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Framework

Psychological evidence proves we don't identify with our future selves.

Opar 14. [Alisa Opar (articles editor at Audubon magazine; cites Hal Hershfield, an assistant professor at New York University's Stern School of Business; and Emily Pronin, a psychologist at Princeton) "Why We Procrastinate" Nautilus January 2014]

"The British philosopher Derek Parfit espoused a severely reductionist view of personal identity in his seminal book, Reasons and Persons: It does not exist, at least not in the way we usually consider it. We humans, Parfit argued, are not a consistent identity moving through time, but a chain of successive selves, each tangentially linked to, and yet distinct from, the previous and subsequent ones. The boy who begins to smoke despite knowing that he may suffer from the habit decades later should not be judged harshly: "This boy does not identify with his future self," Parfit wrote. "His attitude towards this future self is in some ways like his attitude to other people." Parfit's view was controversial even among philosophers. But psychologists are beginning to understand that it may accurately describe our attitudes towards our own decision-making: It turns out that **we see our future selves as strangers.** Though we will inevitably share their fates, the people we will become in a decade, quarter century, or more, are unknown to us. This impedes our ability to make good choices on their—which of course is our own—behalf. That bright, shiny New Year's resolution? If you feel perfectly justified in breaking it, it may be because it feels like it was a promise someone else made. "It's kind of a weird notion," says Hal Hershfield, an assistant professor at New York University's Stern School of Business. "On a psychological and emotional level **we really consider that future self as if it's another person." Using MRI, Hershfield and colleagues studied brain activity changes when people imagine their future and consider their present. They homed in on two areas** of the brain called the medial prefrontal cortex and the rostral anterior cingulate cortex, which are **more active when a subject thinks about himself than when he thinks of someone else. They found these same areas were more strongly activated when subjects thought of themselves today, than of themselves in the future. Their future self "felt" like somebody else. In fact, their neural activity when they described themselves in a decade was similar to that when they described Matt Damon** or Natalie Portman. And subjects whose brain activity changed the most when they spoke about their future selves were the least likely to favor large long-term financial gains over small immediate ones. Emily Pronin, a psychologist at Princeton, has come to similar conclusions in her research. In a 2008 study, Pronin and her team told college students that they were taking part in an experiment on disgust that required drinking a concoction made of ketchup and soy sauce. The more they, their future selves, or other students consumed, they were told, the greater the benefit to science. Students who were told they'd have to down the distasteful quaff that day committed to consuming two tablespoons. But those that were committing their future selves (the following semester) or other students to participate agreed to guzzle an average of half a cup. We think of our future selves, says Pronin, like we think of others: in the third person.

This means util is the only coherent moral theory. A. Since there are not continuous persons, distribution of goods among people is irrelevant, so we just maximize benefits among people. B. It is impossible to violate a constraint since identity is in constant flux. Anything such as a promise a made a year ago is no long my promise, etc.

And

All humans have an intrinsic desire to preserve wellbeing and minimize pain.

Nagel '86. [Thomas Nagel 86, The View From Nowhere, HUP, 1986: 156-168].

I shall defend the unsurprising claim that sensory **pleasure is good and pain [is] bad,** no matter whose they are. The point of the exercise is to see how the pressures of objectification operate in a simple case. Physical pleasure and pain do not usually depend on activities or desires which themselves raise questions of justification and value. **They are** just [is a] **sensory experiences in** relation tO **which** we are fairly passive, but toward which **we feel involuntary desire or aversion.** Almost

