## Generics DA

#### Patents keep generic drugs off the market.

Gupta et. Al 10, Gupta, Himanshu et al. (Faculty of Pharmacy, Jamia Hamdard (Hamdard University), New Delhi-110 062, India1School of Pharmacy and Technology Management, SVKM's NMIMS University, Mumbai-56, India )“Patent protection strategies.” Jan-March 2010, Journal of pharmacy & bioallied sciences vol. 2,1 (2010): 2-7. doi:10.4103/0975-7406.62694

A patent is a legal device that grants an inventor market exclusivity over a new invention or medication. Market exclusivity can mean tremendous economic rewards for the patent holder because it provides the inventor with a monopoly over the invention for the 20-year patent term. Obtaining a patent and retaining market exclusivity can be a treacherous process, especially in the arena of pharmaceutical patents. Pharmaceutical companies today are facing increased costs for drug discovery and development and aggressive competition from generic drug companies [Table 1]. As research costs skyrocket, generic drug companies sit poised and are ready to compete as soon as a patent expires [Table 2]. Maximizing patent term for successful products is an effective strategy for fending off generic competition and extending product lifecycle. Patents grant the creators of new inventions exclusive control and possession over these inventions. This allows the inventor to prevent others from commercially using ideas or inventions without the creator's permission during the life of the patent.[1] Scientific, legal, and practical considerations must be carefully weighed to best protect an inventor's rights. Creating and protecting or attacking pharmaceutical patents requires close interaction between pharmaceutical scientists and lawyers. It also requires a good understanding of key concepts of each other's discipline. Therefore, there should be collaboration between scientists and attorneys.[2,3]

#### Generic drugs do more harm than good – don’t cure illnesses and cause superbugs.

**Eban 19**, Eban, Katherine. (an investigative journalist and the author of the New York Times bestseller Bottle of Lies: The Inside Story of the Generic Drug Boom. ) “How Some Generic Drugs Could Do More Harm than Good.” How Some Generic Drugs Could Do More Harm Than Good, Time, 17 May 2019, time.com/5590602/generic-drugs-quality-risk/.

