## 1AC – Pricing

## Framework

#### The standard is maximizing expected well-being

#### [1] Policy focus - Ethical policymaking requires calculation of consequences

Gvosdev 5 – Rhodes scholar, PhD from St. Antony’s College, executive editor of The National Interest (Nikolas, The Value(s) of Realism, SAIS Review 25.1, pmuse, AG)

As the name implies, realists focus on promoting policies that are achievable and sustainable. In turn, the morality of a foreign policy action is judged by its results, not by the intentions of its framers. A foreign policymaker must weigh the consequences of any course of action and assess the resources at hand to carry out the proposed task. As Lippmann warned, Without the controlling principle that the nation must maintain its objectives and its power in equilibrium, its purposes within its means and its means equal to its purposes, its commitments related to its resources and its resources adequate to its commitments, it is impossible to think at all about foreign affairs.8 Commenting on this maxim, Owen Harries, founding editor of The National Interest, noted, "This is a truth of which Americans—more apt to focus on ends rather than means when it comes to dealing with the rest of the world—need always to be reminded."9 In fact, Morgenthau noted that "there can be no political morality without prudence."10 This virtue of prudence—which Morgenthau identified as the cornerstone of realism—should not be confused with expediency. Rather, it takes as its starting point that it is more moral to fulfill one's commitments than to make "empty" promises, and to seek solutions that minimize harm and produce sustainable results. Morgenthau concluded: [End Page 18] Political realism does not require, nor does it condone, indifference to political ideals and moral principles, but it requires indeed a sharp distinction between the desirable and the possible, between what is desirable everywhere and at all times and what is possible under the concrete circumstances of time and place.11 This is why, prior to the outbreak of fighting in the former Yugoslavia, U.S. and European realists urged that Bosnia be decentralized and partitioned into ethnically based cantons as a way to head off a destructive civil war. Realists felt this would be the best course of action, especially after the country's first free and fair elections had brought nationalist candidates to power at the expense of those calling for inter-ethnic cooperation. They had concluded—correctly, as it turned out—that the United States and Western Europe would be unwilling to invest the blood and treasure that would be required to craft a unitary Bosnian state and give it the wherewithal to function. Indeed, at a diplomatic conference in Lisbon in March 1992, the various factions in Bosnia had, reluctantly, endorsed the broad outlines of such a settlement. For the purveyors of moralpolitik, this was unacceptable. After all, for this plan to work, populations on the "wrong side" of the line would have to be transferred and resettled. Such a plan struck directly at the heart of the concept of multi-ethnicity—that different ethnic and religious groups could find a common political identity and work in common institutions. When the United States signaled it would not accept such a settlement, the fragile consensus collapsed. The United States, of course, cannot be held responsible for the war; this lies squarely on the shoulders of Bosnia's political leaders. Yet Washington fell victim to what Jonathan Clarke called "faux Wilsonianism," the belief that "high-flown words matter more than rational calculation" in formulating effective policy, which led U.S. policymakers to dispense with the equation of "balancing commitments and resources."12 Indeed, as he notes, the Clinton administration had criticized peace plans calling for decentralized partition in Bosnia "with lofty rhetoric without proposing a practical alternative." The subsequent war led to the deaths of tens of thousands and left more than a million people homeless. After three years of war, the Dayton Accords—hailed as a triumph of American diplomacy—created a complicated arrangement by which the federal union of two ethnic units, the Muslim-Croat Federation, was itself federated to a Bosnian Serb republic. Today, Bosnia requires thousands of foreign troops to patrol its internal borders and billions of dollars in foreign aid to keep its government and economy functioning. Was the aim of U.S. policymakers, academics and journalists—creating a multi-ethnic democracy in Bosnia—not worth pursuing? No, not at all, and this is not what the argument suggests. But aspirations were not matched with capabilities. As a result of holding out for the "most moral" outcome and encouraging the Muslim-led government in Sarajevo to pursue maximalist aims rather than finding a workable compromise that could have avoided bloodshed and produced more stable conditions, the peoples of Bosnia suffered greatly. In the end, the final settlement was very close [End Page 19] to the one that realists had initially proposed—and the one that had also been roundly condemned on moral grounds.

#### [2] No moral intent/foresight distinction for states—it’s just avoiding responsibility.

David **Enoch 7** [The Faculty of Law, The Hebrew University, Mount Scopus Campus, Jerusalem], “INTENDING, FORESEEING, AND THE STATE,” Legal Theory, 13 (2007), 69–99, pg. 90-1, beckert

The general difficulty of the intending-foreseeing distinction here stemmed, you will recall, from the feeling that attempting to pick and choose among the foreseen consequences of one’s actions those one is more and those one is less responsible for looks more like the preparation of a defense than like a genuine attempt to determine what is to be done. Hiding behind the intending-foreseeing distinction seems like an attempt to evade responsibility, and so thinking about the distinction in terms of responsibility serves to reduce even further the plausibility of attributing to it intrinsic moral significance. This consideration—however weighty in general—seems to me very weighty when applied to state action and to the decisions of state officials. For perhaps it may be argued that individuals are not required to undertake a global perspective, one that equally takes into account all foreseen con- sequences of their actions. Perhaps, in other words, individuals are entitled to (roughly) settle for having a good will, and beyond that let chips fall where they may. But this is precisely what stateswomen and statesmen—and certainly states—are not entitled to settle for.44 In making policy decisions, it is precisely the global (or at least statewide, or nationwide, or something of this sort) perspective that must be undertaken. Perhaps, for instance, an individual doctor is entitled to give her patient a scarce drug without think- ing about tomorrow’s patients (I say “perhaps” because I am genuinely not sure about this), but surely when a state committee tries to formulate rules for the allocation of scarce medical drugs and treatments, it cannot hide behind the intending-foreseeing distinction, arguing that if it allows45 the doctor to give the drug to today’s patient, the death of tomorrow’s patient is merely foreseen and not intended. When making a policy-decision, this is clearly unacceptable. Or think about it this way (I follow Daryl Levinson here):46 perhaps restric- tions on the responsibility of individuals are justified because individuals are autonomous, because much of the value in their lives comes from personal pursuits and relationships that are possible only if their responsibility for what goes on in the (more impersonal) world is restricted. But none of this is true of states and governments. They have no special relationships and pursuits, no personal interests, no autonomous lives to lead in anything like the sense in which these ideas are plausible when applied to individuals persons. So there is no reason to restrict the responsibility of states in anything like the way the responsibility of individuals is arguably restricted.47 States and state officials have much more comprehensive responsibilities than individuals do. Hiding behind the intending-foreseeing distinction thus more clearly constitutes an evasion of responsibility in the case of the former. So the evading-responsibility worry has much more force against the intending-foreseeing distinction when applied to state action than elsewhere.

#### [3] Ethical agnosticism means we should default towards preventing extinction as a meta-constraint on all ethical theories.

Nick **Bostrom 13** [Faculty of Philosophy & Oxford Martin School, Oxford], “Existential Risk Prevention as Global Priority”, Global Policy, Vol 4, Issue 1 (2013): 15-31, BE

**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**.¶ We thus want to reach a state in which we have (*a*) far greater intelligence, knowledge, and sounder judgment than we currently do; (*b*) far greater ability to solve global-coordination problems; (*c*) far greater technological capabilities and physical resources; and such that (*d*) our values and preferences are not corrupted in the process of getting there (but rather, if possible, improved). Factors *b* and *c* expand the option set available to humanity. Factor *a* increases humanity's ability to predict the outcomes of the available options and understand what each outcome would entail in terms of the realization of human values. Factor *d*, finally, makes humanity more likely to want to realize human values.

