Off

Biotech is the new frontier; America is ahead but China is dangerously close

Gupta 6/11 [Gaurav Gupta, Biotech Investor, Founder of Ascendant BioCapital, a life science investment firm based in New York. Previously, Gaurav worked at OrbiMed Advisors, and served as a resident in neurological surgery at Columbia University Medical Center. He has co-authored over a dozen articles in peer-reviewed journals, filed a patent on a device for use in spine surgery, and edited a book on the technical and ethical implications of using tissue engineered products in the operating room. Dr. Gupta obtained his M.D. from the Stanford University School of Medicine, where he was a Paul and Daisy Soros Fellow, and B.S. and M.S.E. in biomedical engineering from Johns Hopkins University, where he was a Charles R. Westgate Scholar.) "As Washington Ties Pharma's Hands, China Is Leaping Ahead" Barron's Magazine: Commentary, China., 6/11/2021] RM

There should be no doubt that we are living at the dawn of a golden age of biomedical innovation. The American scientific engine that produced Covid-19 vaccines in record time was fueled by a convergence of advances in genomics, biomarkers, data science, and manufacturing years in the making. The first Food and Drug Administration approvals of a host of new product formats—oligonucleotide, bispecific, oncolytic virus, CAR-T, and lentivirus/AAV—all took place within the last decade. These represent an unprecedented expansion of the armamentarium that physicians have at their disposal to treat and cure disease. **In the last few years, 47% of all new medicines were invented by U.S. biopharma companies,** with homegrown startups driving the majority of innovation. The bulk of the remainder were developed by foreign companies specifically for the U.S. market.

An indirect benefit of these trends is that most novel therapeutics undergo clinical development and early commercial launch here in the U.S. The rest of the world understands that the American patient has earlier and broader access to groundbreaking therapies via these mechanisms. Indeed, the past decade is filled with examples of medical "firsts" for American patients: the first cure for Hepatitis C, the first gene therapy for blindness, the first immunotherapy for cancer. Future rewards will be greater still if we preserve our current system of incentivizing and protecting innovation.

The remarkable innovation capacity of our biopharmaceutical industry ought to be a source of national pride. Yet while "Made in America" is the global standard for medicines in development today, misguided policy risks ceding our scientific prowess to other countries in the future. **This is particularly true in the case of China, where biotechnology has become a strategic pillar for the health of its people and economy.**

From 2016 to 2020, the market capitalization of all Chinese biopharma companies increased exponentially from $1 billion to over $200 billion. **China saw over $28 billion invested in its life sciences sector in 2020, double the previous year's amount. Returns on China's investment are already arriving**. The FDA approved a drug developed in China for the first time ever in 2019. **While China's innovation capacity currently remains behind America's, my experiences as a biopharma professional make it clear they are doing everything they can to catch up and catch up fast.**

In fact, when I speak to Chinese biotechnology executives, they boast that they can run clinical trials faster than their U.S. counterparts. The danger of misguided policies that disincentivize pharmaceutical innovation in the U.S. is effectively driving that same innovation to China. If we close off the market in

the U.S. at the same time that China is opening its market to innovative new products, then we will see companies choose to first launch impactful novel medicines in China, based on clinical trials conducted in China. Because the FDA rarely accepts data generated entirely outside the U.S., this relocation of research capacity will negatively affect Americans' access to cutting-edge therapies.

The biotechnology field is advancing rapidly. Promising technologies such as targeted protein degradation and gene editing are perhaps not far from being developed into impactful medicines, and **the U.S. risks these technologies being mastered by Chinese companies.**

It is widely held that allowing China to gain an asymmetric edge in critical technologies such as AI or quantum computing could destabilize the geopolitical balance of power. The same is true of biotechnology. Chinese scientists were the first to edit the genomes of human embryos, in contravention of international standards, and the U.S. national security community believes China is pushing ahead with experimental concepts for biological and cognitive enhancement of soldiers and civilians. **American policy should be focused on protecting, rather than undermining, the global dominance of our biotechnology industry.**

Data exclusivity fosters investment in biologic medicines – reduction kills incentive to innovate

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Why regulatory data protection matters for medicines In medicine, the dominance of small-molecule drugs is coming to an end. Increasingly, current and future treatments will be biologic – complex drugs with molecular structures many times larger, manufactured inside living structures such as animal cells or bacteria. The new era of biotechnology promises a revolution in how doctors treat and prevent disease, in many cases offering hope to patients where there is no current treatment. Advances in gene therapy, the development of safer vaccines, precision medicine and superior diagnostics stand to benefit millions around the world. Despite its transformative potential for humanity, biotechnology medicine research and development remains geographically concentrated. The world leader in biotechnological output by some margin is the United States, followed by a handful of high income countries – the United Kingdom, Switzerland, Germany, France and Japan. While emerging markets such as China have nascent biotech industries, there is a long way to go before medical biotech R&D goes global, harnessing the scientific potential that is found in most countries. So why is it that medical biotech companies and their lifeblood – the small start-ups with promising technology to develop – are clustered in a handful of countries? Human capital, a good regulatory environment and adequate R&D infrastructure are obviously key 1. Also crucial are strong and readily enforceable intellectual property (IP) rights that are necessary to mobilise the large investments required to fund risky biotech R&D. For innovation in biologic medicines the key IP right is not patents but regulatory data protection (RDP**), which prevents competitors from exploiting the data generated during clinical trials for a certain period of time**. The most innovative countries in the biotechnology sphere all have one thing in common – they all have clear rules on their statute books for the protection of this data. So what precisely is regulatory data protection, and why is it so important? Regulatory data protection explained Broadly defined, the 'data' element of regulatory data protection refers to the information that is required by regulatory authorities in order to approve a technology for consumer use. Therefore, regulatory data protection is relevant to technologies for which safety and effectiveness are paramount, and which need regulatory approval before entering the market; in particular, pharmaceutical products – both 'small molecule', chemically-synthesised formulations, and more complicated biologics – and various products used in agriculture. In the context of the former, the data will typically be generated and collected from conducting the preclinical and clinical trials that are required to demonstrate a medicine is safe and efficacious for humans. This painstaking clinical trials