But **many** of the **generic drug companies** that Americans and Africans alike depend on, which I spent a decade investigating, hold a dark secret: they routinely **adjust their manufacturing standards** depending **on the country buying their drugs**, a practice **that could endanger** not just those who take the lower-quality medicine but **the population at large**. **These companies send** their **highest-quality drugs to** markets with the most **vigilant regulators**, such as **the U.S. and** the **E**uropean **U**nion. **They send** their **worst drugs** — made **with lower-quality ingredients and less** scrupulous **testing — to countries** with the **weak**est review. **The U.S. drug supply is not immune to quality crises** — over the last ten months, dozens of **versions of** the **generic blood pressure drugs** valsartan, losartan and irbesartan **have** been subject to sweeping recalls. The active ingredients in some, manufactured in China, contained **a probable carcinogen** once **used in** the production of liquid **rocket fuel**. But the patients who suffer most are those in so-called “R.O.W. markets” — the generic-drug industry’s shorthand for “Rest of World.” **In** swaths of Africa, Southeast Asia and other **areas with developing markets**, some **generic drug companies** have made a cold calculation: they can **sell their cheapest drugs** where they will be **least likely to get caught**. **In Africa**, for instance, pharmaceuticals used to come from more developed countries, through donations and small purchases. So when Indian drug reps offering cheap generics started arriving, the initial feeling was positive. But Africa soon became an avenue “to send anything at all,” said Kwabena Ofori-Kwakye, associate professor in the pharmaceutics department at the Kwame Nkrumah University of Science and Technology in Kumasi, Ghana. The poor quality has affected every type of medication, and the adverse impact on health has been “astronomical,” he told me. Multiple **doctors** I spoke to throughout the continent said they have adjusted their medical treatment in response, sometimes tripling recommended doses to produce a therapeutic effect. Dr. Gordon Donnir, former head of the psychiatry department at the Komfo Anokye teaching hospital in Kumasi, treats middle-class Ghanaians in his private practice and **says** that **almost all** the **drugs** his **patients take are substandard**, leading him to increase his patients’ doses significantly. While his European colleagues typically prescribe 2.5 milligrams of haloperidol (a generic form of Haldol) several times a day to treat psychosis, he’ll prescribe 10 milligrams, also several times a day, because he knows the 2.5 milligrams “won’t do anything.” Donnir once gave ten times the typical dose of generic Diazepam, an anti-anxiety drug, to a 15-year-old boy, an amount that should have knocked him out. The patient was “still smiling,” Donnir said. Many hospitals also keep a stash of what they call “fancy” drugs — either brand-name drugs or higher-quality generics — to treat patients who should have recovered after a round of treatment but didn’t. Confronted with the ailing boy at the Mulago hospital, Westerberg’s colleagues swapped in the more expensive version of ceftriaxone and added more drugs to the treatment plan. But it was too late. In the second week of his treatment, the boy was declared brain dead. Westerberg’s Ugandan colleagues were not surprised. Their patients frequently died when treated with drugs that should have saved them. And there were not enough “fancy” drugs to go around, making every day an exercise in pharmaceutical triage. **It** wa**s** also **hard to** keep **track** of **which generics were safe and which were not** to be trusted, said one doctor in Western Uganda: “It’s anesthesia today, ceftriaxone tomorrow, amoxicillin the next day.” **Westerberg**, shaken by his newfound knowledge, flew back to Canada **and** teamed up with a Canadian respiratory therapist, Jason **Nickerson**, who’d had similar experiences with bad medicine in Ghana. They **decided to test the** chemical properties of the **generic ceftriaxone** that had been implicated in the Ugandan boy’s death. Another of Westerberg’s colleagues brought him a vial from the Mulago hospital pharmacy. The drug had been made by a manufacturer in northern China, which also exported to the U.S. and other developed markets. But when they tested the ceftriaxone at Nickerson’s lab, **it contained less than half the** active drug **ingredient stated on the label**. At such low concentration**, the drug was basically useless**, Nickerson said. He and Westerberg published a case report in the CDC’s Morbidity and Mortality Weekly Report. Although they couldn’t say with certainty that the boy had died due to substandard ceftriaxone, their report offered compelling evidence that he had. Some companies claim that, while their drugs are all high-quality, there may be some variance in how they are produced because regulations differ from market to market. But Patrick H. Lukulay, former vice president of global health impact programs for USP (formerly U.S. Pharmacopeia), one of the world’s top pharmaceutical standard-setting organizations, calls that argument “totally garbage.” **For any** given **drug**, he says, “**There’s only one standard, and that** standard **was set by the originator**,” meaning the brand-name company that developed the product. It’s not just those in developing markets who should be alarmed. **Often, substandard drugs do not contain enough** active **ingredient to** effectively **cure** sick **patients. But** they do contain **enough to kill** off the **weakest microbes while leaving the strongest intact.** These **surviving microbes** go on to **reproduce**, **creating** a new generation of **pathogens capable of resisting even** fully potent, **properly made medicine**. **In 2011**, during **an outbreak of drug-resistant malaria** on the Thailand-Cambodia border, USP’s chief of party in Indonesia Christopher Raymond strongly **suspected substandard drugs as a culprit**. Treating patients with drugs that contain a little bit of active ingredient, as he put it, is like “putting out fire with gasoline.” USP is so concerned about this issue that in 2017 it launched a center called the Quality Institute, which funds research into the link between drug quality and resistance. In late 2018, Boston University biomedical engineering professor Muhammad Zaman studied a commonly used antibiotic called rifampicin that, if not manufactured properly, yields a chemical substance called rifampicin quinone when it degrades. When Zaman subjected bacteria to this substance, it developed mutations that helped it resist rifampicin and other similar drugs. Zaman concluded from his work that substandard drugs are an “independent pillar” in the global menace of drug resistance. **The low cost of generic drugs makes them essential to global public health. But** if those bargain drugs are of low quality, **they do more harm than good**. For years, politicians, regulators and aid workers have focused on ensuring access to these drugs. Going forward, they must place equal value on quality, through an exacting program of unannounced inspections, routine testing of drugs already on the market and strict legal enforcement against companies manufacturing subpar medicine. One model is the airline industry, which through international laws and treaties, has established clear global standards for aviation safety. Without something similar for safe and effective drugs, the twin forces of subpar medicine and growing drug resistance will be so destructive that developed countries won’t be able to ignore them. As Elizabeth Pisani, an epidemiologist who has studied drug quality in Indonesia, put it, “The fact is, pathogens know no borders.”