## Contention – Pricing

#### Data exclusivity ramps up drug prices – best empirics prove TRIPS-plus rules create a monopoly over drug prices

**Thrasher 21**, Rachel JD, MA IR @ BU, co-editor of The Future of South-South Economic Relations, Researcher at BU (May 25, 2021, "Chart of the Week: How Data Exclusivity Laws Impact Drug Prices," BU Global Development Policy Center, <https://www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data-exclusivity-laws-impact-drug-prices/>) KD

As a [***recent working paper***](https://www.bu.edu/gdp/2021/04/21/evaluating-the-impact-of-data-exclusivity-on-the-price-per-kilogram-of-pharmaceutical-imports/) by Michael Palmedo shows, **countries that have enacted data exclusivity into their intellectual property laws have faced increased pharmaceutical import prices over the past 20 years:**

Chart, scatter chart

Description automatically generated

Data exclusivity is a form of intellectual property protection that applies specifically to data from pharmaceutical clinical trials. While innovator firms run their own clinical trials to gain marketing approval, generic manufacturers typically rely on the innovator’s clinical trials for the same approval. **Data exclusivity rules keep generic firms from relying on that data for 5 to 12 years**, depending on the specific law. Data exclusivity **operates independently of patent protection** and **can block generic manufacturers from gaining marketing approval even if the patent has expired** or the original pharmaceutical product does not qualify for patent protection. Although data exclusivity laws are matters of domestic legislation, the United States, the EU and others increasingly demand in their free trade agreement (FTA) negotiations that their trading partners protect clinical trial data in this way. Data exclusivity is just one of a host of “TRIPS-plus” treaty provisions designed to raise the overall level of intellectual property protection for innovator firms. Although the WTO’s Agreement on Trade-Related Intellectual Property Rights (**TRIPS) does require Member states to protect clinical trial and other data from “unfair commercial use**,” it does not require exclusivity rules that block the registration of generic products. “**TRIPS-plus”** rules, more severe protections that go beyond what is required in the TRIPS Agreement, generally **increase the monopoly power of branded pharmaceutical producers by extending the period they have exclusive access to the market**. Many experts have attempted to find out whether, in fact, this increased monopoly power actually causes prices to rise and, correspondingly, reduces access to those medicines. [Predictive studies which attempt](https://www.bu.edu/gdp/2019/11/06/rethinking-trade-treaties-access-to-medicines-toward-a-policy-oriented-research-agenda/) to determine price changes prior to a proposed policy change largely show that **stricter intellectual property rules lead to higher medicine prices**, as well as **increasing medicine expenditure** by states and individuals **and**, consequently, **lower availability of those medicines**. Studies which measure the impacts of a particular FTA on medicine prices [have found smaller effects](https://www.bu.edu/gdp/2019/11/06/rethinking-trade-treaties-access-to-medicines-toward-a-policy-oriented-research-agenda/), in part due to the time required for the resultant policy changes to make real impacts and mitigating policies that countries have put in place to dampen the impacts of longer monopolies. On the other hand, studies which have looked at the impact of specific TRIPS-plus – patent term extension, protection of test data and the like – [have](https://doi.org/10.1371/journal.pone.0124257) [often](https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470) [found](https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf) [significant](https://www.nejm.org/doi/full/10.1056/NEJMp1003126) [impacts](https://www.mision-salud.org/wp-content/uploads/2013/02/IMPACTO-DE-10-A%C3%91OS-DE-PROTECCION-DE-DATOS-EN-COLOMBIA.pdf) on prices or availability of medicines. Still, many of these studies focus only on one country or pharmaceutical process. Palmedo’s research conclusively shows that **data exclusivity, a measure required in all FTAs with the United States**, **is associated with increased prices across pharmaceutical imports for 41 countries**. Countries on the brink of initiating negotiations with the United States should be on notice that the **TRIPS-plus rules preferred by the United States negotiators may have real impacts on the affordability and accessibility of medicines for their constituents**.

#### DE props up monopolies, which prevents development of life-saving drugs while increasing profit margins for pharma manufacturers

**DWB 12,** Doctors Without Borders, international humanitarian medical non-governmental provides pro-boo medical assistance in conflict zones and initiatives to help countries plagued by diseases (Trading Away Health: How the U.S.’s Intellectual Property Demands for the Trans-Pacific Partnership Agreement Threaten Access to Medicines, Issue Brief, August 2012, Access Campaign, Medicine Sans Frontiers) KD

The introduction of data exclusivity prevents drug regulatory agencies from referring to existing clinical data to approve registration of generic versions of a drug by “locking up” the clinical data for a period of years, shutting down the entry of price-lowering generic competition for the duration. Data exclusivity essentially **creates a new system for granting monopolies in order to prevent generic competition**. Generic manufacturers are forced to wait for the “data monopoly” period to end, **even if the drug is unpatented**, and even when a compulsory license is issued to override the patent. The only way a generic manufacturer can get a drug registered without access to existing clinical data is to repeat the clinical trials. However, duplicating clinical trials is not only extremely **costly,** but also **unethical,** since safety and efficacy has technically already been established, rendering further clinical trials medically unnecessary. Many experts and UN agencies, including WHO, UNDP and UNAIDS, have recommended developing countries do not incorporate data exclusivity in their national laws (see Appendix B). What the U.S. Wants: The USTR is currently proposing at least five years of data exclusivity for new chemical entities and at least three years of data exclusivity for drugs containing an already approved active ingredient. 26 Moreover, the placeholder text calling for data exclusivity for ‘biologic’ medicines in the TPP is especially alarming. Pharmaceutical firms are lobbying for the data exclusivity period for biologics to be set at a minimum of 12 years.27 Because biologics are structured differently than traditional chemical medicines, second-entrant “generic” biologics are called ‘biosimilars’ or “follow-on biologics,” and require a different regulatory approval process. This would be the first time the U.S. has included a demand on biologics in a trade agreement, and if incorporated in the TPP, it would considerably delay the market entry of biosimilars. It is unclear if the U.S. will renege on the public health safeguards specified in the May 10 Agreement, where exceptions were allowed in order to ensure governments could still effectively implement public health safeguards, including compulsory licenses, caps and concurrent periods of exclusivity (vs. effectively longer ‘consecutive’ periods of exclusivity). Impact on Access to Medicines: **Data exclusivity can delay the registration of generic or biosimilar versions of a medicine for many years. Some of the newest breakthrough medicines are biologics sold at extremely high prices**. The introduction of data exclusivity for biologics will **delay the introduction of affordable versions of these medications**. The need for low-cost biosimilar alternatives to highly expensive lifesaving drugs, including pegylated interferon to treat Hepatitis C and herceptin to treat breast cancer, is acute. Some Members of U.S. Congress have expressed formal opposition to the inclusion of any data exclusivity relating to biologics in the TPP. 28 In fact, the U.S itself is considering reducing its current data exclusivity provision for biologics from 12 to 7 years, in order to reduce the cost of medicines. 29 In addition, the Federal Trade Commission (FTC) has even recommended eliminating data exclusivity for biologics in the U.S. 30 Examples: How Data Exclusivity Keeps Prices High and Delays Generic Introduction **Data exclusivity,** when implemented in national law, **provides a distinct monopoly from patent rights that often results in high prices and a delay in market entry of generics**. As a part of the U.S.-Jordan FTA, Jordan implemented data exclusivity. A 2007 study by Oxfam(1) found that of 103 medicines registered and launched since 2001 that had no patent protection in Jordan, at least 79 percent had no competition from a generic equivalent as a consequence of data exclusivity. The study also found that **prices of these medicines under data exclusivity were up to 800% higher than in neighboring Egypt.** A 2010 CPATH study(2) determined that once Guatemala enacted data exclusivity, some medicine prices rose as much as 846 percent – **even though just a handful of medicines were under patent protection**. Data exclusivity raises the price of medicines **even when no patent exists**. For example, in the U.S., the price of colchicine, a treatment used mainly for gout, rose more than 5000% after data exclusivity was enacted.(3) Colchicine has been in use for thousands of years, **costs almost nothing to produce**, and cannot be patented. Therefore, generic formulations of the tablet have been widely available since the 19th century. However, a new monopoly on colchicine was created in 2009 when the FDA accepted clinical data from a one-week trial of the drug and granted data exclusivity to URL Pharma. URL Pharma subsequently sued to force other manufacturers off the market, and **raised prices from $0.09 to $4.85 per pill**.