everyone takes the avoidance of his [her] own **pain and the promotion of** his [her] own **pleasure as** subjective **reasons for action** in a fairly simple way; **they are not back[ed] up by any further reasons**. On the other hand if someone pursues pain or avoids pleasure, either it as a means to some end or it is backed up by dark reasons like guilt or sexual masochism. What sort of general value, if any, ought to be assigned to pleasure and pain when we consider these facts from an objective standpoint? What kind of judgment can we reasonably make about these things when we view them in abstraction from who we are? We can begin by asking why there is no plausibility in the zero position, that pleasure and pain have no value of any kind that can be objectively recognized. That would mean that I have no reason to take aspirin for a severe headache, however I may in fact be motivated; and that looking at it from outside, you couldn't even say that someone had a reason not to put his hand on a hot stove, just because of the pain. Try looking at it from the outside and see whether you can manage to withhold that judgment. If the idea of objective practical reason makes any sense at all, so that there is some judgment to withhold, it does not seem possible. If the general arguments against the reality of objective reasons are no good, then it is at least possible that **I have a reason,** and not just an inclination**, to refrain from putting my hand on a hot stove.** But given the possibility, it seems meaningless to deny that this is so. Oddly enough, however, we can think of a story that would go with such a denial. It might be suggested that the aversion to pain is a useful phobia—having nothing to do with the intrinsic undesirability of pain itself—which helps us avoid or escape the injuries that are signaled by pain. (The same type of purely instrumental value might be ascribed to sensory pleasure: the pleasures of food, drink, and sex might be regarded as having no value in themselves, though our natural attraction to them assists survival and reproduction.) There would then be nothing wrong with pain in itself, and someone who was never motivated deliberately to do anything just because he knew it would reduce or avoid pain would have nothing the matter with him. [S]He would still **[People] have involuntary avoidance reactions**, otherwise it would be hard to say that [s]he felt pain at all. And [s]he would be motivated to reduce pain for other reasons—because it was an effective way to avoid the danger being signaled, or because interfered with some physical or mental activity that was important to him [or her]. He just wouldn't regard the pain as itself something he had any reason to avoid, even though he hated the feeling just as much as the rest of us.

And

Only pleasure and pain are intrinsically valuable – all other values can be explained with reference to pleasure.

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

I think several things should be said in response to Moore's challenge to hedonists. First, I do not think the burden of proof lies on hedonists to explain why the additional values are not intrinsic values. If someone claims that X is intrinsically valuable, this is a substantive, positive claim, and it lies on him or her to explain why we should believe that X is in fact intrinsically valuable. Possibly, this could be done through thought experiments analogous to those employed in the previous section. Second, there is something peculiar about the list of **additional intrinsic values** that counts in hedonism's favor: the listed values have a strong **tend**ency **to be** well **explained as things that** help **promote pleasure and avert pain.** To go through Frankena's list, **life** and **consciousness** are necessary presuppositions for pleasure; **activity,** health, and strength **bring about pleasure;** and happiness, beatitude, and contentment are regarded by Frankena himself as "pleasures and satisfactions." The same is arguably true of beauty, harmony, and "proportion in objects contemplated," and also of affection, friendship, harmony, and proportion in life, experiences of achievement, adventure and novelty, self-expression, good reputation, honor and esteem. Other things on Frankena's list, such as understanding, wisdom, freedom, peace, and security, although they are perhaps not themselves pleasurable, are important means to achieve a happy life, and as such, they are things that hedonists would value highly. Morally good dispositions and virtues, cooperation, and just distribution of goods and evils, moreover, are things that, on a collective level, contribute a happy society, and thus the traits that would be promoted and cultivated if this were something sought after. To a very large extent, the intrinsic values suggested by pluralists tend to be hedonic instrumental values. Indeed, pluralists' suggested intrinsic values all point toward pleasure, for while the other values are reasonably explainable as a means toward pleasure, pleasure itself is not reasonably explainable as a means toward the other values. Some have noticed this. Moore himself, for example, writes that though his pluralistic theory of intrinsic value is opposed to hedonism, its application would, in practice, look very much like hedonism's: "Hedonists," he writes "do, in general, recommend a course of conduct which is very similar to that which I should recommend."24 Ross writes that "[i]t is quite certain that by promoting virtue and knowledge we shall inevitably produce much more pleasant consciousness. These are, by general agreement, among the surest sources of happiness for their possessors."25 Roger Crisp observes that "those goods cited by non-hedonists are goods we often, indeed usually, enjoy."26 What Moore and Ross do not seem to notice is that their observations give rise to two reasons to reject pluralism and endorse hedonism. The first reason is that if the suggested non-hedonic intrinsic values are potentially explainable by appeal to just pleasure and pain (which, following my argument in the previous chapter, we should accept as intrinsically valuable and disvaluable), then—by appeal to Occam's razor—we have at least a pro tanto reason to resist the introduction of any further intrinsic values and disvalues. **It is ontologically** more **costly to posit a plurality of intrinsic values and disvalues, so in case all values admit** of **explanation by reference to a single intrinsic value and** a single intrinsic **disvalue, we have reason to reject more complicated accounts.** The fact that suggested non-hedonic intrinsic values tend to be hedonistic instrumental values does not, however, count in favor of hedonism solely in virtue of being most elegantly explained by hedonism; it also does so in virtue of creating an explanatory challenge for pluralists. The challenge can be phrased as the following question: If the non-hedonic values suggested by pluralists are truly intrinsic values in their own right, then why do they tend to point toward pleasure and away from pain?27