process comes at great expense, in terms of both time and money, to the innovator company which has developed the technology. Some estimates of the cost of developing a new medicine range between $1.2bn to $2.6 billion 2 3. Susan Finston, co-founder and director at Indian biomedicine start-up Amrita Therapeutics and a strategic consultant, points out that **this situation fundamentally puts biologic innovators and other biotech companies at a competitive disadvantage**, since the test data, vital for gaining regulatory approval, would likely be protected as a trade secret in any other context. "Every company has recourse to similar protection under trade secrecy laws," she says. "But biopharma companies actually face an additional requirement to disclose trade secrets, in the form of regulatory data. A typical food and beverage company can hold trade secrets on their recipes and so forth, and they can do that in perpetuity. But **if you are a biopharma innovator, you have to disclose to regulators what your cookbook is**." As such, she argues that there is an imperative to incentivize these innovators. This ensures that competition cannot enter the market by gaining approval on the back of the innovator's regulatory data before the innovator itself has had a fair opportunity to recoup its hefty investment in compiling it. And that's where the 'exclusivity' part of the equation comes in. "In highly regulated industries like biopharma or agritech, there is a compelling public interest in regulators having access to the innovator's test data," says Finston. "Regulatory data protection allows for regulators to gain that access on the basis that they will not disclose it." In return for access to test data, governments commit to refraining from public disclosure of the data – ensuring that competitors are not able to rely on it to seek approval for their own drugs for a limited period of time. The scope and term of that exclusivity can vary according to jurisdiction and subject matter. Furthermore, the full extent of what is broadly categorized as regulatory data protection may include periods of exclusivity concerning the test data itself, as well as additional spells of market exclusivity where prospective competitors may have their follow-on drugs approved but are still restricted from selling them until the term of the protection expires. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), of which World Trade Organisation (WTO) members are signatories, includes obligations for the protection of proprietary data submitted by innovators to governments for regulatory purposes. Article 39.3 of the TRIPS Agreement requires governments of WTO member states to protect test data submitted to regulatory authorities against unfair commercial use and disclosure, except when necessary to protect the public, or unless the data is otherwise protected against unfair commercial use. Since 1st January 2000, all WTO members, with the exception of those which are classified as least developed countries, have been required to have TRIPS-compliant protection for proprietary registration data. Many, though, have failed to implement it. Clinical test data and biosimilars Among other things, regulators want access to an innovator's test data in order to vet and approve follow-on versions of its drug that are produced by competitors. Just as originators of small-molecule pharmaceuticals face follow-on competition from generics, biologic innovators must contend with competition from 'biosimilars'. But there is a marked difference. Compared to 'traditional' chemically synthesised pharmaceuticals, biologics, as noted above, are far more structurally complex. As such, it is not currently possible for a competitor to precisely replicate the original biologic. Rather, the competitor can only produce a biosimilar – a product that may be structurally similar to the original biologic it follows on from but likewise may only be similar, rather than identical, in terms of its effectiveness. As a result, regulatory authorisation of a biosimilar is **conditional on it demonstrating comparable efficacy**, quality and safety to the innovator's original product. This means that the innovator's original test data is instrumental for approval – and explains why regulatory authorities require access to it. Moreover, these nuances make the protection of biologics using patent law a complicated affair. In many jurisdictions the question of whether biotechnological inventions are eligible for patent protection remains unsettled. Why patents aren't enough According to Dr Kristina Lybecker, an associate professor at Colorado College whose research focuses on IP rights in the pharmaceutical space, regulatory data protection grants biologics innovators some much-needed additional security. "Patent protection and data exclusivity are complementary forms of IP protection that both serve to incentivise the tremendous investments required for the development of biologic medicines," she says. Despite this, critics often argue that regulatory data protection is an overreach, gifting additional quasi-monopolistic power on top of that already obtained through patent ownership. From this perspective, regulatory data protection only serves to further delay cheaper biosimilars, keeping prices higher for healthcare providers and patients. Jack Lasersohn is a general partner with the Vertical Group, a healthcare-focused venture capital firm based in New Jersey. In July 2009, while he was on the board of directors at the US National Venture Capital Association (NVCA), Lasersohn testified at a US Congressional hearing in support of legislative proposals to secure a significant, 12-year regulatory data protection period for biologics in the United States. The following year, the Biologics Price Competition and Innovation Act was signed into law, ushering in 12-year regulatory exclusivity for new biologics starting from the date of first approval by the US regulator. Venture capital investment is absolutely critical to the biotechnology industry; US VC firms pumped a record $8.95 billion into biotech start-ups during 2015. That's around 50% more than the previous year. Nonetheless, these figures give an indication of the scale of venture capital's contribution. Without the promise of returns, VCs would have little reason to invest in such a high-cost, high-risk sector – and billions of dollars in funding for cutting-edge medicines would be lost. Based on his experience investing in and managing biotechnology companies, Lasersohn thinks that regulatory data protection is vital if there is to be continued, sustained investment. "The patent laws give you that protection up to a point, but not completely," he says. "Put simply, the main reason is that it is more difficult to protect a biologic from a biosimilar than it is to protect a small molecule from a generic that is chemically identical. The patent laws simply do not afford the same level of protection if you are going to allow similar drugs to be approved using the same data." In addition to