#### High medicine costs bad – best research confirms widespread shortages for specialty medicines not covered by insurance

**Radcliffe 17,** Health and Science Journalist, science writer and yoga teacher ("High Drug Prices Tipping Point," Healthline, https://www.healthline.com/health-news/have-drug-prices-finally-reached-tipping-point#2) KD

The report also showed that overall prescription drug prices increased 8 percent in 2015, **mainly due to new drugs, higher costs for existing drugs**, and fewer drug patents expiring. The list prices for the most commonly used brand-name drugs increased almost 208 percent between 2008 and 2016. However, during the same time, generic drug prices fell about 74 percent. Some people pay more for their prescription drugs, while others pay less, depending on what their health insurance plan covers. In 2015 the average out-of-pocket spending was $142 per person. Among traditional therapies, diabetes medications were the most expensive, in terms of out-of-pocket costs. This was followed by drugs for pain and inflammatory conditions, high blood cholesterol, and ADHD. For specialty drugs, out-of-pocket costs were highest for drugs used to treat inflammatory conditions, cancer, multiple sclerosis, and HIV. **People skip pricy meds** High prescription drug prices offer a harsh economic lesson — **as the out-of-pocket cost goes up, the number of people using the drug often goes down.** In a recent [study Trusted Source](https://jamanetwork.com/journals/jamacardiology/fullarticle/2654960) in JAMA Cardiology, researchers saw this happen with people who were approved by their insurer to fill a prescription for alirocumab or [evolocumab](https://www.healthline.com/health-news/evolocumab-plus-statin-lowers-cholesterol-further-051314), two new specialty drugs for treating elevated “bad” cholesterol levels. Co-pays for these drugs ranged from $0 to $2,822 per month. Almost 93 percent of people with no co-pay filled their prescription. **This dropped to 20 to 25 percent for people with a co-pay over $350 per month**. A group of researchers from the Cleveland Clinic found a similar trend with two common heart medications — nitroprusside and isoproterenol. In a [letter to the editor](http://www.nejm.org/doi/full/10.1056/NEJMc1700244) of the New England Journal of Medicine, the researchers reported that between 2012 and 2015 the cost of nitroprusside increased from about $27 to $881. The cost of isoproterenol increased from about $26 to $1,790. During this time, **patient use of these drugs decreased by 53 percent and 35 percent**, respectively. **For people struggling to make ends meet, the cost of prescription drugs may have already reached a tipping point.** According to a recent [Truven Health Analytics-NPR Health Poll](http://truvenhealth.com/Portals/0/Assets/TRU_18156_0617_NPR_Poll_Prescription_Drugs_FINAL.pdf), people with annual incomes under $25,000 were more likely to not fill a prescription, compared to people with higher incomes. Almost all of the lower-income people cited high cost as the reason. But this group isn’t alone. “**High drug prices appear to affect everyone across the socioeconomic spectrum**. So it’s not just low-income people who are having these issues,” Minal Patel, PhD, MPH, an assistant professor in the University of Michigan School of Public Health, told Healthline. Patel added that this is **especially true “in the context of severe, acute illnesses** like cancer, or major chronic diseases.” These conditions are often **treated with newer — and more expensive — specialty medications**, which may not be fully covered by insurance. High drug prices impact health When faced with high out-of-pocket costs, people may opt to skip their medications. This can worsen their health and quality of life. It may also lead to higher medical costs down the road. “There have been some **studies showing** that people **who cut back on medicines are at increased risk for hospitalizations** and emergency department visits, which we know are very expensive forms of care,” said Patel. Some [researchTrusted Source](http://annals.org/aim/article/1357338/interventions-improve-adherence-self-administered-medications-chronic-diseases-united-states) estimates that when people don’t take their medications as prescribed for a chronic health condition, it **costs the U.S. health care system between $100 billion and $289 billion annually**. This includes people not filling their prescriptions due to high cost, skipping doses, or cutting their pills in half to make them last longer. It also includes people forgetting to take their medications or not taking them because of side effects. Other [studiesTrusted Source](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3781951/) on Medicare enrollees found that older adults sometimes cut back on basic needs such as food in order to pay for their medications.

#### Cost-related nonadherence kills millions – best bipartisan empirics confirm

**Brierly 20**, Director of Communications at West Health, former US House of Representatives Press Secretary ("New Study Predicts More Than 1.1 Million Deaths Among Medicare...," West Health, https://www.westhealth.org/press-release/study-predicts-1-million-deaths-due-to-high-cost-prescription-drugs/) KD

**More than 1.1 million** Medicare **patients could die over the next decade because they cannot afford to pay for their prescription medications**, according to [**a new study**](https://www.cidsa.org/publications/xcenda-summary) released today by the [**West Health Policy Center**](https://www.westhealth.org/what-we-do/policy-advocacy-2/), a nonprofit and nonpartisan policy research group. If current drug pricing trends and associated cost-sharing continue, researchers estimate cost-related non-adherence to drug therapy will result in the premature deaths of 112,000 beneficiaries a year, **making it a leading cause of death in the U.S.,** ahead of diabetes, influenza, pneumonia, and kidney disease. Millions more will suffer worsening health conditions and run up medical expenses that will cost Medicare an additional $177.4 billion by 2030 or $18 billion a year for the next 10 years. Researchers also modeled what would happen if Medicare was allowed to bring down drug prices for its beneficiaries through direct negotiation with drug companies, as described in H.R. 3, the [**Elijah E. Cummings Lower Drug Costs Now Act**](https://www.congress.gov/bill/116th-congress/house-bill/3/text), passed by the U.S. House of Representatives last year. They found Medicare negotiation could result in 94,000 fewer deaths annually. Additionally, the model found that the policy would reduce Medicare spending by $475.9 billion by 2030. “One of the **biggest contributors to poor health**, hospital admissions, higher healthcare costs and preventable death is patients failing to take their medications as prescribed,” said Timothy Lash, President, West Health Policy Center. “**Cost-related nonadherence** is a significant and growing issue that is direct result of runaway drug prices and a failure to implement policies and regulations that make drugs more affordable.” The price of prescription medications has skyrocketed in recent years. Between 2007 and 2018, list prices for branded pharmaceutical products increased by 159% and there are few signs of it slowing.[**[i]**](https://www.westhealth.org/press-release/study-predicts-1-million-deaths-due-to-high-cost-prescription-drugs/#_edn1) According to the Centers for Medicare & Medicaid Services (CMS), spending on prescription drugs will grow faster than any other major medical good or service over the next several years.[**[ii]**](https://www.westhealth.org/press-release/study-predicts-1-million-deaths-due-to-high-cost-prescription-drugs/#_edn2) Under Medicare, beneficiaries must pay 25% of the cost of generic and brand-name medications. For many people with multiple chronic conditions, this could add up to thousands of dollars a year in out-of-pocket costs. “**The costs of doing nothing about high drug prices are too high especially when policy changes such as allowing Medicare to negotiate drug prices would result in saving millions of lives and billions of dollars**,” said Sean Dickson, Director of Health Policy at West Health Policy Center and Chair of the [Council for Informed Drug Spending Analysis (CIDSA)](https://www.cidsa.org/), an independent group of experts on drug spending from leading academic institutions. For the study, researchers developed a 10-year model representative of the majority of Medicare beneficiaries with chronic conditions. The model allows users to estimate how different levels of price reductions would lower the number of premature deaths and decrease Medicare spending on a sliding scale. The [interactive tool](https://www.cidsa.org/xcenda-interactive-report) and the [complete technical report](https://global-uploads.webflow.com/5e5972d438ab930a0612707f/5fa9bf4419f4da03a7daf190_WHPC-Xcenda_NonAdherence%20Population%20Model_Report_22Oct2020r.pdf) can be found on the CIDSA website.