Thus, the value is morality, and the standard and role of the ballot is maximizing social welfare. Prefer additionally because:

1) Hijacks Other Frameworks: Threats to bodily security and 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, so stopping death is a prerequisite to other frameworks.

2) Degrees of Wrongness: Only consequentialism explains degrees of wrongness—if I break a promise to meet up for lunch, that is not as bad as breaking a promise to take a dying person to the hospital. Only the consequences of breaking the promise explain why the second one is much worse than the first. Intuitions outweigh—they're the foundational basis for any argument.

Resolved: The member nations of the WTO ought to reduce intellectual property protection for medicines.

Definitions

"Intellectual Property" is defined as "a work or invention that is the result of creativity, such as a manuscript or a design, to which one has rights and for which one may apply for a patent, copyright, trademark, etc." by Oxford Languages.

"Reduce" is defined as "to make something less in size, amount, degree, importance, or price" by Cambridge.

"Medicines" is defined as "a substance, especially in the form of a liquid or a pill, that is a treatment for illness or injury" by Cambridge.

"Vaccines are medicines that contain weakened or dead bacteria or viruses" by the Medical Dictionary. So in this resolution, a vaccine will be considered.

Contention 1- Increases Health Gaps

Many pharmaceutical manufacturers develop "patent thickets", which discourages competitors from entering the market.

CRS 20 [Congressional Research Center, "Drug Pricing and Pharmaceutical Patenting Practices", February 11 2020, https://sgp.fas.org/crs/misc/R46221.pdf]

Critics have argued that pharmaceutical manufacturers develop "patent thickets" to protect their products. This term is used in two slightly different ways, both relating to products covered by a high number of patents. **First, a patent thicket may describe the situation in which multiple parties have overlapping patent rights on one product, such that a "potential manufacturer must negotiate licenses with each patent owner in order to bring a product to market without infringing." Patent thickets, in this sense, raise concerns about inefficient exploitation of a technology because the multiplicity of patent owners increases transaction costs and creates coordination challenges. Second, the term may be used in a different sense to describe an incumbent manufacturer's practice of amassing a large number of patents relating to a single product, with the intent of intimidating competitors from entering the market, or to make it too costly and risky to do so.**

These patent thickets drive up prices dramatically, making it harder to gain access to generic drugs.

I-Mak 18 1 [Initiatives for Medicines, Access, and Knowledge, "Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices" August 2018, http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf]

A recently issued report by I-MAK shows the extent of this problem. **I-Mak found that, on average, across the top 12 grossing drugs in America: There are 125 patent applications filed and 71 granted patents per drug. Branded drug prices have increased by 68 percent since 2012, and only one of the top 12 drugs has actually decreased in price. There are 38 years of attempted patent protection blocking generic competition sought by drugmakers for each of these top grossing drugs – or nearly double the 20-year monopoly intended under U.S. patent law. These top-grossing drugs have already been on the U.S. market for 15 years. Over half of the top 12 drugs in America have more than 100 attempted patents per drug.**

Many Big Pharma companies game the patenting system to stop generic competition and make the most profit: for example, Pfizer's patenting strategy with Lyrica.