the high costs of producing the relevant data, uncertainty over the eligibility of biotech inventions for patent protection – as well as the ability to effectively enforce these rights – further underlines the need for regulatory data protection. “The trend has gotten worse,” says Lasersohn, speaking specifically about the US market. “Patent laws offer even less protection today, as a result of eBay and a whole bunch of other Supreme Court decisions. So in that sense, regulatory data protection has become even more important.” The US Supreme Court’s eBay v MercExchange decision in 2006 significantly raised the bar for obtaining injunctive relief for patent infringement, while its rulings in Mayo v Prometheus in 2012 and Association for Molecular Pathology v Myriad in 2014 placed restrictions on the patentability of inventions relating to diagnostic methods and isolated genetic material. Property rights, including patents and regulatory data protection, are the foundation of investment. No-one wants to invest in something that they don’t own a part of Throw in the astronomical costs of US litigation, and it is clear to see that it is probably tougher than ever to be a biotech start-up today than at any point in the past. “For a small company like Amrita, regulatory data protection is very much of practical importance because you can’t count on being able to make it through a lengthy patent litigation,” says Finston. “But if you have RDP and marketing exclusivity, then you essentially have some administrative protection from the state. That provides more assurance that you are not relying merely on patent protection.” Return on investment For Lasersohn and other VCs like him, the bottom line is simple: They are more likely to invest in a biotech company if its test data is protected for a reasonable period of time. “When a VC looks to make an investment, they need to justify it on the rate of return over time,” he says. “The return you get is directly a function of the durability of the investment – in other words, how long it will produce cash flows and profit. The shorter the period of durability, the less profit that could be made; and therefore, the smaller the investment that could be justified.” He gives the same analogy that he used when arguing the case for a 12-year RDP period before Congress in 2009: “Say you’ve invested in a $100-million-dollar apartment building for rental. If it lasts for 10 years and then crumbles, it is only worth what it earned during those 10 years. But if it stands for a hundred years, it is potentially going to earn much, much more, which means you can sell it before the 100 years is up based on how much cash flow a prospective buyer can anticipate.” In the VC business – where the aim is often to achieve exit by selling a start-up on to a larger company – this represents the durability in the investment. “For biotech, that durability is associated with data exclusivity,” he adds. “Once you lose that, the apartment building crumbles to dust – and it just doesn’t generate profits any more.” Lasersohn argues that strong IP protections have been the cornerstone of the United States’ longstanding leadership in the development of new, gamechanging technologies. “Property rights, including patents and RDP, are the foundation of investment,” he says. “No-one wants to invest in something that they don’t own a part of. Patents and RDP give you a form of ownership, and therefore make it possible to invest.” Emerging markets Despite the important role played by RDP in making the US a biotech innovation world leader, the availability, strength and scope of RDP for biologics differ from country to country, with many not providing any. The United States stands alone in offering a 12-year term (in a 2011 paper, Duke University economist Henry Grabowski reasoned that a representative biologic could not recoup its R&D costs with a data protection period of less than 12 years). The European Union provides for up to 11 years of regulatory exclusivity protection in certain circumstances (see Fig 2 – European Union 8+2(+1) formula) – and this particular regime is generally applicable to both biologics and small-molecule drugs. Canada and Japan each offer eight years of RDP for biologics, while a significant number of jurisdictions make provision for five to six years. At the other end of the scale, it is typically developing economies that fail to provide any form of RDP for biologics. Anil Joshi is managing partner at Unicorn Ventures, a Mumbai-based venture capital firm. He notes that India has some way to go to catch up with the likes of the United States and Japan in terms of the IP protections on offer for biotech innovators. “These are early days for India’s IP system, but we can say that positive steps have been initiated,” he says, pointing to the Indian government’s recently launched ‘Startup India’ initiative. “From an investor’s perspective, it would be risky if there is not a strong IP regime, especially with regard to biotech, as a lot of investment goes into research and if the IP is not there to protect the innovation then the entire investment could be at risk.” There are a number of reasons why Amrita Therapeutics is looking to move many of its operations out of Ahmedabad, India, to the United States. One of the major factors in the decision is the perceived weakness of the country’s IP protections for biotech businesses. “Amrita is transitioning towards becoming a US company,” says Finston. “There are many challenges for biotech start-ups in India – corporate governance issues, special burdens under the tax code and weaknesses in IP. So RDP is just one of a plethora of issues. When we set up Amrita we did it partly as a demonstration, to show, from soup to nuts, you could set up a business like this in India, to bring something important to market. But we didn’t claim we could spearhead a biotech angel and VC culture in the country. To actually get to the clinic, we need to be a US company.” From the VC perspective, Joshi agrees that the introduction of RDP would have a positive impact on biotech investment in India. “With regards to biotech, investors would prefer exclusivity as it is important to protect the investment,” he says. “I would like to see more refined and clear guidelines in protecting IP not only for biotech but for all innovation. I think the government needs to promote the importance of IP rights more heavily and encourage innovators to file for IP rights.” Last year, Finston was commissioned by the development-focused Wadhwani Foundation to compile a report on India’s high-tech start-up environment. Among the policy recommendations made in the final report are a call to address the difficulty faced by biotech start-ups in “gaining regulatory exclusivity for commercially valuable clinical dossiers (data exclusivity periods)”, as well as the “less than effective patent protection for new chemical entities and biotechnology inventions”. It was hoped that the Biotechnology Regulation Bill – first introduced into the Indian parliament in April 2013 – would aim to address some of these issues. But at the end of 2015, the bill was returned to the drawing board after objections from some lawmakers, activists and NGOs. “You need incentives for primary research,” says Finston. “It needs to be a holistic environment. In that context RDP is very important – particularly for small companies that don’t have deep pockets for litigation. But the bill was defeated mainly due to the objections of academics and NGOs that didn’t really know what they were objecting against.” Does regulatory data protection undermine access to medicines? Critics of India’s biotech regulation bill, and of IP protections more generally, have characterised RDP as another avenue for large pharmaceutical corporations to maintain a monopoly over the drugs they have invented, even after their patents expire. This, they argue, increases the price of medicines, restricting access to healthcare for the world’s poorer patients and creating insurmountable public welfare costs for developing nations. The

main fear of critics is that RDP will drive up healthcare costs to unsustainable levels by prolonging the period of market exclusivity enjoyed by biologic drugs. However, research from Geneva Network suggests that such fears are ungrounded. **Analysing the examples of Canada and Japan, which have both lengthened their respective terms of RDP in recent years, shows that state expenditure on pharmaceuticals as a percentage of GDP remained pretty much flat in the years preceding and following the change.** Moreover, any consideration of the costs associated with longer RDP periods should also take into account the value they add in regards to long-term investment in, and availability of, treatments. The implementation of an RDP framework may even encourage more innovation, suggests Lybecker: "Regulatory data protection provides an additional form of IP protection and will delay biosimilar firms from bringing their product to market unless they generate their own preclinical and clinical safety and efficacy data." While RDP may extend the period of time in which biologic drugs do not face biosimilar competition, several additional elements must be weighed against this effect, she adds. "First, data exclusivity incentivises innovation which results in the development of biologic treatments and cures that might not otherwise come into existence. Second, these medicines provide significant benefits to patients, both improving and extending their lives. This results in healthier individuals and cost savings to healthcare systems." Source: 'Will increasing the term of data exclusivity for biologic drugs in the TPP reduce access to medicines?' Philip Stevens, Geneva Network, July 2015 Refraining from granting an innovator an RDP period may lead to much cheaper versions of the same drug arriving on the market more quickly. But this would only be a short-term benefit – and would be shortsighted too, Lasersohn suggests. "Data exclusivity may raise the cost of a particular drug," he says. "But I think 'supports the price' is the better way to put it. It doesn't raise prices above a natural level, but rather supports the price that the market should pay for the investment of time and money that has gone into the development of the drug." Without the availability of IP rights like RDP in the biotech space, there wouldn't be any drugs to begin with, he concludes. "The reality is that VCs are not required by law to invest in biotech. We could invest in social media and smartphone apps instead. But as a society, it is probably more important that we are able to fund the next Herceptin, rather than the next WhatsApp."