#### Non-adherence causes extinction

**Farrah 20,** AMR Insights offers valuable information, targeted training and global networking and partnering opportunities("A Threat Deadlier Than Climate Change: Antibiotic Resistance," AMR Insights, https://www.amr-insights.eu/a-threat-deadlier-than-climate-change-antibiotic-resistance/) KD

In 2019, England’s Chief Medical Officer warned that **antimicrobial resistance might cause the death of around 10 million people every year**. This is a threat that **may overtake climate change in causing humanity’s extinction**. What are antibiotics? Antibiotics are drugs that are designed to either destroy bacteria or slow down their growth. They can cost billions of euros and take years to develop. Unfortunately, they don’t work against fungal or viral infections which means there’s no point in taking them for coughs, colds or influenza. **The problem is that resistance to these drugs is growing rapidly**. Professor Dame Sally Davies noted that the number of **bugs immune to antibiotics is on the rise**, with a variety of causes being cited, including: The high volume of people carrying harmful bacteria Overuse of antibiotics **Non-adherence to prescribed hygiene practice** These are also the primary reasons why numerous large infection outbreaks occur in hospital. In this setting, many patients are susceptible due to their weak immune systems. **When a particular bacteria strain becomes resistant to antibiotics**, **treatment is** often difficult or even **impossible**. There are also cases where these resistant bacteria will pass their genes to other strains. Antibiotic resistance in farming and the environment The farming industry also uses antibiotics to protect livestock from bacterial infection. However, in some countries, farmers administer these drugs in low doses as a preventive measure or even to promote growth. Unfortunately, both the drug and the anti-resistant bacteria can escape farms and contaminate the local food chain and environment. Nurses.co.uk published an article in which Dame Sally proposed that, in order to protect the British public, the UK should stop importing beef and other meats from countries that misuse antibiotics. Why do humans need antibiotics? Every day, you can encounter bacteria that could potentially be harmful to your health. For instance: Due to injury, even if it’s just a small scratch When you have been exposed to a contaminated environment After undergoing a medical procedure (ranging from dental work to cancer therapy) Doctors administer antibiotics to people with a bacterial infection, a condition where the uncontrolled growth of harmful bacteria can cause cell damage. These bacteria also excrete toxins that are harmful to the human body. Usually, people’s immune systems can fight off the bacteria. However, if the infection is too strong, they will need antibiotics to help the body recover. Currently, around 46,000 people die from sepsis in the UK every year, it is a severe condition where harmful bacteria invade an individual’s bloodstream or tissues. The primary treatment for sepsis is antibiotics. Otherwise, **the infection could lead to organ failure, shock and ultimately death**.

#### Plan key – solving public health emergencies requires multilateral cooperation that only the 1AC ensures through strengthening global health diplomacy

* Vaccine science diplomacy: branch of science diplomacy that could lead to lifesaving vaccines developed between nations with strongly different ideologies.
* MDA – Mass Drug Administration
* NTD – Neglected Tropical Diseases

**Hotez 16**, MD, PhD, Dean for the National School of Tropical Medicine and Professor at Baylor College of Medicie (Blue Marble Health: An Innovative Plan to Fight Diseases of the Poor amid Wealth, Johns Hopkins University Press) KD

**Global partnerships.** Much of the global governance for NTD control and elimination falls on the World Health Organization. Approximately 40% of the world’s population that requires MDA now receives access to essential NTD medicines through WHO, working in collaboration with a consortium of partners, including ministries of health and their community based drug distributors and some key nongovernmental organizations [5]. **Falling into the big gaps in treatment coverage among the other 60% are the vulnerable populations** living in the G20 countries and Nigeria. The annual G20 summits and the preparatory meetings leading up to them provide a potential new venue for ensuring that these neglected populations have access to NTD medicines. But beyond mass drug administration, **there is an urgent need to create new products**. **There is a significant level of innovation among** selected countries of the G20, especially in large **middle-income countries** such as Argentina, Brazil, China, India, Indonesia, and Mexico, as well as in Saudi Arabia, where member organizations of the Developing Country Vaccine Manufacturers Network operate  [6]. These efforts are partly monitored through WHO’s new Product Development for New Vaccines Advisory Committee and the Special Programme for Research and Training in Tropical Diseases, but again **the G20 government leaders need to assume a greater role in spurring medical advances in the prevention and treatment of those diseases that disproportionately afflict the most vulnerable populations in their countries** [7]. **People living in poverty not only have a fundamental human right of access to essential medicines, but to innovation as well.** An attractive mechanism for each nation might resemble what Japan has done through its GHIT Fund, such that each of the G20 countries could create a similar mechanism but with its own unique national character. Global funds for innovation also offer promise, but these multinational mechanisms bring with them added complexities. One new auspicious approach is through the World Intellectual Property Organization, whose Re:- Search organization has created some links between academic partners and industry. I believe that WIPO, as a self-supporting UN agency through its revenue-generating supervision of patents under the Patent Cooperation Treaty, could further tap into this mechanism to spawn funds for product development partnerships committed to NTDs. The concept of blue marble health helps to illustrate some key failings among the elected leaders and the leadership of the G20 countries in looking after the weakest members of their nations. Today, hundreds of millions of people living in the G20 are essentially ignored and lack access to essential medicines, innovation, or health systems. As Elie Wiesel once said, “The opposite of love is not hate; it’s indifference.”

#### Drug pricing decks international cooperation over global health – empirics prove the plan is reverse casual

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One of the best examples of the close cooperation between the Ministry of Foreign Affairs and the Ministry of Health in Brazil **is global policy on human immunodeficiency virus**/acquired immunodeficiency syndrome (HIV/AIDS), in particular, the access to antiretroviral drugs. The presence of health experts was crucial, since a diplomat when discussing his own field of expertise, such as intellectual property, does not necessarily know about specific aspects of the production of drugs in the country or the policies regarding drug prices. The Ministry of External Relations has pointed out that the “visibility of the Ministry of Health, both in the technical and political levels, was crucial for the credibility of this position. Our leadership was, therefore, doubtlessly, a result of this credibility.” The **participation of the Brazilian diplomats** in the fight against tobacco reinforced the country’s **leading role in international health forums, and** has **further strengthened the bonds between health and diplomacy**. When assuming the presidency of the Intergovernmental Negotiating Body, Ambassador Celso Amorim from Brazil reaffirmed not only **the need to bring health into foreign policy, but also to bring foreign policy into health**. Brazilian global health diplomacy was grounded on the country’s solid preparation “back home” with the National Commission for Tobacco Control, headed by the Ministry of Health and gathering representatives from different ministries (health, agriculture, international relations, treasury, education, environment, trade and industry, and communications). Again this illustrates the point that good global health governance begins at the national level: this intensive multi-sector preparation allowed the Brazilian delegation to intervene in almost all working groups of the negotiation process. The final document, therefore, had major contributions from the Brazilian delegation, which underlined the crucial link between the national and the global and further manifested itself in the success of the Tobacco and Other Cancer Risk Factors National Control Program in Brazil.

