicine. When outbreaks begin, the poor are also more likely to have already been suffering from malnutrition and immunosuppressive conditions, which can increase susceptibility to infectious diseases. Epidemics and pandemics can cause enormous economic damage as workers fall sick, fearful people avoid markets and public places, and quarantines and disease control measures reduce travel and clamp down on trade. Acute economic disruption carries particular risks for poor households, whose livelihoods are already precarious. All three countries affected by the 2014 West African Ebola epidemic suffered large GDP growth shocks, totaling $2.8 billion in lost GDP. This figure probably underestimates the true economic impact. Victoria Fan and colleagues calculated the “inclusive” cost of outbreaks (the sum of the cost in lost income and a dollar valuation of the cost of early death) and found that for Ebola, the inclusive costs are two to three times the income loss.

#### Disease causes extinction---defense doesn’t rule out the possibility and empirics

Piers Millett 17, Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization.

A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6

While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-2

#### Independently, Superbugs are inevitable, existential and require innovation – we’re massively underprepared

Talkington 20 [Kathy Talkington, Kathy Talkington oversees teams of policy experts, scientists, and advocates for Pew’s work on public health issues, including the rise of antibiotic-resistant bacteria and the need for new antibiotics and safe drugs, health care products, and food. She also oversees the Health Impact Project, a partnership with the Robert Wood Johnson Foundation. She has a bachelor’s degree in psychology from the University of Virginia and a master’s degree in public affairs from the University of Texas, Austin, 07-27-2020, "The U.S. Is Not Prepared to Combat 'Existential Threat' of Antibiotic-Resistant Superbugs," PEW Trusts, https://www.pewtrusts.org/en/research-and-analysis/articles/2020/07/27/the-us-is-not-prepared-to-combat-existential-threat-of-antibiotic-resistant-superbugs] simha

At the July launch of the AMR Action Fund, Admiral Brett P. Giroir, U.S. assistant secretary for health, said the following:

"Antimicrobial resistance, I do believe, is the existential threat of this century."

Giroir’s warning is dire—but it’s not new. For years, leading public health and national security experts around the world have sounded the alarm about the growing threat posed by antibiotic-resistant bacteria. Commissions led by world-renowned economists, declarations from the United Nations General Assembly, urgent threat reports from the Centers for Disease Control and Prevention, and more have all come to the same conclusion: Antimicrobial resistance is a known and certain danger—and the global level of preparedness does not match the magnitude of the threat.

In June, The Pew Charitable Trusts sent a letter to the leaders of the Senate Committee on Health, Education, Labor, and Pensions, providing recommendations for how the U.S. can better prepare for future pandemics. The letter highlighted the urgent need for government incentives to help fix the broken antibiotic market. Pew recently reiterated this call to action in partnership with the World Health Organization.

There is widespread and longstanding consensus that such incentives are needed to revitalize and sustain the woefully inadequate antibiotic pipeline. Without them, antibiotic developers will continue to go bankrupt, and innovation will continue to stagnate. Now is the time for action. Policymakers must ensure that the U.S. is not caught flat-footed when the inevitable superbug outbreak hits. Some threats we cannot begin to anticipate, but when it comes to antibiotic-resistant bacteria, there’s no excuse for being unprepared.

#### Generics are key to LMIC public health investment – empirics prove

Brittany L. Bychkovsky 16. Oncologist, teaches at Harvard Medical School. 2016. “Compulsory Licenses for Cancer Drugs: Does Circumventing Patent Rights Improve Access to Oncology Medications?” <https://ascopubs.org/doi/full/10.1200/jgo.2016.005363>. // rct AAli