I-Mak 18 2 [Initiatives for Medicines, Access, and Knowledge, "Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices" August 2018, http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf]

Lyrica, one of Pfizer's top-selling drugs used to treat neuropathic pain, **is a prime example of the type of over-patenting based on trivial inventions that are often used by drugmakers in order to artificially extend their commercial exclusivity while raising prices. With a first patent filed in 1995, and the drug on the market for the past fourteen years, Lyrica has been a major source of revenue for Pfizer. The drug grossed over $5 billion in global sales last year, $3 billion of from U.S. payers, including insurance companies and Medicare and Medicaid. The commercial success of this product was driven in large part by the 163% price increases in the last six years, the most severe hike amongst the top twelve drugs.** Additionally, the drug ranked as the second-highest (behind Humira) in total amount of direct-to-consumer spending in 2017 with $216 million spent by Pfizer on television ads alone10. **Lyrica was set to go off-patent at the end of 2018 and the entry of generic competition would have quickly and markedly reduce Pfizer's revenue from Lyrica by 70-90% in less than two years. But Pfizer had filed and was issued patents for an additional twenty year period on a controlled-release formulation of the product (Lyrica CR), meaning that patients would take a single pill instead of two or three pills daily. With these patents, Pfizer's hold on the market will remain and, if history is a guide, they will continue major repeated increases in the price of the drug. Pfizer's patenting strategy with Lyrica illustrates how drugmakers game the patent system in order to extend the patent-protected lifespan of their key products and garner billions more in revenue beyond the twenty year period.**

Enabling drugmakers to maintain patent monopolies far beyond twenty years has significant consequences on the American healthcare system.

I-Mak 18 3 [Initiatives for Medicines, Access, and Knowledge, "Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices" August 2018, http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf]

The strategy to expand **monopolies** without any meaningful new science or invention **exacts a heavy cost on American payers and households. Specifically, these twelve highest grossing drugs cost $96 billion to health insurers, government payers, and consumers in 2017 alone. Since drugmakers often continue to increase the prices of medicines once or twice a year, even after the product has already been on the market for many years,**

revenues may continue to grow for these medicines until there is generic competition.

Generic competition is the only way of sustainably reducing medicine and drug prices.

Hosford 21 [Derek Hosford, 4-7-2021, "Want Lower Drug Costs? Increase Generic Competition," American Consumer Institute, https://www.theamericanconsumer.org/2021/04/want-lower-drug-costs-increase-generic-competition/]

Over the last decade, generic drugs have saved patients around $2.2 trillion, according to an AAM study by IQVIA. Generics work in the same way as name brands and have the same clinical benefits. Despite using approved formulas and ingredients, **generic drugs are required to demonstrate the same levels of performance and safety to receive Food and Drug Administration (FDA) approval. The entry of new generic drugs into the market is proven to lower the cost of prescription medications. Data from a 2019 FDA study showed that 6 or more generic producers would cause prices to be 95% cheaper than the brand name alternative. An analysis by the Association for Accessible Medicine found similar results, showing that access to generics would save seniors over $4 billion per year.**

Increased IP protections are delaying generic competition and increasing prices, which cuts off a lifeline for poorer communities.