They're qualitatively distinct from small molecules and require further IP protection

BIO 07, The Biotechnology Innovation Organization is the world's largest biotech trade association, "Why is a Significant Period of Data Exclusivity Necessary in a Pathway for Biosimilars?," https://archive.bio.org/articles/why-significant-period-data-exclusivity-necessary-pathway-biosimilars]//AAli

- large molecules are more specific and require narrower patents which lets biosimilars creep in

Biotechnology companies must have some certainty that they can protect their investment in the development of new breakthrough therapies for a substantial period of time in order to secure the necessary resources from venture capital firms and other funding sources. Thus, in order to preserve incentives for biomedical innovation, any statutory pathway for follow-on biologics (FOBs) must include a substantial period of data exclusivity. Such non-patent exclusivity is necessary because, due to the very nature of a FOBs regime, the patent system may not provide innovator biologics with effective protection against follow-on manufacturers prematurely entering the market. For biologics to receive the same length of effective market protection as small molecule drugs receive under the Hatch-Waxman Act, the period of data exclusivity in any FOBs framework must be no less than 14 years. Anything less could skew investment away from biologics research and development. The similarity standard for FOBs creates a "protection gap" that may allow for abbreviated regulatory approval while eluding an innovator's patents. That likelihood exists because of the confluence of two critical factors not present in the Hatch-Waxman Act construct for generic small molecule drugs. **First**, unlike a generic drug which must be the same as an innovator product, a FOB may be only "similar' to the corresponding innovator product, and thus the innovator's patents may not be infringed. **Second**, because of the nature of biologic products – large molecules produced by living cells and organisms – patent protection is often narrower and easier to "design around" than that of small molecule drugs, and the trend is towards increasingly narrow patents.

Impact – Biopharma + Terror

Biopharma innovation is key to prevent future pandemics and bioterror

Marjanovic and Feijao 20 [Sonja Marjanovic Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon. "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, accessed 8-8-2021, https://www.rand.org/pubs/perspectives/PEA407-1.html] HWIC

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences 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-recognised 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 competition 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 pharmaceutical 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 sector. 2 It is therefore unsurprising that we are seeing industry-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 compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials 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 accelerate 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 relatively few companies that are 'commercial' winners. Those who might gain substantial revenues will be under pressure 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 combination product that is being tested for therapeutic potential 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, bioterrorism 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 immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious 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 contributions 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 innovation conditions.

Extinction

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

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 biotech**nology 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 **m**utually **a**ssured **d**estruction 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

OFF

The US maintains a shaky yet tenable lead in biotech over China – that's critical for technological competition

Moore 2/17, Scott Moore is a political scientist and administrator at the University of Pennsylvania and the author of a forthcoming book, "How China Shapes the Future," on China's role in public goods and emerging technologies., 2-17-2021, "In Biotech, the Industry of the Future, the U.S. Is Way Ahead of China," Lawfare, https://www.lawfareblog.com/biotech-industry-future-us-way-ahead-china]//AAli

- potemkin = fake

It was supposed to be China's moment of technological triumph—one that would show the world Beijing had not only conquered the coronavirus but also emerged as a biotechnology superpower. But when clinical data on China's flagship CoronaVac vaccine finally flowed in, they showed it was barely more than 50 percent effective—just clearing the minimum standard set by the World Health Organization. In contrast, not one but two vaccines developed by U.S. firms have been found to be upward of 95 percent effective, a standard no other country's vaccines have yet met in rigorous clinical trials. The United States's overall track record in responding to the pandemic has been awful. Yet the success of its vaccine development efforts shows that when it comes to biotechnology, the industry of the future, the U.S. is way ahead of China and most of its other rivals. A continuing refrain from Washington in recent years has been that the United States is falling behind China in the development of critical emerging technologies. In some fields, this may be true. But not in biotechnology. To be sure, **China's biotech sector is growing at a torrid pace**, and some of its firms are becoming leaders in certain areas, such as cancer treatment. Yet the U.S. retains a dominant position in research, development and commercialization, accounting for almost half of all biotech patents filed from 1999 to 2013. The triumph of its biotechnology industry during the coronavirus pandemic, producing two highly effective vaccines using an entirely new approach based on messenger RNA, and in record time, shows that the U.S.'s competitive edge in biotechnology remains largely intact. And that has important implications as Washington gears up for a sustained period of geopolitical competition with Beijing. Biotech is such a critical area for technological competition between the U.S. and China because it is transforming fields from medicine to military power. The great advances of the 19th century, like chemical fertilizers, resulted from mastering chemistry. In the 20th century, mastery of physics led to nuclear energy—and, more ominously, nuclear weapons. In the 21st century, biology offers a similar mix of peril and promise. This was illustrated dramatically by the award of the 2020 Nobel Prize for the discovery of an enzyme system known as CRISPR-Cas9, which allows an organism's genomes to be edited with high precision. It is a transformational breakthrough. But while CRISPR shows great promise in the development of new cures for long-untreatable diseases, it could also lead to a whole new generation of deadly bioweapons. That's a prospect that increasingly alarms U.S. intelligence officials. In 2016, then-Director of National Intelligence James Clapper warned Congress that "[r]esearch in genome editing conducted by countries with different regulatory or ethical standards than those of western countries probably increases the risk of the creation of potentially harmful biological **agents or** products." Although Clapper didn't name specific countries, it soon became clear that he was referring mainly to China. Four years later, his successor, John Ratcliffe, issued a far more pointed warning that "China has even conducted human testing on members of the People's Liberation Army in hope of developing soldiers with biologically enhanced capabilities. There are no ethical boundaries to Beijing's pursuit of power." Such capabilities are almost certainly only speculative—but they underscore why biotech leadership is so important for national security as well as economic competitiveness. Beijing has long envied the United States's dominant position in biotechnology and spent heavily to overtake it. Biotech has been a priority sector for state investment since the 1980s, and by one estimate Beijing had poured some $100 billion into the sector by 2018. Nowhere did it lavish more attention or invest more of its propaganda power than in developing a coronavirus vaccine. State media have spent months crowing that "China is working around the clock for breakthroughs in COVID-19 vaccines." Yet despite this push, China's vaccine program quickly took on a Potemkin air. In February 2020, barely two months after the onset of the pandemic and after a supposedly crash vaccine effort, a military doctor stood in front of a Chinese flag to receive what was billed as an experimental vaccine dose but was widely suspected to be a staged photo op. Now, having spent months talking up its two primary vaccine candidates to developing countries like Brazil and Indonesia, both of which have entered into purchase agreements with Chinese biotech firms**, Chinese officials face severe mistrust among their nation's overseas partners. For China's leaders, the disappointing returns on their big bet on biotechnology look likely to cause them more headaches at home as well as abroad—there are already signs that affluent Chinese place more trust in foreign-developed coronavirus vaccine**s than the homegrown ones produced at such great expense. For U.S. officials, though, China's relative underperformance in vaccine development presents an opportunity to reassert the United States's leadership in biotechnology and public health and bolster the nation's depleted soft power in the process. The Biden administration has already signaled it will reengage in multilateral bodies such as the World Health Organization. Yet the U.S. shouldn't stop there. Washington should begin thinking now about how to emulate the success of the President's Emergency Plan for AIDS Relief (PEPFAR)—which, though imperfect, is widely regarded as one of the most successful single public health interventions in history—to address growing disparities in access to coronavirus vaccines between countries. At the moment, vaccine supplies are controlled largely by rich countries, creating the risk of moral and public health failure if the gap persists. While COVID-19, the respiratory disease caused by the novel coronavirus, differs in many respects from AIDS, PEPFAR combined research, prevention, and access to therapeutics. Developing a comparable institutional structure to close the coronavirus vaccine access gap is the right thing to do—but it would also go a long way to restoring America's battered global reputation. At the same time, the United States can't afford to rest on its laurels in biotechnology, or any other field. Aside from China, other nations like Singapore and Israel have also invested heavily to develop their biotechnology sectors, with Israel in particular giving rise to a