#### This turns their generic advantage – generics uniquely harm the public, especially the LMIC. None of their cards explicitly say how generics are good, just affordable.

## Innovation DA

#### Pharma innovation is high now – profit incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

**Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered policies that would lower drug prices and reduce federal drug expenditures. Such policies would probably reduce the industry’s incentive to develop new drugs.** In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? T**he pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions**, and clinical testing for **safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation.** The share of revenues that drug companies devote to R&D has also grown: **On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses** in 2019, which is **almost twice as large a share of revenues as they spent in 2000.** That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On averace, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. **Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients**. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), **which are costly to develop, hard to imitate, and frequently have high prices.** Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. **What Factors Influence Spending for R&D?** Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, **Expected costs to develop a new drug**, and Policies and programs that influence the supply of and demand for prescription drugs. Various considerations inform companies’ expectations about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA. In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug**. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatmentscof uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D. Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. **In particular, spending on drug R&D increased by nearly 50 percent between 2015 and 2019.** Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. **Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs,** many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

#### The aff crushes drug innovation.

Glassman 21 [Amanda; 5/6/21; Executive vice president and a senior fellow at the Center for Global Development, a nonpartisan, nonprofit think tank in Washington and London; “*Big Pharma Is Not the Tobacco Industry*,” Barron, <https://www.barrons.com/articles/big-pharma-is-not-the-tobacco-industry-51620315693>] Justin

But here is the crux of the problem: The pharmaceutical industry is not the tobacco industry. They are not merchants of death. The companies are amoral and exist to make money, but their business is not fundamentally immoral. Big Pharma (mostly) develops and sells products that people need to survive and thrive. Their products improve health and welfare. Fights over access to medicines are possible because medicines exist in the first place—medicines that were usually developed by Big Pharma. And yes, the pharmaceutical industry benefits from public subsidy and publicly financed foundational research. But the companies also put their own capital at risk to develop new products, some of which offer enormous public benefits. In fact, several of them did just that in the pandemic: invested their own money to develop patented manufacturing technologies in record time. Those technologies are literally saving the world right now. Public funding supported research and development, but companies also brought their own proprietary ingenuity and private investments to bear toward solving the world’s singular, collective challenge. Their reward should be astronomical given the insane scale of the health and economic benefits these highly efficacious vaccines produce every day. Market incentives sent a clear signal that further needed innovation—greater efficacy, single doses, more-rapid manufacturing, updated formulations, fast boosters, and others—would be richly rewarded. Market incentives could also have been used to lubricate supply lines and buy vaccines on behalf of the entire world; with enough money, incredible things can happen. But activist lobbying to waive patents—a move the Biden administration endorsed yesterday—sends exactly the opposite signal. It says that the most important, valuable innovations will be penalized, not rewarded. It tells innovators, don’t bother attacking the most important global problems; instead, throw your investment dollars at the next treatment for erectile disfunction, which will surely earn you a steady return with far less agita. It is worth going back to first principles. What problem are we trying to solve? We have highly efficacious vaccines that we would like to get out to the entire world as quickly as possible to minimize, preventable disease and deaths address atrocious inequities, and enable the reopening of society, trade, and commerce. Hundreds of millions of people have been plunged into poverty over the past year; in the developing world, the pandemic is just getting started. What is the quickest way to get this done? Vaccine manufacturing is not just a recipe; if you attack and undermine the companies that have the know-how, do you really expect they’ll be eager to help you set up manufacturing elsewhere? Is the plan to march into Pfizer and force its staff to redeploy to Costa Rica to build a new factory? Do the U.S. administration or activists care that this decision could take years to negotiate at the World Trade Organization, and will likely be litigated for years thereafter? Does it make sense to eliminate the incentive for private companies to invest in vaccine R&D or in the response to the next health emergency? And if the patent waiver is only temporary and building a factory takes months or years, will anyone bother to do so, even if they could? No, none of it makes sense. Worse still, we could solve the policy problem more easily by harnessing market incentives for the global good by ponying up cash to vaccinate the entire world. No confiscation necessary.