Kwon 15 ["(PDF) The Effects of Intellectual Property Rights on Access to Medicines and Catastrophic Expenditure," ResearchGate, https://www.researchgate.net/publication/278732481_The_Effects_of_Intellectual_Property_Rights_on_Access_to_Medicines_and_Catastrophic_Expenditure]

Following is the list of 22 patentable pharmaceuticals: Cefuroxime sodium, Cefaclor, Netilmicin, Albendazole, Fluoxetine, Aciclovir, Domperidone, Ranitidine, Cefotaxime Sodium, Ketorolac, Norfloxacin, Pefloxacin, Ketoconozole, Famotidine, Enalapril Maleate, Omeprazole, Astemizole, Ceftazidime, Ciprofloxacin, Ofloxacin, and Roxithromycin). **This price rise was estimated from 26% up to 242%, depending on demand function.** Maskus and Konan7 and Subramanian8 estimated maximum price increases up to 67% as a result of the introduction of pharmaceutical product patent rights. **In addition to these increases in medicine prices, disparities in pharmaceutical research and development are expected to grow because the current system for IPR does not provide an incentive for pharmaceutical companies to invest in developing medicines for the treatment of neglected diseases in poor countries.** 9–12 Me´decins Sans Frontie`res estimates that 90% of the world's health research and development expenditure is devoted to conditions that affect just 10% of the world's population, with priority conditional upon ability to pay.13 Global inequities in access to medicines are also obvious. **Nearly one-third of the**

world's population is estimated to lack regular access to essential medicines that they need, a figure that rises to one in two in the most impoverished parts of Africa and Asia. In 2006, just 20% of the world's population in high-income countries was responsible for about 80% of global pharmaceutical sales, whereas the poorest 80% of the population in developing countries accounted for only 20% of global pharmaceutical expenditures.

The high prices lead to the death of millions, or cause them to spend unreasonable amounts of money.

Mehta 14 [8-6-2014, "Patenting of life-saving drugs has created a global health crisis where human life has become a commercial commodity.," Impact of Social Sciences, https://blogs.lse.ac.uk/impactofsocialsciences/2014/08/06/the-morality-of-patenting-life-saving-drugs/]

Scholarly research in this area can discern the fault lines in the theoretical basis of the economics of health care models and economics of drug pricing followed world over. Sustained high quality research in this area can result in improving the quality and life expectancy for millions who have no say in this matter. **Today about 14 million people die every year from infectious diseases surprisingly many of which are curable and preventable** such as acute respiratory infections, diarrhoeal diseases, malaria and tuberculosis. **The death toll is unacceptably high specially in developing nations. This health crisis is largely due to the lack of economic accessibility of life saving medicines.** Many of the lifesaving drugs are also beyond the reach of common man. For example, the cost of drug used for the treatment of bone cancer costs £2,375 for one dose and £114,000 pounds for a full course of 48 doses making it highly unaffordable. **High prices of such drugs and medicines can be attributed to the patenting system which allows the drugs companies to gain a monopoly over the production and marketing of pharmaceutical products and processes permitting them to fix prices at high rates to maximize profits.** Millions of diseased people round the world —mostly in developing countries—lack access to life-saving drugs.

Increased patent protections also prevent the distribution of vaccines to many countries.

Lindsey 21 [Brink Lindsey, 6-3-2021, "Why intellectual property and pandemics don't mix," Brookings, https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/]

The world needs around 11 billion doses of coronavirus vaccine to immunize 70% of the world's population, assuming two doses per person. As of last month, orders had been confirmed for 8.6 billion doses, a remarkable achievement. But some 6 billion of these will go to high- and upper-middle-income countries. Poorer nations — which account for 80% of the world's population — so far have

access to less than one-third of the available vaccines. One reason for this imbalance is that wealthier countries have been able to place substantial advance orders with the relatively small group of companies that are making vaccines, most of which are based in richer countries. Unless manufacturing and supply can be distributed more evenly, researchers forecast that it will be at least another two years before a significant proportion of people in the lowest-income countries are vaccinated.

This prevents herd immunity leading to the exposure of many new mutants, and eventually extinction.

Government spends a lot of money on bad health.