thriving biotech industry. U.S. public investment in basic scientific research and development has meanwhile been on the decline for decades, and there are worrying signs that America's once world-beating innovation ecosystem is less productive, and less entrepreneurial than it once was. Despite strengths in translational research, moreover, the frontiers of biology increasingly sit at the intersection with other disciplines like computer science, meaning that funding agencies, universities and other organizations need to break down disciplinary silos. Boosting support for biotechnology research, while reforming how that money is used, will go a long way toward shoring up the United States's leading position in the global biotech sector. The U.S. biotechnology sector also faces other threats, not least growing espionage and intellectual property theft by foreign actors, especially those linked to China. Several high-profile cases brought by the U.S. Department of Justice's China Initiative have involved biotechnology researchers, and American biotech firms have been top targets for cyber theft and intrusion. Sustained outreach to researchers and research institutions is critical to preventing such theft. But efforts to clamp down on the threats posed by espionage and intellectual property theft can easily go too far and must preserve the researcher mobility and data-sharing that is essential to doing cutting-edge science. Beyond its shores, the United States should work with its partners and allies to enhance export controls on dual-use biotechnology—used for both peaceful and military gain—especially DNA templates. Many forms of genetic material and synthetic biology products are already subject to U.S. export controls, but gaps remain, and screening for genetic sequence orders relies primarily on voluntary regulation by biotech firms. Better coordinating export controls among major economies and U.S. allies can dramatically reduce the risk of sophisticated bioweapons development in the decades to come. When it comes to biotechnology, the industry of the future, the U.S. remains well ahead of its rivals, including China. That's something Americans can, and should, take pride in. But the U.S. must make proactive investments and undertake significant reforms now to ensure that things stay that way.

Biotech is the new frontier; America is ahead but China is dangerously close

Gupta 6/11 [Gaurav Gupta, Biotech Investor, Founder of Ascendant BioCapital, a life science investment firm based in New York. Previously, Gaurav worked at OrbiMed Advisors, and served as a resident in neurological surgery at Columbia University Medical Center. He has co-authored over a dozen articles in peer-reviewed journals, filed a patent on a device for use in spine surgery, and edited a book on the technical and ethical implications of using tissue engineered products in the operating room. Dr. Gupta obtained his M.D. from the Stanford University School of Medicine, where he was a Paul and Daisy Soros Fellow, and B.S. and M.S.E. in biomedical engineering from Johns Hopkins University, where he was a Charles R. Westgate Scholar.) "As Washington Ties Pharma's Hands, China Is Leaping Ahead" Barron's Magazine: Commentary, China., 6/11/2021] RM

There should be no doubt that we are living at the dawn of a golden age of biomedical innovation. The American scientific engine that produced Covid-19 vaccines in record time was fueled by a convergence of advances in genomics, biomarkers, data science, and manufacturing years in the making. The first Food and Drug Administration approvals of a host of new product formats—oligonucleotide, bispecific, oncolytic virus, CAR-T, and lentivirus/AAV—all took place within the last decade. These represent an unprecedented expansion of the armamentarium that physicians have at their disposal to treat and cure disease. **In the last few years, 47% of all new medicines were invented by U.S. biopharma companies,** with homegrown startups driving the majority of innovation. The bulk of the remainder were developed by foreign companies specifically for the U.S. market.

An indirect benefit of these trends is that most novel therapeutics undergo clinical development and early commercial launch here in the U.S. The rest of the world understands that the American patient has earlier and broader access to groundbreaking therapies via these mechanisms. Indeed, the past decade is filled with examples of medical "firsts" for American patients: the first cure for Hepatitis C, the first gene therapy for blindness, the first immunotherapy for cancer. Future rewards will be greater still if we preserve our current system of incentivizing and protecting innovation.

The remarkable innovation capacity of our biopharmaceutical industry ought to be a source of national pride. Yet while "Made in America" is the global standard for medicines in development today, misguided policy risks ceding our scientific prowess to other countries in the future. **This is particularly true in the case of China, where biotechnology has become a strategic pillar for the health of its people and economy.**

From 2016 to 2020, the market capitalization of all Chinese biopharma companies increased exponentially from $1 billion to over $200 billion. **China saw over $28 billion invested in its life sciences sector in 2020, double the previous year's amount. Returns on China's investment are already arriving**. The FDA approved a drug developed in China for the first time ever in 2019. **While China's innovation capacity currently remains behind America's, my experiences as a biopharma professional make it clear they are doing everything they can to catch up and catch up fast.**

In fact, when I speak to Chinese biotechnology executives, they boast that they can run clinical trials faster than their U.S. counterparts. The danger of misguided policies that disincentivize pharmaceutical innovation in the U.S. is effectively driving that same innovation to China. If we close off the market in the U.S. at the same time that China is opening its market to innovative new products, then we will see companies choose to first launch impactful novel medicines in China, based on clinical trials conducted in China. Because the FDA rarely accepts data generated entirely outside the U.S., this relocation of research capacity will negatively affect Americans' access to cutting-edge therapies.