From an economic perspective, substitution of patented drugs with generic versions is cost saving, and from a public health standpoint, not only permitting but also encouraging generic drug production and use increases access to essential cancer medications in LMICs. For example, in India, if generic versions of paclitaxel, docetaxel, gemcitabine, oxaliplatin, and irinotecan—five commonly used chemotherapeutic agents—were introduced, the potential annual savings for the health care system is nearly US$843 million (or €670 million).40 In fact, generic versions of these drugs are already available and cost 8.9% to 36% less than the equivalent branded drug, and there is only a need to permit their use in the Indian market.40 Although some critics have suggested that the failure to uphold intellectual property rights will decrease incentives for innovation and, therefore, lead to fewer new medications in the future, evidence in support of this notion is scant. In fact, > 80% of financial gains from cancer drugs comes from high-income countries in which compulsory licensing is rarely used or approved.13 One observational study investigated this issue and found that pharmaceutical companies affected by compulsory licenses did not have a decline in the rate of new medicines patented or their measured inventive and innovation activity. Obviously, some pharmaceutical companies view compulsory licenses as a threat to their intellectual property, research and development, and medication sales. There have been a few cases in which the pharmaceutical industry has tried to pressure countries to deter them from issuing compulsory licenses. For example, Pfizer announced that it would rethink investments in Egypt after the country issued a compulsory license for sildenafil in 200242; however, this is unusual, and pharmaceutical investment and growth continues in many countries, such as Brazil and South Africa, where compulsory licenses have been issued.13 In place of using compulsory licensing, LMICs may benefit from negotiating directly with the patent owner, that is, pharmaceutical companies, to offer essential drugs to their populations. In many cases, pharmaceutical companies have offered affordable prices for medications, if ordered in bulk, to serve a large population, which is an approach that we support. However, there are no data on how long these negotiations take before a decision is made and if pharmaceutical companies purposefully delay this process so that an agreement or a compulsory license is not immediately granted. There is also the argument that the price of patented medications is not the main barrier to medication access in LMICs and, in fact, that lack of manufacturing capacity or poor health care systems are larger contributors that impact access.10,15 Counter arguments to this point are simple: if LMICs save money on medication expense, then these savings can be invested in improvement of their own drug manufacturing capacity and health systems. In Thailand, a study found that if relevant HIV/AIDs drugs were not patented, an additional 10,000 prescriptions could be made, which would increase access by 50%.10 The high costs of cancer drugs threaten access to cancer treatment even in high-income countries. As a result of its extremely high cost, trastuzumab emtanzine (T-DM1), a drug used to treat metastatic HER2-positive breast cancer, has not been made available to patients treated in the national health system in the United Kingdom, according to a recent recommendation by the National Institute for Health and Care Excellence. The National Institute for Health and Care Excellence estimates that only 1,500 women in the United Kingdom would benefit from treatment with T-DM1 every year and that a year of treatment costs £102,405, roughly 3.9 times the 2014 per capita income of £26,350 in the United Kingdom.43,44 Compared with lapatinib plus capecitabine therapy in this setting, T-DM1 costs £166,400 per quality-adjusted life year (QALY) gained,45 which is significantly higher than the cost-effectiveness threshold in the United Kingdom of £30,000/QALY gained.46 In contrast to lapatinib and capecitabine, T-DM1 therapy has a more favorable adverse effect profile and is generally well tolerated, an important consideration in patients with advanced cancer where preserving quality of life is a major goal; this fact is not accounted for in the cost and QALY calculation. Out of concern of the access barrier to T-DM1 therapy, the Coalition for Affordable T-DM1, a civil organization, sent a formal letter to United Kingdom secretary of state for health to ask that the government use provisions in United Kingdom patent laws to authorize the manufacture or importation of generic versions of T-DM1 without the permission of Roche.43,44 This case simply exemplifies the exorbitantly high price of cancer medications and the urgent need to find solutions to this problem, especially in resource-conscious or resource-constrained settings.

#### Affordable healthcare solves warming – Indonesia gets modeled

**UCSB 20**, University of California - Santa Barbara, 10-26-2020, "Healthcare as a climate solution: A new analysis reveals that accessible and affordable healthcare could be a key tool for addressing the climate crisis," <https://www.sciencedaily.com/releases/2020/10/201026184029.htm> ]//AAli