TPC 20 [Tax Policy Center, xx-xx-xxxx, "How much does the federal government spend on health care?," https://www.taxpolicycenter.org/briefing-book/how-much-does-federal-government-spend-health-care]

The federal government spent nearly $1.2 trillion on health care in fiscal year 2019 (table 1). Of that, Medicare claimed roughly $644 billion, Medicaid and the Children's Health Insurance Pro-gram (CHIP) about $427 billion, and veterans' medical care about $80 billion. In addition to these direct outlays, various tax provisions for health care reduced income tax revenue by about $234 billion. Over $152 billion of that figure comes from the exclusion from taxable income of employers' contributions for medical insurance premiums and medical care. The exclusion of employer contributions to medical care also substantially reduced payroll taxes, though that impact is not included in official tax expenditure estimates. Including its impact on both income and payroll taxes, the exclusion reduced government revenue by $273 billion in 2019.

With more generic competition, we can reduce spending money on bad health and redirect the funds to things like solving climate change, etc.

Contention 2- Data Exclusivity

TRIPs Plus Provisions, namely data exclusivity, are being used in many bilateral trade agreements.

Thrasher et al 21 [Thrasher, Rachel, Veronika J. Wirtz, Warren Kaplan, Kevin P. Gallagher, Hattie Werk. "How Data Exclusivity Laws Impact Drug Prices:" *Global Development Policy Center Chart of the Week How Data Exclusivity Laws Impact Drug Prices Comments*, 25 May 2021, www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data]

Despite these decisions at Doha (and post-Doha) there continue to be concerns about the extent to which the trading system is compatible with SDG 3. **Trading partners from high-income countries continue to pursue bilateral and regional trade agreements that seek intellectual property and investment protections beyond what is required by the TRIPS Agreement (TRIPS-plus).** Those same partners also tend to **limit the adoption and use of public health flexibilities in the TRIPS Agreement**

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

Replicating a drug as an alternative to data exclusivity is costly and inefficient.

Park 21 [Caroline Park, 7-7-2021, "Data Exclusivity: What is it and why does it matter?," No Publication, https://www.senseandsustainability.net/2016/01/20/data-exclusivity-what-is-it-and-why-does-it-matter/]

In the situation where a compound is covered by data exclusivity but not by a patent, a company can create a knock-off generic based on the original compound's chemical properties. And nothing legally bars that company from generating its own data to eventually market the generic drug. The lack of legal barriers, however, is meaningless, because the financial barrier is essentially insurmountable. No company will go through the effort of replicating a full three-pronged clinical trial process for a drug that is already on the market. Though price secrecy is ubiquitous in the pharmaceutical industry, it is well-known that **the bulk of production cost comes from the clinical trials. A highly-cited Tufts study on pharmaceutical data in 2003 suggests that the average total development cost of a new drug is US$800 million, of which 60% is incurred through clinical trials. As**

of 2014, the Tufts Center for the Study of Drug Development has updated that cost to $2.6 billion, which is the number that PhRMA (Pharmaceutical Research and Manufacturers of America) likes to cite. These figures, however, are still being hotly debated, with some experts claiming that the cost is inflated.

And

Havenaar 18 [Author, 11-29-2018, "6 Factors causing replication crisis in medical research," Castor, https://www.castoredc.com/blog/replication-crisis-medical-research/]

In the past few years, there has been a growing controversy surrounding the validity of a number of cornerstone medical research papers. **For example, Amgen, a US biotech company, attempted to replicate 53 high-impact cancer research studies and were reportedly able to replicate only six. Similarly, researchers from Bayer, a German pharmaceutical company, reported that they were only able to replicate 24 out of 67 studies. Moreover, John Ioannidis, MD, Professor of Medicine and Statistics at Stanford University—a strong voice in the replication debate—showed that of 45 of the most influential clinical studies, only 44% were successfully replicated.**

The effects of data exclusivity on duplicate research can be seen in the status quo.