The biotechnology field is advancing rapidly. Promising technologies such as targeted protein degradation and gene editing are perhaps not far from being developed into impactful medicines, and **the U.S. risks these technologies being mastered by Chinese companies.**

It is widely held that allowing China to gain an asymmetric edge in critical technologies such as AI or quantum computing could destabilize the geopolitical balance of power. The same is true of biotechnology. Chinese scientists were the first to edit the genomes of human embryos, in contravention of international standards, and the U.S. national security community believes China is pushing ahead with experimental concepts for biological and cognitive enhancement of soldiers and civilians. **American policy should be focused on protecting, rather than undermining, the global dominance of our biotechnology industry.**

Link - Innovation

The plan recapitulates IP to China, destroying competitive advantages

WSJ 5/6 [Wall Street Journal Editorial Board, WSJ Opinion Philosophy: "We speak for free markets and free people, the principles, if you will, marked in the watershed year of 1776 by Thomas Jefferson's Declaration of Independence and Adam Smith's "Wealth of Nations." So over the past century and into the next, the Journal stands for free trade and sound money; against confiscatory taxation and the ukases of kings and other collectivists; and for individual autonomy against dictators, bullies and even the tempers of momentary majorities." Edited by Paul A. Gigot and Daniel Henninger, "Biden's Vaccine IP Debacle: His patent heist is a blow to the Covid fight and U.S. biotech." The WSJ Opinion: Review and Outlook, May 6, 2021] RM

We've already criticized President Biden's bewildering decision Wednesday to endorse a patent waiver for Covid vaccines and therapies. But upon more reflection this may be the single worst presidential economic decision since Nixon's wage-and-price controls.

In one fell swoop he has destroyed tens of billions of dollars in U.S. intellectual property, **set a destructive precedent that will reduce pharmaceutical investment, and surrendered America's advantage in biotech, a key growth industry of the future**. Handed an American triumph of innovation and a great soft-power opportunity, Mr. Biden throws it all away.

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India and South Africa have been pushing to suspend patents at the World Trade Organization for months. They claim that waiving IP protections for Covid vaccines and therapies is necessary to expand global access, but their motivation is patently self-interested.

Both are large producers of generic drugs, though they have less expertise and capacity to make complex biologics like mRNA vaccines. They want to force Western pharmaceutical companies to hand over IP free of charge so they can produce and export vaccines and therapies for profit. Their strategy has been to shame Western leaders into surrendering with the help of Democrats in the U.S.

But suspending IP isn't necessary to expand supply and will impede safe vaccine production. The global vaccine supply is already increasing rapidly thanks to licensing agreements the vaccine makers have made with manufacturers around the world.

Pfizer and BioNTech this week said they aimed to deliver three billion doses this year, up from last summer's 1.2 billion estimate. Moderna increased its supply forecast for this year to between 800 million and a billion from 600 million. AstraZeneca says it has built a supply network with 25 manufacturing organizations in 15 countries to produce three billion doses this year.

AstraZeneca and Novavax have leaned heavily on manufacturers in India to produce billions of doses reserved for lower-income countries. But **India has restricted vaccine exports to supply its own population**. IP simply isn't restraining vaccine production.

Busting patents also won't speed up production, since it would take months for these countries to set up new facilities. **Competition will increase for scarce ingredients, and less efficient manufacturers with little expertise would make it harder for licensed partners to produce vaccines.**

There's also the problem of safety. Johnson & Johnson has experienced quality problems at an Emergent plant making its vaccines, and that's in Baltimore. Imagine the potential problems with unlicensed producers in, say, Malaysia or Brazil. If vaccines made there have complications, confidence in licensed vaccines could plummet too. And who would Pfizer and Moderna sue to get their reputations back?

The economic self-damage is also hard to fathom. The U.S. currently has a competitive advantage in biotech and biologics manufacturing, which could be a growing export industry. Waiving IP protections for Covid vaccines and medicines will give away America's crown pharmaceutical jewels and make the U.S. and world more reliant on India and **China** for pharmaceuticals.

Moderna has been working on mRNA vaccines for a decade. Covid represents its first success. Ditto for Novavax, which has been at it for three decades. Small biotech companies in the U.S. have been studying how to create vaccines using nasal sprays, pills and patches.

Thanks to Mr. Biden, all **this could become the property of foreign governments**. Licensing agreements allow developers to share their IP while maintaining quality control. **Breaking patents and forcing tech transfers will enable China** and low-income countries **to manufacture U.S. biotech products on their own.**

China's current crop of vaccines are far less effective than those in the West, but soon Beijing might be able to purvey Pfizer knock-offs. **The U.S. has spent years deploring China's theft of American IP, and now the Biden Administration may voluntarily let China could reap profits from decades of American innovation.**

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Instead of handing over American IP to the world, Mr. Biden could negotiate bilateral vaccine agreements and export excess U.S. supply. If Mr. Biden wants to increase global supply safely, the U.S. could spend more to help the companies produce more for export. Then the jobs would go to Americans. We thought this was the point of the production deal Mr. Biden negotiated between J&J and Merck.

Alas, this President seems to be paying more attention these days to Elizabeth Warren, Bernie Sanders, Alexandria Ocasio-Cortez and Nancy Pelosi. They think vaccines and new drugs can be conjured by government as a public good with no incentive for risk-taking or profit. This really is destructive socialism.

Mr. Biden ought to listen to Angela Merkel. Pfizer's partner BioNTech is a German firm, and the German Chancellor said Thursday that she opposes the WTO heist: "The protection of intellectual property is a source of innovation and it must remain so in the future."

At least IP is safe in Germany. Mr. Biden has sent a signal around the world that **nobody's intellectual property is safe in America.**

OFF

Counterplan: The member states of the World Trade Organization ought to

- **offer generous payment per immunization in [-------] and subsidies to oversee distribution of [-----] to local pharmaceutical companies**
- **make rewards conditional upon speed and inoculation efficacy**
- **create IPTK banks to bypass trade secrets and encourage public-private collaboration**

Subsidized reward mechanisms harness market demand

Karan et al 4/2, Abraar Karan is an internal medicine physician at the Brigham and Women's Hospital/Harvard Medical School and a columnist at The BMJ. He previously worked on the covid-19 response in Massachusetts state. The views expressed here are his own and do not represent those of his employers, Thomas Pogge is a professor and director of the Global Justice Program at Yale University. He co-founded Incentives for Global Health, a team effort toward creating the Health Impact Fund , 4-2-2021, "Solving global vaccine inequity requires new incentives for pharmaceutical companies,", The British Medical Journal
https://blogs.bmj.com/bmj/2021/04/02/solving-global-vaccine-inequity-requires-new-incentives-for-pharmaceutical-companies/]AAli