#### Medical diplomacy spreads accessibility of critical drugs – saves millions of lives per year

**Zarocostas 07,** Geneva-based independent international correspondent and broadcaster, with more than 20 years experience in covering international global issues, including world health, development and humanitarian issues (“Better access to drugs could save 10 million lives a year, says UN expert,” PubMed Central (PMC), BMJ. 2007 Sep 29; 335(7621): 635. doi: 10.1136/bmj.39349.706782.DB, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1995491/) KD

**Better access to drugs, especially in poor countries, could save 10 million lives each year**, four million of them in Africa and South East Asia, an **independent UN expert** said as he unveiled a set of draft guidelines for pharmaceutical companies on access to drugs. The 50 draft provisions drew a mixed response from interested parties. They were welcomed by groups that advocate for access to affordable drugs but were strongly criticised by the industry. Announcing the guidelines, Paul Hunt, the United Nations' special rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, said, “**Almost two billion people lack access to essential medicines**. Improving access to existing medicines could save 10 million lives each year. Professor Hunt, who is professor at the department of law and the human rights centre at Essex University, continued: “**Access to medicines is characterised by profound global inequity**, as **15% of the world's population consumes over 90% of the world's pharmaceuticals.**” The 12 pages of recommendations, which are available for public comment until the end of 2007, are likely to be finalised next year, he said. They were drafted “to help pharmaceutical companies enhance their contribution to these vital human rights issues” and “to assist those who wish to monitor the human rights performance of the pharmaceutical sector in relation to access to medicines.” Professor Hunt said, “It is time to identify what pharmaceutical companies should do to help realise the human right to medicine. **How can we expect pharmaceutical companies to respect human rights if we fail to explain what they are to do?”** The draft terms, which UN officials say are not mandatory, include recommendations on public policy influence, advocacy and lobbying; research and development of neglected diseases; patents and licensing; quality and technology transfer; pricing, ethical promotion and marketing; clinical trials; public-private partnerships; and corruption. Thiru Balasubramaniam, the Geneva representative of the advocacy group Knowledge Economy International, said, “They look quite encouraging, specifically on the section on patents and the fact that **companies should respect the letter and the spirit of the Doha declaration** [the World Trade Organization declaration on trade related aspects of intellectual property rights (TRIPS)].” The Doha declaration, which was brokered in August 2003, calls on states to issue compulsory licences for exports to poor nations that don't have a drug manufacturing capacity. Moreover, on patents and licensing, Professor Hunt recommends that companies should make a public commitment “not to lobby for more demanding terms in poor developing nations than those required under World Trade Organization norms governing protection of TRIPS.” Recent free trade agreements between the United States and developing nations in Latin America and Asia have resulted in so called **“TRIPs plus” accords**. Harvey Bale, director general of the International Federation of Pharmaceutical Manufacturers and Associations, said that the draft guidelines **seemed to be “a fairly biased approach, even in the consultation phase**.” He complained that the **worldwide pharmaceutical research and development sector had had little input in the initial drafting and that the draft guidelines made no reference to manufacturers of generic drugs or to companies in developing countries**. He also criticised the lack of reference to “para-statals,” the state owned companies that are prominent in countries such as Brazil, Thailand, and China.

#### Critiques of clinical testing miss the boat – the 1AC’s orientation towards clinical studies positively reduces unethical testing

**Boyle 21,** Senior Staff Writer, Association of American Medical Colleges ("Five ways that clinical trials might change for good," AAMC, https://www.aamc.org/news-insights/five-ways-clinical-trials-might-change-good) KD

Even before COVID-19, momentum was building among researchers, regulators, and sponsors to rethink the rules and practices that have built up over the years around clinical trials. The pandemic provided opportunities to test some of the ideas. “Major changes in clinical trials practice have been embraced nationwide,” a group of researchers wrote in the [Journal of the National Cancer Institute](https://academic.oup.com/jnci/advance-article/doi/10.1093/jnci/djaa162/5924372) last fall. “There is a growing consensus that the regulatory and clinical research process alterations that have been adopted in response to the pandemic … should be implemented long term.” Alan Bryce, MD, chair of the Division of Hematology and Medical Oncology at Mayo Clinic in Arizona, says most of the ideas share one objective: “We can make trials more friendly to both patients and staff.” Below are some of the main ideas for how to do that. **Recruit remotely** Participating in a clinical trial is such a big decision that researchers almost always sit down with potential participants in person to walk them through the process and answer all questions: about the science behind the therapy that’s being tested (including how an experimental drug works in the body), about procedure details (such as how often the person will have to visit the clinic where the trial is being conducted), about potential benefits (such as slowing degradation from a disease), and about risks (including side effects). The pandemic forced many researchers to conduct those conversations online and get written consent through electronic documents. That allowed people to join trials that they otherwise might not have. For example, Massachusetts General Hospital (MGH) and Boston Medical Center used a mix of in-person and remote meetings to enroll dozens of women in a study of breast cancer survivors, says Erica Warner, ScD, MPH, project director of the Harvard/MGH Center on Genomics, Vulnerable Populations, and Health Disparities. But while remote consent “sounds good in theory, many patients and research teams might not prefer it,” says Daniel Ford, MD, MPH, director of the Johns Hopkins Institute for Clinical and Translational Research (ICTR) in Baltimore. At the ICTR, **people didn’t sign up for trials any more frequently after remote consultations than they did through in-person meetings before the pandemic**, Ford says. Other trials reported mixed results. Researchers believe the remote process can impede their ability to personally connect with some potential participants and instill confidence in the trial. Still, they hope that remote screening and consent will remain an option. “We’re not saying replace” in-person consent, Vonderheide says. “We’re saying permit this tool to be deployed” in the right circumstances. **Reduce travel** One common impediment for participating in a clinical trial is traveling to the trial site for various procedures and consultations anywhere from every couple of months to several times a week. The burden is particularly heavy for people who must travel long distances or have limited access to transportation, such as those who need to use public transit or rely on someone to drive them to their appointments. “When a patient has to come to Center City Philadelphia once a week, and they live an hour away, that’s discouraging” for those who are thinking of joining a trial, Vonderheide notes. During the pandemic, researchers rethought what procedures needed to be done in person. “Suddenly, you could do video visits” and accomplish many of the same objectives, explains Bryce at Mayo. Some trials at Mayo, he explains, **expanded the period between required visits to the site by several weeks**. But as anyone who has joined a Zoom meeting knows, video gatherings can be clunky. Some patients are not adept at using computers and phones to participate in meetings. Others feel that in-person meetings give them more personal and focused attention, which can be especially important to people who are in a clinical trial to treat a severe disease, notes a [journal article](https://www.appliedclinicaltrialsonline.com/view/covid-19-and-its-impact-on-the-future-of-clinical-trial-execution) by researchers at Tufts University. “We’ll find the balance” on when to use remote and in-person visits, Ford says. **Send medicine** Traditionally, clinical trial medications are administered at the trial site, where staff can assess patients to determine **if doses should be changed, correctly administer the drugs**, and (in some cases) monitor the effects. During the pandemic, many patients were reluctant or unable to come in to receive their medications. Some trials started sending research medicines to their patients — particularly those that people could easily and safely take at home, such as certain pills and liquids. Several factors must be taken into account, explains Ruben Mesa, MD, executive director of the Mays Cancer Center, home to UT Health San Antonio MD Anderson. The center’s questions included: Does the medication require special skills or supplies (such as injections)? Does it need to be shipped or stored in a specific way (such as at certain temperatures)? Can the researchers monitor the patient remotely to adjust the doses if necessary? Adopting this as a routine procedure would make it easier for people to join and remain in trials — especially those who travel long distances to get to the trial site. “You’ve got to drop everything and hang out at the medical center that’s providing the medicine,” Mesa says of the requirement. “If a patient is self-administering a medicine, it certainly makes the trial much easier to participate in.” Mesa suggests that in the future, even medications that need to be administered by trained medical personnel — such as through an IV — could be sent to a medical facility near a patient’s home. He wonders, “What if you have a local doctor on the other side who is willing to accept the medicine and administer it to the patient?” **Reduce testing Participants in clinical trials often undergo a dizzying array of tests and biological data collection that they don’t understand the need for** — and sometimes the researchers don’t, either. Many of the procedures are required by government oversight agencies and trial sponsors (which provide funding, oversight, and data analysis), in part based on the theory that the more information that’s gathered, the better. “**Many of these tests are unnecessary for the purposes of the trial,**” Vonderheide notes. The requirements have grown over the years along with the development of more ways to measure and assess elements in the human body, like the makeup of tumors, says James Doroshow, MD, director of the Division of Cancer Treatment and Diagnosis at the National Cancer Institute. He notes that requirements have gradually expanded to a point “that is difficult to sustain.” “Someone has to get it [the sample] from the patient,” he explains. “Someone records that in the health record. It gets put into another database. It involves data managers, doctors, nurses, pharmacists. It becomes very expensive” and time-consuming. When COVID-19 hit, trial investigators worked with regulators and sponsors to implement several changes already under consideration to make testing less burdensome for patients. They reduced the number of tests required, lengthened the time between tests, and arranged for samples to be collected at sites closer to patients’ homes, such as at local hospitals. “We learned that not every blood test for every time point for every trial has to happen at our clinic,” Vonderheide explains. Collecting those samples at facilities near participants’ homes “was really convenient for patients. There was no degradation of data integrity and there was no danger to patient safety.” **Oversee from a distance** Staff from organizations that sponsor clinical trials typically spend a significant amount of time at the sites before and during the trials. They examine each site to ensure that it meets the sponsor’s requirements, train investigators on procedures such as data input, monitor the trial for quality control, and interview investigators and patients. “Clinical trials normally have a fairly intense face-to-face monitoring process,” Mesa says. Much of that work was done remotely during the pandemic. Monitors received data and reports electronically, conducted interviews by phone and videoconference, and had their questions answered by email. Many investigators and monitors think a lot of those practices should continue. The in-person visits “impose tremendous travel requirements on sponsor employees,” require significant coordination between trial and sponsor staff, and consume precious time and space at the site during the visits, nine University of Pennsylvania researchers wrote in a [paper published online](https://pubmed.ncbi.nlm.nih.gov/33849079/) last month in the journal Cancer. They urged that sponsors conduct “nearly all” of their activities remotely. “The pandemic has demonstrated that most sponsor activities can be performed virtually without compromising quality,” they wrote. In a [presentation last December](https://www.aaci-cancer.org/Files/Admin/Webinars/2020-12-16-CRI-Webinar-Virtual-Clinical-Trials.pdf) about remote monitoring and auditing of trials during the pandemic, administrators at Memorial Sloan Kettering Cancer Center presented data about the impact of that practice since it began there in 2011. The center, based in New York, reported that remote monitoring resulted in shorter visits between research associates and monitors, faster turnaround time for answering monitors’ questions, and significant cost reductions for each monitor. **Researchers are optimistic that regulators and sponsors will provide continuing flexibility to implement these and other changes**. Some **changes are already underway**: The Food and Drug Administration, which had started to explore clinical trial changes before the pandemic, published [updated guidelines](https://www.fda.gov/media/127712/download) last November. More revised guidelines appear likely, as everyone rethinks many of the trial requirements that have accumulated over the years. “A lot of questions [about requirements] are evolving,” Mesa says. “Which of them really were necessary versus which were just business as usual? What’s effective? What isn’t?”