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

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

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

#### Innovation is key to stopping bioterror

**Marjanovic and Fejiao ‘20** Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." https://www.rand.org/pubs/perspectives/PEA407-1.html (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well recognized as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterror-ism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

#### State-created bioweapons uniquely risk extinction in the hands of bioterrorists

**Millett & Snyder-Beattie ‘17**. Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed -CAT

In the decades to come, advanced bioweapons could threaten human existence. Although the probability of human extinction from bioweapons may be low, the expected value of reducing the risk could still be large, since such risks jeopardize the existence of all future generations. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity's favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a long historical track record of state-run bioweapon research applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and mutually assured destruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The possibility of a war between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27 Non-state actors may also pose a risk, especially those with explicitly omnicidal aims. While rare, there are examples. The Aum Shinrikyo cult in Japan sought biological weapons **for the express purpose of causing extinction**.28 Environmental groups, such as the Gaia Liberation Front, have argued that “we can ensure Gaia's survival only through the extinction of the Humans as a species … we now have the specific technology for doing the job … several different [genetically engineered] viruses could be released”(quoted in ref. 29). Groups such as R.I.S.E. also sought to protect nature by destroying most of humanity with bioweapons.30 Fortunately, to date, non-state actors have lacked the capabilities needed to pose a catastrophic bioweapons threat, but this could change in future decades as biotechnology becomes more accessible and the pool of experienced users grows.31,32 What is the appropriate response to these speculative extinction threats? A balanced biosecurity portfolio might include investments that reduce a mix of proven and speculative risks, but striking this balance is still difficult given the massive uncertainties around the low-probability, high-consequence risks. In this article, we examine the traditional spectrum of biosecurity risks (ie, biocrimes, bioterrorism, and biowarfare) to categorize biothreats by likelihood and impact, expanding the historical analysis to consider even lower-probability, higher-consequence events (catastrophic risks and existential risks). In order to produce reasoned estimates of the likelihood of different categories of biothreats, we bring together relevant data and theory and produce some first-guess estimates of the likelihood of different categories of biothreat, and we use these initial estimates to compare the cost-effectiveness of reducing existential risks with more traditional biosecurity measures. We emphasize that these models are highly uncertain, and their utility lies more in enabling order-of-magnitude comparisons rather than as a precise measure of the true risk. However, even with the most conservative models, we find that reduction of low-probability, high-consequence risks can be more cost-effective, as measured by quality-adjusted life year per dollar, especially when we account for the lives of future generations. This suggests that despite the low probability of such events, society still ought to invest more in preventing the most extreme possible biosecurity catastrophes.

#### Innovation is key for making new drugs and providing to LMICs in the aff.

## Framing --- Util

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

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

#### 2] Extinction matters under any framework:

#### ---A] It precludes the possibility of any kind of moral value – we can’t confer value onto anything if we’re not alive.

#### ---B] Future generations means infinite magnitude – we have to look towards future lives too

## 1AR Theory

No 1AR theory a] There is a 7-6-time skew after NC, negs get 1 less minute text b] They get new 2AR responses to 2NR counter-interps, that makes theory irresolvable because I don’t have a 3NR, and they win every theory debate because I can’t answer their responses c] AC spikes solve there aren’t that many theory issues d] deters 1NC abuse checking because of meta-theory, that means 6 minutes of aff abuse e] infinite abuse doesn’t exist, 1] 7 minutes if finite, 2] resolvability is a pre-req to checking abuse, you cant check abuse on a irresolvable issue

### Case CP: HIF (Price/Access)

#### Counterplan – add a Health Impact Fund to incentivize Pharmaceuticals to voluntarily lower prices and increase access. This would add a complement to IPP rather than reducing it.