Scientists have been successful in bringing several highly effective covid-19 vaccines to market in record time. But manufacturing scale-up is slow—with a few companies holding the "know-how," but unenthusiastic about licensing this to others. Current trends predict that 90% of people in 67 low income countries will not be vaccinated this year and that most poorer populations will not gain herd immunity even in 2022. This delay will facilitate the emergence of new disease strains that may endanger even those already vaccinated. More importantly, millions of people in poor countries will needlessly die, particularly those who are at higher risk of mortality, such as those who are older and immunocompromised. To speed up manufacturing, some 119 developing countries have called for a temporary suspension of intellectual property rights related to covid-19 to allow manufacturers worldwide to produce and sell approved vaccines without the patentee's permission. Patentees and the affluent countries representing them have opposed such a waiver: it would undermine incentives to innovate against future pandemics, they say, and it would not help much because patentees would not share crucial technologies and know-how with manufacturers who had not paid them for a license to produce and sell (as was the case with Moderna, which liberalized its intellectual property, but little else). And there is a further problem: **even with generic manufacturers in the driver's seat, the world's poorest populations are still very poor, and thus would still be served last**, if ever. Ultimately, waiving global policy agreements like TRIPS is a stopgap measure; the system needs more fundamental change. The urgent needs of the world's poorest people must be subsidized into effective market demand. This might be done through a massive increase in funding for the existing COVAX facility, which is currently projected to provide two billion doses per year, at best only around 20% of global vaccine needs. COVAX **could** then offer a generous payment per immunization to pharma companies, featuring a declining premium for early delivery and payment adjustment with regard to quality (for example, how much protection an immunization affords, for how long, against which variants). Such a pay for performance scheme would give firms with approved vaccines a financial incentive to ramp up production for fast delivery. To this end, they would, competing with one another, seek to engage and expand available manufacturing capacity while fully supporting contracted manufacturers. Supplies produced would be directed to where they can be most effective in suppressing the pandemic, without consideration for the poverty or affluence of the various populations. Even if such an initiative were to raise cost by a factor of 10—from the $6 billion COVAX currently has to $60 billion— this would still be a tiny fraction of the economic harm this pandemic has caused and might yet cause in the future. The US alone has just allocated $1.9 trillion to avert some of the economic damage it has sustained from covid-19. An extra $54 billion, spread over many countries, is a small price to pay for bringing this pandemic under control at least two years sooner. A key lesson of covid-19 is that the great benefits the pharmaceutical sector has to offer must fully include the world's poorest people. This is a firm command of justice and, at least with communicable diseases, an imperative of prudence as well. We must place advanced pharmaceuticals within reach of poor communities and must ensure that the diseases concentrated among them are lucrative targets of pharmaceutical research and development. To achieve global pharmaceutical equity in a sustainable way, we should create a complementary reward mechanism, **additional to patent monopolies**, that is designed to pay for better health outcomes. This mechanism can be but is not limited to the Health Impact Fund (a system one of us, TP, co-founded), which gives innovators the option to have any of their new pharmaceuticals rewarded according to the health gains achieved with it, on condition that it is sold at the variable cost of supplying it. Here "health gains" would be understood to cover not merely the therapeutic improvements that users experience, but also wider societal benefits, such as reduced infections among non-users. Moreover, pharmaceutical companies would be incentivized to effectively **oversee and coordinate** the **delivery of therapeutics** to end users, whether that be **through**

national health systems or public-private partnerships. As an immediate example, such a system could effectively benefit latecomers to vaccine rollouts, given that there is an immense market potential remaining in low and middle income countries, which is largely uninteresting to early comers like Moderna and Pfizer whose supply has already been sold to high income countries. With the Health Impact Fund in place, the global pharmaceutical sector would be much better prepared to respond effectively to future pandemics, and would have been for past ones too (we wrote about this in the context of the Ebola and Zika viruses previously). Furthermore, it would be able to profitably unleash its skills upon the enormously harmful diseases associated with poverty, including the 20 WHO listed neglected tropical diseases, which affect over a billion people, as well as tuberculosis, malaria, hepatitis, and pneumonia, which together kill millions of people each year. We can and must tackle these diseases. The investment for doing so would pay for itself many times over.

IPTK banks are key to DCVMs

Crager 18 [Dr. Sara Crager, MD is a board certified emergency medicine physician in Los Angeles, California. She is affiliated with Ronald Reagan UCLA Medical Center, 2018 December, "Improving Global Access to New Vaccines: Intellectual Property, Technology Transfer, and Regulatory Pathways," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6291766/]//AAli

*developing country vaccine manufacturers

I propose a strategy that would integrate key aspects of both these models, creating a structure capable of facilitating access to new vaccines by establishing an entity that pools all relevant intellectual property, technology, and know-how: an IPTK bank. An IPTK bank would bring together the necessary intellectual property rights, manufacturing process information, know-how, and regulatory expertise into a single platform that could be licensed as a package with associated training modules; it could also offer assistance in navigating vaccine registration with national regulatory authorities. A licensing approach similar to that used by the MPP would be employed to address intellectual property barriers by creating a structure whereby the patented technology could be disseminated to multiple DCVMs, each paying royalties to the patent holder. The manufacturing process information, know-how, and regulatory expertise would be brought together through the organization hosting the IPTK bank, which would closely mirror the organizational model of the WHO technology transfer hub. Barriers to Creation of the Proposed Banks Funding, inevitably, will be a major barrier to the creation of IPTK banks. IPTK banks would require an initial period of funding in order to acquire and then disseminate the vaccine technology. Once a critical mass of DVCMs began producing the vaccine, however, provision of affordable vaccines would be self-sustaining, with reliance on market forces to ensure appropriate price declines. IPTK banks thus would not be as subject to the vagaries of sustained donor funding as organizations like GAVI, but would rather need to raise enough money to support the initial acquisition and dispersal period for each new vaccine technology. Given that projected spending on new vaccines necessary to achieve the GVAP goals is estimated at nearly US $30 billion, it may ultimately be more cost-effective to invest in upstream mechanisms to rapidly achieve sustained price reductions for new vaccines. The greatest barrier to the creation of IPTK banks is the need for close cooperation with innovator companies. Fundamentally, engaging with an IPTK bank would be similar to the technology transfer arrangements that multinational pharmaceutical companies frequently enter into with individual DCVMs to expand their regional vaccine production and distribution. The major departures from a traditional technology transfer agreement would include licensing terms that allow the IPTK bank to grant nonexclusive licenses to multiple DCVMs and the transfer of technology to a hub organization at a publicly funded institution rather than directly to a DCVM. Because an IPTK bank strategy depends on significant involvement from innovator companies, creating appropriate conditions that incentivize their participation is key to the success of this model. Engagement With Innovator Companies Multinational pharmaceutical companies frequently engage in successful technology transfer with DCVMs, and this trend appears to be growing. According to an International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) spokesperson, Technology transfer in medicines and vaccines were growing rapidly in the past decade, benefiting both pharmaceutical companies and the health of recipient countries' population alike.51 In fact, so much interest has developed around this topic that the IFPMA recently issued a research paper titled "Technology Transfer: a Collaborative Approach to Improve Global Health—the R&D Pharmaceutical Industry Experience." In addition to providing numerous case studies of technology transfer partnerships, the paper identified 8 conditions that the pharmaceutical industry considers necessary for successful technology transfer relationships: a viable and accessible local market, political stability and good economic governance, clear economic development priorities, adherence to high regulatory standards, availability of skilled workers, adequate capital markets, strong intellectual property rights and effective enforcement, and a high-quality relationship between industry and government, and their ability to work together effectively for long periods of time. An IPTK bank as a technology partner would fulfill most of these criteria. The fact that an IPTK bank would almost certainly be based in a high-income country would also address a number of these issues. In this context, there should be relatively little concern over issues such as political stability and good economic governance, and most industrialized-country governments are generally considered to have relatively good relationships with industry and a long history of working together effectively. These conditions may not be guaranteed to the same degree in all countries that receive technology from an IPTK bank, but that risk would not be directly borne by the company and would be distributed over multiple potential technology partners. In addition, high-income countries generally have well-established systems of strong intellectual property rights with effective enforcement. Again, this may or may not be true to the same extent in all countries that are recipients of IPTK bank technology; however, industry has already shown itself willing to discuss licensing arrangements with the MPP that would involve licensing intellectual property rights to a central organization, which would then provide nonexclusive licenses to multiple other entities in countries that may not have similarly strong enforcement of intellectual property rights. Regarding access to viable local markets, although the IPTK bank itself would not directly have such access, licenses would be granted only to partners with demonstrable access to local