### Plan

#### The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines with data exclusivity protections.

## Solvency

#### Shorter DE solves pricing by improving clinical trial success and efficiency – that resolves alt causes

**Kimball and Ragavan et al 20,** Vice President of Trade and International Affairs at the Association for Accessible Medicines, Professor at Texas A&M University School of Law, (Reconsidering the Rationale for the Duration of Data Exclusivity, Texas A&M University School of Law, Texas A&M Law Scholarship, 51 U. Pac. L. Rev. 525, https://scholarship.law.tamu.edu/facscholar/1399) KD

**For biologics, which are increasingly important (and expensive)** options for patients living with cancer, autoimmune and other maladies, **the exclusivity period is not only longer** (12 vs. 5-7.5 years in the United States), **but also provides a guaranteed market exclusivity period extending to 12 years**. During the first four years of the 12-year period, the **original reference brand product has both data exclusivity and market exclusivity,** based on the pathway described in Section 351(k) of the Public Health Services Act.6 Specifically, data exclusivity is provided to the original biologic drug for four years, during which time the **FDA cannot accept an application for a biosimilar product referencing that original product.** Following the end of that four-year period and for an additional eight years, a biosimilar manufacturer can submit a marketing authorization application, but the FDA cannot approve that application, resulting in a combined 12 years of market exclusivity for the original biologic product.7 Duke University professor Henry G. Grabowski had defended—and continues to defend8 —the 12-year exclusivity period for biologics.9 His study, published in 2008 with data from 2006 and earlier,(and paid for by the Pharmaceutical Research and Manufactures of America (“PhRMA”)), found that “break-even lifetime for the portfolio occurs at 12.9 years . . .. This sensitivity reflects the lengthy research and development (“R&D”) investment periods associated with pharmaceutical and biopharmaceutical investments.”10 Professor Grabowski takes the example of bevacizumab (Avastin; Genentech/Roche), which is one of the first of a new class of drugs to treat colorectal cancer. The paper illustrates that in 1997, Genentech submitted information on bevacizumab, a workable antibody, to the FDA. Although Phase I of the clinical trials commenced the same year, the trial finally ended in February 2004, allowing the FDA to approve bevacizumab as the first anti-angiogenic drug for treating cancer. While confirming that biologics overall had a better success rate than chemicals for approval, the study focuses on failure rates and probabilities of success as opposed to actual rates of success to arrive at the 12.9 years of exclusivity. Since its publication, this study has raised questions repeatedly, with critics challenging its premise that 12 years is necessary to incentivize the development of biosimilars.11 In fact, just recently, Nature Biotechnology found that “preclinical development times were not different between biologic and small-molecule drugs but were shorter for biologics.”12 The Grabowski argument is sometimes justified on the grounds that patents on biologics are not always granted and often are more susceptible to being invalidated. Hence, the wisdom is to bestow drug companies inordinate periods of exclusivity so they would not be discouraged from investing in research over biological substances. Others assert that “biotech products, like monoclonal antibodies, are very difficult for generic companies to develop and the absence of data exclusivity in a country would discourage the originator company from entering this market, which would have the deleterious effect of depriving people of the benefits of these drugs.”13 Nevertheless, even Professor Grabowski highlights a red-flag that can potentially choke competition in adding that, “**if data exclusivity periods are too long, price competition could be delayed beyond what is necessary to encourage innovation.”**14 Two important changes comport with the red flags that Professor Grabowski raises and consequently, makes his analysis dated. First, new technology such as AI has contributed to shortening the time required for clinical trial such that the long period of exclusivity is not justified. Second, **pharmaceutical companies have tended to seek additional periods of exclusivity such as through orphan designation or, pediatric exclusivity**.15 For example, in the United States, in addition to the data and market exclusivity period awarded for NCEs, **a pediatric exclusivity of 6 months,16 which is a form of market exclusivity for the pediatric designation is added to some existing drugs.** This extension attaches at the end of term if the sponsor submits pediatric studies on the active moiety in response to a Written Request from FDA. The real world experience of biologic producers demonstrates that exclusivity for biologics can be much longer than even the 12.9 years that Grabowski suggested. For an increasing number of approved biologics, a separate period of 7 years of exclusivity may be awarded under the Orphan Drugs Act for each use of the drug to treat an orphan condition.17 For the orphan indication, a biosimilar (section 351(k) of Public Health Services Act) product may not be licensed by the FDA until after the expiration of the 7-year orphan drug exclusivity period or the 12-year reference product exclusivity, whichever is later. Thus, if the product with a 12-year exclusivity gets approval for an orphan indication in its, say, 11th year, the biosimilar will benefit from 17 years of different forms of hybrid exclusivities.18 Recently, National Public Radio reported that more than 70 drugs) that were approved as Orphan Drugs were in fact familiar brand names which were strategically later approved as orphans - out of the 148 records the Government Accountability Office reviewed, 38.5% had been previously approved drugs.19 Such examples include popular mass market drugs, such as the cholesterol blockbuster Crestor, Abilify for psychiatric conditions, cancer drug Herceptin, and rheumatoid arthritis drug Humira, which is the best-selling medicine in the world (earning more than $19 billion in 2018 alone).20 Each of these represent the reapproval of a mass marketed drug as an orphan drug when their patent was about to expire. In essence, **the orphan status essentially enabled an additional seven years of exclusivity for a drug which already benefitted from patent protection as well as one layer of data and market exclusivity for treating another disease**. **This phenomenon is the red-flag** that Grabowski himself highlighted, making a case **for reduced term of protection.** Second, the use of **a**rtificial **i**ntelligence, **biomarkers**, patient-centered mobile technology, and other medical and technological advancements has improved drug candidate identification, patient participation in and engagement during clinical trials, and the overall likelihood of trial success. For example, in oncology, advanced analytics and the increased use of biomarkers have improved the ability to identify unique gene signatures and support the identification of clinical trial participants at a faster rate and with greater precisions than previously. Considering these developments, IQVIA’s Clinical Trial Trends Impact Assessment tool suggests that there will be a **104% and 71% increase in oncology R&D productivity because of advanced analytics and biomarkers**, respectively.21 Technological advancements such as these promise to **significantly reduce the time between initial research and regulatory approval, increase the likelihood of trial success**, **while also reducing the cost of such trials**. In doing so, they defy the logic behind the Grabowski analysis based on which the current terms of exclusivity are structured. That is, as these technologies are increasingly used in biopharmaceutical R&D, **the need for long periods of exclusivity is reduced**. In fact, **as technology advances** and continues to increase efficiencies in drug development, **the case for lengthy exclusivity periods weakens considerably.**