**Pogge 10** [Thomas Pogge, Thomas Winfried Menko Pogge is a German philosopher and is the Director of the Global Justice Program and Leitner Professor of Philosophy and International Affairs at Yale University. Cambridge University Press, “Incentives for Global Health: Patent Law and Access to Essential Medicines. The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices,” 2010, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=1431180]/ lm

The exclusion of the poor by the existing patent regime requires reform. Given the foregoing discussion, a straightforward and moderate reform would create a supplementary mechanism that, by addressing the needs of the poor, would remedy the injustice now imposed upon them. This reform proposal comprises six elements. First, just as the patent regime provides a general innovation incentive, so its complement encourages pharmaceutical innovation through an incentive that is specified in general terms: as a promise to reward any successful new medicine, in proportion to its success. This kind of mechanism has been described as a comprehensive AMC.14 Second, while the patent regime rewards medicines on the basis of the market demand each generates and then satisfies, thereby effectively excluding the poor, its complement gives equal standing to all by defining success simply in terms of human health. On this complementary track, the success of a medicine is assessed by the reduction in human morbidity and premature mortality it achieves – regardless of whether these harms are averted from rich or poor patients. Third, in order to help overcome the last-mile problem, the rewards available under the complementary mechanism should be tied not to what a medicine can do, but to what it actually achieves in the world. Fourth, when such a general mechanism provides large enough health impact rewards, it will attract sufficient innovation and sufficient efforts to ensure real access to new medicines worldwide. This avoids any need for compulsion. Innovators can be left free to choose between the two tracks, developing on the new track high-impact medicines needed also by many poor patients and on the conventional patent track low-impact medicines desired by the more affluent. Making the health-impact track optional is also crucial for the political success of the proposal. Fifth, in order to reinforce the incentive toward facilitating real access, health impact rewards should be conditional on the medicine being priced no higher than the lowest feasible cost of production and distribution.

Sixth, health impact rewards should be funded by governments as a public good. In order to minimise burdens and deadweight losses due to taxes, the cost should be spread as widely as possible. This suggests that the complementary funding mechanism should be global (rather than national) in scope. The reasons that make the reform compelling in any one country or region make it compelling everywhere. Moreover, global scope avoids the problems associated with large price differentials. Global scope also brings huge efficiency gains by diluting the cost of the scheme without diluting its benefits: no matter how many beneficiaries we may add, the cost of achieving an innovation remains the same even while its aggregate benefit increases with the number of beneficiaries.15 Finally, an international agreement would also reinforce the commitment of individual countries to the scheme. Pharmaceutical innovation is therefore best encouraged by promising to reward any safe and effective new medicine in proportion to its global health impact. Such a promise constitutes an AMC that is fully comprehensive: by including not merely all diseases but also all patients.

The proposal is then for the creation of a new international agency that offers to reward any new medicine based on its health impact during its first decade or so.16 This Health Impact Fund („HIF‟) would provide ample rewards for the development of new high-impact medicines without excluding the poor from its use.

#### That solves the aff by including the poor and increasing access but doesn’t trigger the disad because it’s voluntary, IPP remains unchanged, and increases innovation. This keeps generics off the market too.

**Pogge 10** [Thomas Pogge, Thomas Winfried Menko Pogge is a German philosopher and is the Director of the Global Justice Program and Leitner Professor of Philosophy and International Affairs at Yale University. Cambridge University Press, “Incentives for Global Health: Patent Law and Access to Essential Medicines. The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices,” 2010, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=1431180]/ lm