markets large enough to achieve economies of scale such that significant price reductions could be generated (as occurs with the MPP). Finally, if the IPTK bank is based at an institution such as the Netherlands Vaccine Institute or the International Vaccine Institute, availability of skilled workers should be more than adequate. Basing the IPTK bank within such organizations would provide a strong base of experience in adherence to high regulatory standards that would be passed on to IPTK bank technology recipients. Overall, IPTK banks would fulfill the criteria that the IFPMA has identified as being critical to the decision of multinational pharmaceutical companies to engage with a technology transfer partner. The major departure from the technology transfer arrangements described in the IFPMA report would be use of a licensing covering all necessary intellectual property modeled on the MPP licenses rather than the traditional sublicense negotiated between pharmaceutical companies and their technology partners. Companies have demonstrated their willingness to enter into negotiations involving such licenses with the MPP, providing a precedent that this may not present an insurmountable barrier to companies engaging in technology transfer agreements with an IPTK bank.

Although an IPTK bank would require a high degree of commitment and cooperation from innovator companies, it seems possible that industry might be willing to consider engaging in discussion regarding this approach to expanding vaccine access.

Case

Warming doesn't cause extinction

Nordhaus 20 Ted Nordhaus, an American author, environmental policy expert, and the director of research at The Breakthrough Institute, citing new climate change forecasts. [Ignore the Fake Climate Debate, 1-23-2020, https://www.wsj.com/articles/ignore-the-fake-climate-debate-11579795816]//BPS

Beyond the headlines and social media, where Greta Thunberg, Donald Trump and the online armies of climate "alarmists" and "deniers" do battle, there is **a real climate debate** bubbling along in **scientific journals**, conferences and, occasionally, even in the halls of Congress. It gets a lot less attention than the boisterous and fake debate that dominates our public discourse, but it is much more relevant to how the world might actually address the problem. In the real climate debate, no one denies the relationship between human emissions of greenhouse gases and a warming climate. Instead, the disagreement comes down to different views of climate risk in the face of multiple, cascading uncertainties. On one side of the debate are optimists, who believe that, with improving technology and greater affluence, our societies will prove quite adaptable to a changing climate. On the other side are pessimists, who are more concerned about the risks associated with rapid, large-scale and poorly understood transformations of the climate system. But **most pessimists** do not believe that **runaway climate change** or **a hothouse earth** are plausible scenarios, **much less** that **human extinction** is imminent. And most optimists recognize a need for policies to address climate change, even if they don't support the radical measures that Ms. Thunberg and others have demanded. In the fake climate debate, both sides agree that economic growth and reduced emissions vary inversely; it's a zero-sum game. In the real debate, the relationship is much more complicated. Long-term economic growth is associated with both rising per capita energy consumption and slower population growth. For this reason, as the world continues to get richer, higher per capita energy consumption is likely to be offset by a lower population. **A richer world** will also likely be **more technologically advanced**, which means that energy consumption should be **less carbon-intensive** than it would be in a poorer, less technologically advanced future. In fact, a number of the high-emissions scenarios produced by the United Nations Intergovernmental Panel on Climate Change involve futures in which the world is relatively poor and populous and less technologically advanced. Affluent, developed societies are also much better equipped to respond to climate extremes and natural disasters. That's why natural disasters kill and displace many more people in poor societies than in rich ones. It's not just seawalls and flood channels that make us resilient; it's air conditioning and refrigeration, modern transportation and communications networks, early warning systems, first responders and public health bureaucracies. New research published in the journal Global Environmental Change finds that **global economic growth** over the last decade has **reduced** climate mortality by **a factor of five**, with the greatest benefits documented in the poorest nations. In low-lying Bangladesh, 300,000 people died in Cyclone Bhola in 1970, when 80% of the population lived in extreme poverty. In 2019, with less than 20% of the population living in extreme poverty, Cyclone Fani killed just five people. "Poor nations are most vulnerable to a changing climate. The fastest way to reduce that vulnerability is through economic development." So while it is true that poor nations are most vulnerable to a changing climate, it is also true that the fastest way to reduce that vulnerability is through economic development, which requires infrastructure and industrialization. Those activities, in turn, require cement, steel, process heat and chemical inputs, all of which are impossible to produce today without fossil fuels. For this and other reasons, the world is unlikely to cut emissions fast enough to stabilize global temperatures at less than 2 degrees above pre-industrial levels, the long-standing international target, much less 1.5 degrees, as many activists now demand. But **recent forecasts** also suggest that many of **the worst-case climate scenarios** produced in the last decade, which assumed unbounded economic growth and fossil-fuel development, are also **very unlikely**. There is **still substantial uncertainty** about how sensitive global temperatures will be to higher emissions over the long-term. But **the best estimates** now suggest that the world is on track for **3 degrees of warming** by the end of this century, not 4 or 5 degrees as was once feared. That is due in part to slower economic growth in the wake of the global financial crisis, but also to decades of technology policy and energy-modernization efforts. "We have better and cleaner technologies available today because policy-makers in the U.S. and elsewhere set out to develop those technologies." The energy intensity of the global economy continues to fall. Lower-carbon natural gas has displaced coal as the primary source of new fossil energy. The falling cost of wind and solar energy has begun to have an effect on the growth of fossil fuels. Even nuclear energy has made a modest comeback in Asia.