#### The plan removes additional protections and slashes monopoly periods to create adequate development incentives.

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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 trialsand 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](https://www.idhifapro.com/?gclid=CjwKCAjw88v3BRBFEiwApwLevS3Uoaz8j88YmtjR87NpozN6lP98nFBS6pLNudVhVAyn2s3iyZS-QRoCmXoQAvD_BwE) 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](https://www.fda.gov/news-events/press-announcements/fda-approves-new-targeted-treatment-relapsed-or-refractory-acute-myeloid-leukemia) 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.,](https://scholarship.law.tamu.edu/cgi/viewcontent.cgi?article=2385&amp;context=facscholar) 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,](https://www.benchsci.com/) 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.

#### International medical cooperation strengthens global health initiatives

**Diallo 21,** Researcher and Project Coordinator at Access to Medicine Foundnation, guides pharmaceutical companies to do more for low and middle-income countries without access to medicine ("Why access matters," Access to Medicine Foundation, https://accesstomedicinefoundation.org/access-to-medicine-index/about-the-index/why-access-matters#) KD

**Sustained commitments and deeper cooperation** The constitution of the World Health Organization (WHO) asserts that all people have the right to the highest attainable standard of health, yet **access to medicine continues to be out of reach for an estimated two billion people**.Further, about 100 million people are pushed into extreme poverty because they have to pay for healthcare. **New and complex health challenges continue to emerge, demanding sustained commitments and deeper cooperation across the ecosystem of global health stakeholders**, as well as wider adoption of proven solutions. Achieving universal healthcare is critical to help populations access health services they need without financial constraint. Access to medicines is an important part of this. Increasing access depends on a range of factors and involves action from a variety of parties. The pharmaceutical industry, in collaboration with the global health community, plays a critical role in responding to defined priorities for global health, developing much-needed innovative products, **expanding access to those products that already exist and forging new partnerships to promote sustainable, long-term access to medicines. Global health issues hit lower-income countries the hardest** The growth in development aid for health has fallen in recent years as donor government budgets have tightened. This is particularly concerning for low-income countries that rely heavily on aid to provide health services to their populations. Low-income countries are being hit the hardest: in these countries, **government health expenditure as a percentage of GDP has been in decline in recent years, resulting in more needing to be done with less.** In 2015, the UN agreed the Sustainable Development Goals, including global health targets such as the elimination of major disease epidemics and the reduction in the burden of childhood obesity. To ramp up progress towards these goals, in September 2019, the UN Secretary General called for a Decade of Action to deliver the Global Goals by 2030. Progress in global health is not inevitable. Non-communicable diseases (NCDs) such as diabetes, cancer and heart disease are a growing challenge due to rapid urbanisation, worsening diets and increasingly sedentary lifestyles, they account for 71% of deaths globally each year, including 15 million people aged between 30 and 69 years, with more than 85% of these so-called premature deaths occurring in low- and middle-income countries**. Access to prevention, detection, screening, treatment for NCDs is essential.** In addition, new public health crises have posed further challenges to global health and have put more pressure on already strained health systems and families paying out of pocket for health services. For instance, in 2019 the resurgence of measles was a threat with 6,000 deaths recorded in the Democratic Republic of the Congo by January 2020. **Antimicrobial resistance,** **which already causes more than 700,000 deaths each year worldwide, is growing.** The newly emergent coronavirus (SARS-CoV-2) which causes a severe acute respiratory disease, COVID-19, was identified in Wuhan, China in December 2019 and has been declared a global health pandemic by the World Health Organization since March 2020. To help address current and future global health issues, **governments and regulators** – as well as stakeholders from the public and private sectors – need to develop, support and implement **innovative** practices to reach more people in need. **Through international cooperation, progress is being made** Despite significant global health challenges, milestones have been reached. These demonstrate that effective approaches are being developed and applied and exemplify the impact that international collaboration and coordination can have on the **health of billions.** For example, under-five child mortality dropped by 59% between 1990 and 2018. There has been more than a 56% decline in AIDS-related deaths since the peak of the HIV/AIDS epidemic in 2004, and more than half of all people living with HIV/AIDS are accessing antiretroviral therapy. In 2017, 81% of countries had a national action plan addressing cancer, up from 66% in 2013, and WHO member states endorsed a set of measures in 2017 to improve cancer control. Vaccine campaigns are enabling movement towards elimination of polio in Haiti, meningitis in 26 countries in sub-Saharan Africa and hepatitis B in China**. New global health conventions and commitments** – including the 2017 London Summit on Family Planning and the 2018 UN High Level Meeting on Ending Tuberculosis, as well as the UN High-Level Meeting on Non-Communicable Diseases – **are helping to set additional priorities, with the goal of inspiring global action.** Progress is being made against neglected tropical diseases (NTDs), with the number of people requiring treatment and care for NTDs dropping from 2.03 billion to 1.58 billion between 2010 and 2017. The Ebola outbreaks which occurred in the Democratic Republic of the Congo in 2018 were contained more quickly than the 2014-2016 West Africa Ebola outbreak was in part due to quicker response times and the use of novel medicine and vaccine candidates.