Let us recapitulate how the HIF would provide a full systemic solution to the seven problems described earlier: High Prices would not exist for HIF-registered medicines. Innovators would typically not even want a higher price as this would reduce their health impact rewards by impeding access to their product by most of the world‟s population. The HIF counts health benefits to the poorest of patients equally with health benefits to the richest. Diseases Concentrated among the Poor, insofar as they substantially aggravate the GBD, would no longer be neglected. In fact, the more destructive ones among them would come to present some of the most lucrative R&D opportunities for biotechnology and pharmaceutical companies. This would happen without undermining the profit opportunities such companies now enjoy by developing remedies for the ailments of the affluent. Bias toward Maintenance Drugs would be absent from HIF-encouraged R&D. The HIF assesses each registered medicine‟s health impact in terms of how its use reduces mortality and morbidity worldwide – without regard to whether it achieves this reduction through cure, symptom relief, or prevention. This would guide firms to deliberate about potential research projects in a way that is also optimal for global public health: namely in terms of the expected global health impact of the new medicine relative to the cost of developing it. The profitability of research projects would be aligned with their cost-effectiveness in terms of global public health. Wastefulness would be dramatically lower for HIF-registered products. There would be no deadweight losses from large mark-ups. There would be little costly litigation as generic competitors would lack incentives to compete and innovators would have no incentive to suppress generic products (because they enhance the innovator‟s health impact reward). Innovators might therefore often not even bother to obtain, police, and defend patents in many national jurisdictions. To register a medicine with the HIF, innovators need show only once that they have an effective and innovative product. Counterfeiting of HIF-registered products would be unattractive. With the genuine item widely available near or even below the marginal cost of production, there is little to be gained from producing and selling fakes. Excessive Marketing would also be much reduced for HIF-registered medicines. Because each innovator is rewarded for the health impact of its addition to the medical arsenal, incentives to develop me-too drugs to compete with an existing HIF-registered medicine would be weak. And innovators would have incentives to urge a HIF-registered drug upon doctors and patients only insofar as such marketing results in measurable therapeutic benefits for which the innovator would then be rewarded. The Last-Mile Problem would be mitigated because each HIF-registered innovator would have strong incentives to ensure that patients are fully instructed and properly provisioned so that they make optimal use (dosage, compliance, etc) of its medicines, which will then, through wide and effective deployment, have their optimal publichealth impact. Rather than ignore poor countries as unprofitable markets, pharmaceutical companies would, moreover, have incentives to work with one another and with national health ministries, international agencies and NGOs toward improving the health systems of these countries in order to enhance the impact of their HIFregistered medicines there.

## Case

### AT: Structural Violence

1. SV is not a fw. Reducing oppression is under a util framework. For example, $20 to a homeless person gives them a lot more well-being than $20 would give to someone like Jeff Bezos. SV has the same end goal as Util, to maximize wellbeing.

ROB: Vote for the best debater.

### AT: Access

#### 1] Flexibilites exist in the status quo.

**Crosby et al. '21** (Daniel Crosby, Evan Diamond, Isabel Fernandez De La Cuesta, Jamieson Greer, Jeffrey Telep, Brian White; Crosby specializes in international trade, investment and matters related to public international law. Diamond is a partner on our Intellectual Property, Patent, Trademark and Copyright Litigation team.; 3-5-2021; "Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products"; https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/, JD Supra, accessed 7-21-2021; JPark)

Existing flexibilities for developing countries. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) protects intellectual property, and recognizes that patents can be licensed either voluntarily on commercial terms, or without the authorization of the rights holder under “compulsory licenses” where “the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.” (TRIPS Agreement, Article 31(b).) Countries are not required to request authorization “in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use,” but must notify rights holders “as soon as reasonably practicable;” and in any case must pay “adequate remuneration” to the right holder. Notably, intellectual property rights may be protected pursuant to bilateral investment treaties or free trade agreements that protect covered investments in certain circumstances. Some such treaties reference the TRIPS Agreement while others do not.

#### 2] The squo proves that existing law is sufficient. Developing countries have been granted COVID19 vaccines and fair deals because pharma companies recognize the importance of getting everyone vaccinated

#### 3] Data exclusivity is necessary to ensure effective clinical research

**Bing 21**

Dr. Han Bing (senior research fellow at the Institute of World Economics and Politics of Chinese Academy of Social Sciences). “TRIPS-plus Rules in International Trade Agreements and Access to Medicines: Chinese Perspectives and Practices.” Global Development Policy Center, Global Economic Governance Iniative. GEGI Working Paper 049, April 2021. JDN. https://www.bu.edu/gdp/files/2021/04/GEGI\_WP\_\_Bing\_FIN.pdf