Felter 21 [Written By, 6-30-2021, "A Guide to Global COVID-19 Vaccine Efforts," Council on Foreign Relations, https://www.cfr.org/backgrounder/guide-global-covid-19-vaccine-efforts]

More than a dozen vaccines have been approved for general or emergency use in countries including China, Russia, the United Kingdom, and the United States. As of summer 2021, more than three billion doses had been administered worldwide. Several countries—including Bahrain, Israel, and the United States—have made significant progress in immunizing their citizens, while others have vaccinated only small fractions of their populations and a handful are yet to start. **Dozens of other COVID-19 vaccine candidates are undergoing large-scale clinical trials and around 180 potential vaccines are in preclinical development by pharmaceutical companies, academic institutions, and government agencies.**

Costs spent on all duplicate research globally is high.

Oxfam International 21 [Oxfam International, xx-xx-xxxx, "Vaccine monopolies make cost of vaccinating the world against COVID at least 5 times more expensive than it could be ," https://www.oxfam.org/en/press-releases/vaccine-monopolies-make-cost-vaccinating-world-against-covid-least-5-times-more]

Due to lack of transparency of pharmaceutical companies, the exact cost of research and development and manufacturing of vaccines are unknown. Estimates used in this release are based on studies of mRNA production techniques, carried out by Public Citizen with engineers at Imperial College. **Their analysis suggests that it could cost $9.4 billion to produce 8 billion doses of the Pfizer/BioNTech vaccine —$1.18 per vaccine and for Moderna it would cost $22.8 billion to produce 8 billion doses —$2.85 per vaccine.** Despite a rapid rise in COVID-19 cases and deaths across the developing world, Pfizer/BioNTech and Moderna have sold over 90 percent of their vaccines so far to rich countries, charging up to 24 times the potential cost of production. Last week Pfizer/BioNTech announced it would licence a South African company to fill and package 100 million doses for use in Africa, but this is a drop in the ocean of need. **Neither company have agreed to fully transfer vaccine technology and know-how with any capable producers in developing countries, a move that could increase global supply, drive down prices and save millions of lives.**

And

Ladyzhets 21 [Betsy Ladyzhets, 6-1-2021, "Vaccinating people in developing countries costs far less than doing nothing," Science News, https://www.sciencenews.org/article/coronavirus-covid-vaccines-developing-countries-cost]

Now a new analysis puts a price tag on what it would cost those countries to catch up. Getting shots to half the adult population of the world's lowest-income countries in 2021 will cost $9.3 billion, the Rockefeller Foundation, a global charitable foundation based in New York City, reports June 1. **That estimate includes 92 nations (representing about 3.8 billion people) that are eligible for vaccine access** through Gavi, the Vaccine Alliance, a public–private global health partnership based in Geneva. With that money, the Alliance could purchase 1.8 billion vaccine doses.

Allowing for sharing of data will reduce the money spent on duplicate research, allowing it to fund other innovations.

Productivity is static, more innovation is needed.

Harvard Business Review 19 [Harvard Business Review, 11-26-2019, "Why the U.S. Innovation Ecosystem Is Slowing Down," https://hbr.org/2019/11/why-the-u-s-innovation-ecosystem-is-slowing-down]

Is American innovation sputtering? The data suggests so: Productivity growth in the United States, which is powered by innovation, has been decelerating. Total factor productivity grew substantially in the middle of the 20th century, but started slowing in 1970. This slow growth continues today, with productivity lower than it was more than 100 years ago.

Data exclusivity raises medicine prices.

Palmedo 21 [Palmedo, Michael. “Evaluating the Impact of Data Exclusivity on the Price per Kilogram of Pharmaceutical Imports.” *Boston University Global Development Policy Center*, Apr. 2021, https://www.bu.edu/gdp/files/2021/04/GEGI_WP_048_Palmedo_FIN.pdf] Michael Palmedo directs interdisciplinary research on intellectual property at American University (AU) Washington College of Law’s Program on Information Justice and Intellectual Property. His research focuses on the empirical evaluation of the impact ochanges to patent and copyright laws. He recently completed the Shamnad Basheer IP/ Trade Fellowship at Texas A&M University, where he researched pharmaceutical industry influence into the U.S. government’s Special 301 Review.

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