A new analysis reveals that accessible and affordable healthcare could be a key tool for addressing the climate crisis Although the link may not be obvious, healthcare and climate change -- two issues that pose major challenges around the world -- are in fact more connected than society may realize. So say researchers, who are increasingly proving this to be true. Case in point: A new study by UC Santa Barbara's Andy MacDonald found that improving healthcare in rural Indonesia reduced incentives for illegal logging in a nearby national park, averting millions of dollars' worth of atmospheric carbon emissions. The analysis, published in the Proceedings of the National Academy of Sciences, finds that deforestation in the national park declined 70% in the 10 years after an affordable health clinic opened in the area. This equates to more than $65 million worth of avoided carbon emissions when translated to the European carbon market, the study reports. "The results illustrate a strong link between human health and conservation in tropical forests in the developing world," said MacDonald, an assistant researcher at the Earth Research Institute who coauthored the study with UC Santa Barbara's David Lopez-Carr and colleagues at Stanford University, North Carolina State University Raleigh, Oregon Health and Science University, Natural Capital Advisors, and two NGOs involved in the intervention. The Indonesian clinic accepts barter as payment and gives discounts to villages based on community-wide reductions in logging. Given its success, it could provide a blueprint for preserving the world's biodiverse carbon sinks while reducing poverty and illness. "This innovative model has clear global health implications," said coauthor Michele Barry, senior associate dean of global health at Stanford and director of the Center for Innovation in Global Health. "Health and climate can and should be addressed in unison, and done in coordination with and respect for local communities." Every second, more than 100 trees disappear from tropical forests around the world. These forests, some of the world's most important carbon reservoirs, are crucial to slowing climate change and mass extinction. The current paradigm for conserving tropical forests -- establishing protected areas -- often excludes and disenfranchises local communities. This failure to address people's needs can lead communities with few economic alternatives to illegally log and convert the land. Lack of access to high-quality, affordable healthcare can compound the problem by perpetuating cycles of poor health and expanding out-of-pocket costs. With this in mind, the nonprofit organizations Alam Sehat Lestari and Health In Harmony in 2007 established a healthcare clinic adjacent to Gunung Palung National Park in West Kalimantan, Indonesia, with the support of the local government. The clinic was able to serve thousands of patients by accepting a range of alternative payments, such as tree seedlings, handicrafts and labor -- an approach that was created in collaboration with the communities themselves. Through agreements with most of the region's district leaders, the clinic also provided discounts to villages that could show evidence of reductions in illegal logging. Between 1985 and 2001, this region had lost 60% of its forest to this activity. In addition to affordable health care, the intervention provided training in sustainable, organic agriculture and a chainsaw buyback program. Researchers worked with the two non-profits to analyze more than 10 years of the clinic's patient health records, coupled with satellite observations of forest cover over that time. "Private foundations funded the interventions, but it's innovative new programs at Stanford and the University of California that are funding the research," MacDonald said. The medical care led to a significant decline in a range of diseases such as malaria, tuberculosis and diabetes. At the same time, satellite images of the national park showed a 70% reduction in deforestation, compared to forest loss at control sites, an amount equivalent to more than 6,770 acres of rainforest. "We didn't know what to expect when we started evaluating the program's health and conservation impacts, but we were continually amazed that the data suggested such a strong link between improvements in healthcare access and tropical forest conservation," said lead author Isabel Jones, who recently earned her doctorate in biology at Stanford. Looking more closely at community-level logging rates, the researchers found that the greatest drop-offs in logging occurred adjacent to villages with the highest rates of clinic usage. A global blueprint "This is a case study of how to design, implement and evaluate a planetary health intervention that addresses human health and the health of rainforests on which our health depends," said coauthor Susanne Sokolow, a senior research scientist at Stanford. Globally, about 35% of protected areas are traditionally owned, managed, used or occupied by Indigenous and local communities. Yet the perspective and guidance of Indigenous peoples and local communities are rarely considered in the design of conservation and climate mitigation programs. By contrast, the Indonesian clinic's success grew out of the early and continued input of local communities who identified the mechanisms driving health and environmental problems as well as possible solutions. Such holistic approaches can have greater long-term effects by preserving and restoring the ecosystem services that protect human health. These include natural filtering processes that reduce the risk of waterborne diseases and shade-providing forest canopies that reduce ground temperature and heat-related illnesses.