Undisclosed test or other data refer to the data obtained in the entire medicine development process to demonstrate the medicine’s safety, efficacy and quality. The medicines and healthcare products regulatory agencies in various countries analyze and evaluate whether to approve the marketing of a new medicine based on such data. Since it is obtained from scientific studies, undisclosed test or other data are unable to satisfy the requirements of patent grant and cannot be protected by patent rights. However, the cost of obtaining marketing approval is expensive and the first registrant needs to be significant to overcome the negative price effects of competition from pharmaceutical manufacturers that free ride on the initial registrant’s marketing approval. Therefore, it is argued that, without a period of monopoly, the new drug developers will have no incentive to “conduct the costly clinical research and trials necessary to obtain marketing approval” (Chow and Lee 2018). Given its importance to the pharmaceutical industry, the United States is a strong proponent of adding such a provision in the TRIPS Agreement (Chow and Lee 2018). However, since the TRIPS Agreement was formally implemented 25 years ago, WTO members had not yet unified their opinions on the application of this provision. The United States, the European Union, and some members argue that, taking into account the considerable amount of efforts and costs for generating the necessary data, unless permitted by the originator, undisclosed test or other data should be granted exclusive rights against disclosure for a specific period of time (UNCTAD & ICTSD 2013, 613-615). During the period, government agencies shall not only protect such data against disclosure, but also prevent generic drug manufacturers from relying upon the data to obtain marketing approval. Developing countries such as Argentina, Brazil, India, and Thailand provide a non-exclusive protection on undisclosed test or other data, that is, such data are protected against unfair commercial use, but not granted exclusive rights, which allows government agencies to rely on such data to approve the marketing of generic medicines (UNCTAD & ICTSD 2013, 615-616). Developing countries believe that if the US and European practices were adopted, the marketing of generic medicines would be delayed, thereby unreasonably restricting the public access to medicines (UNCTAD & ICTSD 2013, 621). Prior to accession to the WTO in 2001, there were no data exclusivity provisions in China. After joining the WTO, China has assumed the obligation to protect such data in compliance with the TRIPS Agreement. Unlike most WTO members, as a condition for accession to the WTO, China agreed to provide data exclusivity protection for a period of six years (Feng 2010). Included in the Part V “Trade-Related Intellectual Property System” of the Report of the Working Party on the Accession of China (World Trade Organization 2001), China reiterated the content of and added what is not stipulated in Article 39(3) of the TRIPS Agreement. That is, during the period of six years, China does not allow approval of marketing for generic medicines, in order to provide exclusive protection for undisclosed test or other data of new chemical entities (World Trade Organization 2001, 284). Moreover, such protection is independent of patent protection, which means such data are protected whether a medicine is granted patent or not. The period of six years exclusive protection for undisclosed test or other data is longer than the period of 5 years of protection in the US and a number of bilateral free trade agreements.

#### 4] Access is an infrastructure issue, not an issue of patenting

**WTO 20** (WTO News Briefing; ; 10-16-2020; "Members discuss intellectual property response to the COVID-19 pandemic"; https://www.wto.org/english/news\_e/news20\_e/trip\_20oct20\_e.htm, World Trade Organization News, accessed 7-21-2021; JPark)

While a number of developing and least developed country members welcomed the proposal as a contribution to the discussion, many were still studying it in their capitals and asked for clarification on certain points, particularly regarding its practical implementation and the possible economic and legal impact of the waiver at national level. A number of developing and developed country members opposed the waiver proposal, noting that **there** is no indication that intellectual property rights (IPRs) have been a genuine barrier to accessing COVID-19 related medicines and technologies. While acknowledging that the sustained and continued supply of such medicines and technologies is a difficult task, they observed that **non-efficient** and underfunded health care and procurement systems, spiking demand **and** lack of manufacturing capacity are much more likely to impede access to these materials. In the view of these members, **solutions** can be legitimately sought within the existing IP system as the TRIPS Agreement provides enough tools and sufficient policy space for members to take measures to protect public health. The suspension of IPRs, even for a limited period of time, was not only unnecessary but it would also undermine the collaborative efforts to fight the pandemic that are already under way.

#### 5] Innovation Is key and comes first--