#### That solves bioterror attacks and antimicrobial resistance, the key internal link to sustained pandemics

* AMR -> no herd immunity -> longer-lasting and stronger pandemics

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There is growing recognition of the **costs and significance of AMR**. Multi-resistant organisms are emerging at much higher rates than seen previously, with **urgent attention needed to mitigate a risk which is predicted in one report to be the greatest global burden of disease** (Review on Antimicrobial Resistance [2016](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR65)). One recent estimate indicates that **by 2050, infections from resistant bacteria may overtake cancer as the leading cause of death in the world and cost US$100 trillion.** This estimate has been questioned and likely an overestimate, but AMR nonetheless causes a significant burden of disease (De Kraker et al. [2016](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR18)). The world is in urgent need of **new strategies** in the human, animal, agricultural and food industries. This includes **reviewing how we price/value antimicrobials, incentives for new antimicrobial development and judicious use, and restrictions around use across sectors**. In addition, **serious AMR could be engineered and released as an act of bioterrorism**, **given** the availability of **technology such as CRISP Cas9** (MacIntyre and Bui [2017](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR42)). A longer-term model of population risk (versus immediate individual risk of often minor infection) is required to guide everyday use and mitigate this global threat. **Whether a bioterrorist attack, pandemic or infections complicated by AMR**, the risk is increasing as outlined above. Infectious diseases do not respect international borders and can spread rapidly around the world. The continued growth in large urban areas, and megacities in particular, in which high population densities represent optimum conditions for spread of infection merits significant attention in biosecurity. This **risk is** **heightened** for megacities **in developing countries in which serious gaps exist in public health surveillance for early detection of epidemic threats**, together with **inadequate critical infrastructure** and other preparedness resources. Prevention, mitigation and control of these threats, therefore, require efforts at local, national and global levels. Despite the call for a One Health approach (Rabinowitz et al. [2013](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR63)), there is **no suitable system for governing use of antimicrobials across human health, animal health and food production, and often no coordination of efforts across these sectors.** **Global legal and governance frameworks for pandemics and bioterrorism are critical**, but there are **gaps in some relevant regulations**—the International Health Regulations (IHR) (World Health Organization [2017c](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR95)), the Biological Weapons Convention (BWC) (United Nations Office for Disarmament Affairs [2016](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR85)) and the Cartagena Protocol (Convention on Biological Diversity [2012](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR15)). The IHR provides a framework for epidemic preparedness, **but many countries do not have the resources to comply with them**, and the IHR has not been fully revised since 2005 (World Health Organization [2008](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR90)). The BWC was revised in 2016, but widely regarded as unenforceable and inadequate in **considering new technologies** such as CRISPR Cas9 (Bulletin of the Atomic Scientists [2016](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR9)). The Cartagena protocol was developed to address regulation of movements of living modified organisms (LMOs) resulting from biotechnology from one country to another, but has focused on ecology and biodiversity and has not been utilised for human biosecurity. The TAPIC framework (Trump [2017](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR81)) is a good starting point for considering how existing regulations can be improved and enforced and how new ones could be developed globally.

#### Bioterrorism and future pandemics cause extinction.

Hamish De Bretton-Gordon, CBRN Expert @ British Army, 20 [Director @ DBG Defense, Consultant on CBRN and Biosecurity], “Biosecurity in the Wake of COVID-19: The Urgent Action Needed,” Combatting Terrorism Center Sentinel, November/December 2020, Volume 13, Issue 11, <https://ctc.usma.edu/biosecurity-in-the-wake-of-covid-19-the-urgent-action-needed/>

Policymakers around the world did not grasp just how large the impact of a bio threat could be. Beyond the enormous human and economic impact, the current pandemic has exposed the weakness, lack of preparedness, and poor responsiveness of healthcare systems of even highly developed countries like the United States and the United Kingdom. And the virus has inflicted carnage, even though SARS-CoV-2 (the virus that causes COVID-19) is not especially virulent. The world may be confronted with other viruses in the future whose combination of virulence (the harm a pathogen does to its host), transmissibility, and other characteristics pose much greater danger. While overwhelming evidence points to SARS-CoV-2 spontaneously spreading to humans, the advances in synthetic biology and the growth in the number of Level 3 and 4 biocontainment facilities around the world storing deadly viruses1 mean there is also the very real possibility that in the future, bad actors will try to engineer or steal/obtain a highly transmissible and highly virulent virus and unleash it onto the world. Another risk is accidental releases from such biocontainment facilities. COVID-19, a highly transmissible but not very virulent pathogen, has had a devastating global impact, a fact that will not have gone unnoticed by rogue states and terror organizations. Advances in synthetic biology have created tools that could be put to malevolent use. In the last two decades, scientists synthesized the poliovirus from its genetic sequence,2 recreated the 1918 Spanish flu virus,3 and succeeded in **modifying the H5N1 avian flu virus so that it resulted** (in a research laboratory) **in airborne transmission** among mammals.4 In the future, we should think of weaponized biology as no less of an existential threat to the planet than weaponized atomic science. It should also be noted that the fear and panic that even a medium-scale bioterror attack could create could have dangerous implications that may rival or even surpass the immediate loss of life. The Need to Rethink Likelihood Given the fact that in late 2019 when, as far as is known, COVID-19 cases first started emerging in China, it had been more than a century since the previous catastrophic outbreak (the 1918-1919 “Spanish flu” pandemic),d it was unsurprising that many thought of such pandemics as a one-in-a-100-year event. Such assumptions should no longer hold. The encroachment of human settlements into areas that had previously been sanctuaries for wildlife5 and the popularity in some parts of the world of markets where people and wild animals are brought into proximity have made it more likely viruses will make the species leap to human beings.e And when they do, as the COVID-19 pandemic illustrated, the interconnectedness of a world in which millions of people fly each day6 means they can spread very rapidly. There is also growing concern about engineered viruses. Not only have advances in synthetic biology (SynBio) created growing capacity for extremely dangerous viruses to be engineered in a laboratory, but the number of people with access to potentially dangerous ‘dual use’ technology has greatly expanded and continues to expand, making malevolent use of such technology ever more likely. In the August 2020 issue of this publication, scientists at the U.S. Military Academy at West Point warned that: The wide availability of the protocols, procedures, and techniques necessary to produce and modify living organisms combined with an exponential increase in the availability of genetic data is leading to a revolution in science affecting the threat landscape that can be rivaled only by the development of the atomic bomb. As the technology improves, the level of education and skills necessary to engineer biological agents decreases. Whereas only state actors historically had the resources to develop and employ biological weapons, SynBio is changing the threat paradigm. The cost threshold of engineering viruses is also lowering, with the West Point scientists warning that synthetic biology has “placed the ability to recreate some of the deadliest infectious diseases known well within the grasp of the state-sponsored terrorist and the talented non-state actor.”7 As already noted, another source of vulnerability is that deadly viruses could be stolen from or escape from a research laboratory. There are now around 50 Biosafety Level 4f facilities around the world, where the deadliest pathogens are stored and worked on, and this figure is set to increase in the next few years.g This is a large increase over the last 30 years, creating bigger risk of a breach. Of equal, if not greater concern are the thousands of Biosafety Level 3 labs globally,8 which handle deadly pathogens like COVID-19.9 Given what has been outlined above, the risk of a future destructive biological attack or another devastating global pandemic should no longer be seen as low. From this point forward, there should no higher priority for the international community than biosecurity.