#### Warming causes extinction – positive feedback loops means adaptation is impossible

Ng ’19 [Yew-Kwang; May 2019; Professor of Economics at Nanyang Technology University, Fellow of the Academy of Social Sciences in Australia and Member of the Advisory Board at the Global Priorities Institute at Oxford University, Ph.D. in Economics from Sydney University; Global Policy, “Keynote: Global Extinction and Animal Welfare: Two Priorities for Effective Altruism,” vol. 10, no. 2, p. 258-266; RP]

Catastrophic climate change

Though by no means certain, CCC causing global extinction is possible due to interrelated factors of non‐linearity, cascading effects, positive feedbacks, multiplicative factors, critical thresholds and tipping points (e.g. Barnosky and Hadly, [2016](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0005); Belaia et al., [2017](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0008); Buldyrev et al., [2010](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0016); Grainger, [2017](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0027); Hansen and Sato, [2012](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0029); IPCC [2014](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0031); Kareiva and Carranza, [2018](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0033); Osmond and Klausmeier, [2017](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0056); Rothman, [2017](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0066); Schuur et al., [2015](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0069); Sims and Finnoff, [2016](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0072); Van Aalst, [2006](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0079)).[7](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-note-1009_67)

A possibly imminent tipping point could be in the form of ‘an abrupt ice sheet collapse [that] could cause a rapid sea level rise’ (Baum et al., [2011](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0006), p. 399). There are many avenues for positive feedback in global warming, including:

* the replacement of an ice sea by a liquid ocean surface from melting reduces the reflection and increases the absorption of sunlight, leading to faster warming;
* the drying of forests from warming increases forest fires and the release of more carbon; and
* higher ocean temperatures may lead to the release of methane trapped under the ocean floor, producing runaway global warming.

Though there are also avenues for negative feedback, the scientific consensus is for an overall net positive feedback (Roe and Baker, [2007](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0065)). Thus, the Global Challenges Foundation ([2017](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0026), p. 25) concludes, ‘The world is currently completely unprepared to envisage, and even less deal with, the consequences of CCC’.

The threat of sea‐level rising from global warming is well known, but there are also other likely and more imminent threats to the survivability of mankind and other living things. For example, Sherwood and Huber ([2010](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0071)) emphasize the adaptability limit to climate change due to heat stress from high environmental wet‐bulb temperature. They show that ‘even modest global warming could … expose large fractions of the [world] population to unprecedented heat stress’ p. 9552 and that with substantial global warming, ‘the area of land rendered uninhabitable by heat stress would dwarf that affected by rising sea level’ p. 9555, making extinction much more likely and the relatively moderate damages estimated by most integrated assessment models unreliably low.

While imminent extinction is very unlikely and may not come for a long time even under business as usual, the main point is that we cannot rule it out. Annan and Hargreaves ([2011](https://onlinelibrary-wiley-com.proxy.lib.umich.edu/doi/full/10.1111/1758-5899.12647#gpol12647-bib-0004), pp. 434–435) may be right that there is ‘an upper 95 per cent probability limit for S [temperature increase] … to lie close to 4°C, and certainly well below 6°C’. However, probabilities of 5 per cent, 0.5 per cent, 0.05 per cent or even 0.005 per cent of excessive warming and the resulting extinction probabilities cannot be ruled out and are unacceptable. Even if there is only a 1 per cent probability that there is a time bomb in the airplane, you probably want to change your flight. Extinction of the whole world is more important to avoid by literally a trillion times.

### 1AC-Util

#### The standard is maximizing expecting well being.

#### 1] Actor specificity

#### ---A] Aggregation – every policy benefits some and harms others, which also means side constraints freeze action.

#### ---B] No act-omission distinction – choosing to omit is an act itself – governments actively decide not to act so there is no omission

#### 2] Util is a lexical pre-requisite to any other framework: Threats to life preclude the ability for moral actors to effectively utilize and act upon other moral theories since they are in a constant state of crisis – that inhibits the ideal moral conditions which other theories presuppose.

#### 3] Moral uncertainty means preventing extinction should be our highest priority Bostrom 12 [Nick Bostrom. Faculty of Philosophy & Oxford Martin School University of Oxford. “Existential Risk Prevention as Global Priority.” Global Policy (2012)]

These reflections on moral uncertainty suggest an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate. ¶ Our present understanding of axiology might well be confused. We may not now know — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet be able to imagine the best ends of our journey. If we are indeed profoundly uncertain about our ultimate aims, then we should recognize that there is a great option value in preserving — and ideally improving — our ability to recognize value and to steer the future accordingly. Ensuring that there will be a future version of humanity with great powers and a propensity to use them wisely is plausibly the best way available to us to increase the probability that the future will contain a lot of value. To do this, we must prevent any existential catastrophe.