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Innovation is high now

Kenan 6-9, The Frank Hawkins Kenan Institute of Private Enterprise develops and promotes innovative, market-based solutions to vital economic issues. With the belief that private enterprise is the cornerstone of a prosperous and free society, the institute fosters the entrepreneurial spirit to stimulate economic prosperity and improve the lives of people in North Carolina, across the country and around the world. Kenan Institute, 6-9-21, "Turbocharging Healthcare Innovation" https://kenaninstitute.unc.edu/kenan-insight/turbocharging-healthcare-innovation/ brett

As COVID-19 began to spread around the globe, **companies** and **entrepreneurs stepped up** to develop new technologies and redeploy existing technologies in their portfolio to tackle the disease and cope with the constraints it brought. The pandemic forced telemedicine into the mainstream and brought mRNA vaccine technology to the forefront. At the same time, new technologies such as CRISPR gene editing and artificial intelligence (AI) approaches have been finding their niche for speeding up drug discovery and development. Healthcare innovation was already on the fast train before the pandemic. Now, it's been turbocharged. In this Kenan Insight, we explore why the 2021 Trends in Entrepreneurship Report names emerging technology in the healthcare industry as a key trend for entrepreneurship, along with some of the challenges that come with fast-moving technology advances. A trajectory of explosive growth The healthcare industry has experienced extraordinary growth over the past four decades. Big pharma is driving much of this boom, accounting for 10% of the U.S. economy's overall R&D spending at the end of 2020.1 The medical device industry, expected to generate $54.5 billion over the next four years, is another important player.2 This growth is catching the attention of investors. In 2020, health tech startups raised approximately $14 billion in venture capital funding, nearly double that of 2019.3 CB Insights estimates there are now 51 healthcare unicorns, defined as startups valued at $1 billion or more. Health-tech venture funding reached **record levels** in 2020 Innovation is a critical driver in the healthcare sector. **Increasing rates of innovation** can be seen in the sharp rise of U.S. **patents** granted for pharmaceuticals and medical devices in recent years. Between 2013 and 2019, more than 60,000 pharmaceutical patents and more than 125,000 medical device patents were granted.4 Today, there are more than 18,500 drugs at various stages of the development process worldwide.5 Maturing technologies The increasing numbers of patent applications, clinical trials and collaborations are leading indicators of a vibrant and growing biopharmaceutical ecosystem. However, the proliferation of innovation tools, rather than just innovative products, is what will allow the next generation of pharmaceutical drugs to be discovered more quickly and more efficiently, to provide more effective treatments and to target diseases that have so far evaded our collective intervention efforts. As scientists learn more about human genes and their connection to diseases, these insights can feed into tools that make drug R&D faster, less expensive and more precise. AI technology has matured to the point where it can now be used reliably to analyze huge amounts of data and solve extremely complex problems. This has made AI attractive to the pharmaceutical industry as a tool that can enable more efficient identification of new drugs and drug targets. In 2020, drug discovery was the focus area that received the most private AI investment, with more than $13.8 billion invested globally. This was 4.5 times higher than the total for 2019.6 CRISPR gene editing is another hot technology that is enabling the development of more innovative and accurate therapeutic strategies. This tool is making it easier to determine the genes and proteins that cause or prevent disease and thus to identify new targets for potential drugs. As of the second quarter of 2020, there were 724 active companies around the world focused on using or developing CRISPR technology and almost 50 clinical trials involving CRISPR.7

mRNA was certainly one of the brightest technology stars of 2020. After decades of research, mRNA proved to be the ideal solution for developing a highly effective COVID-19 vaccine at record speed. However, this is likely **only the beginning** of the story for mRNA. Therapies based on mRNA technology are being developed to treat **malaria, cancer and multiple sclerosis** and we'll likely see more mRNA-based vaccines designed to fight a host of current and **future infectious diseases**. As of February

2021, CB Insights reports more than 520 ongoing clinical trials worldwide that were applying mRNA technology to more than 20 disease classes.8

And decreasing medical IP eliminates incentives for innovation and kills development of new medicines

Bacchus 20 James Bacchus, December 16, 2020, The Cato Institute. An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines. James Bacchus is Adjunct Fellow, Cato Institute, former U.S. Representative (D-FL), and former Chairman, World Trade Organization's Appellate Body
https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#conclusion //AHS

With the belief that medicines should be "public goods," there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which **many medicines would simply not exist if it were not for the existence of IP rights** and the protections they are afforded. Technically, IP rights are exceptions to free trade. A long-standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion. The primary justification for granting and protecting IP rights is that **they are incentives for innovation, which is the main source for long-term economic growth and enhancements in the quality of human life.** IP rights spark innovation by "enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks."18 The knowledge from innovations inspired by IP rights spills over to inspire other innovations. **The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know-how**. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to "the wealth of nations." Digital and other economic growth in the 21st century is increasingly ideas-based and knowledge intensive. **Without IP rights** as incentives, **there would be less new knowledge and thus less innovation.** In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus **preventing the discovery and development of knowledge for new goods and services that the world needs**. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to "foster innovation," they make no mention of IP rights.19

And affirming undermines the economic certainty provided by TRIPS---that disrupts innovation in every sector Lee and Holt 5-10

Tom **Lee &** Christopher **Holt 5-10**, Tom received a B.A. in Economics with a Statistics Minor from the University of Maryland, College Park, in 2018. Christopher has a Master's in Congressional and Presidential Studies from The Catholic University of America, and he studied political science as an undergraduate at Whitman College. American Action Forum, May 10, 2021. "Intellectual Property, COVID-19 Vaccines, and the Proposed TRIPS Waiver" https://www.americanactionforum.org/insight/intellectual-property-covid-19-vaccines-and-the-proposed-trips-waiver/ brett

Public posturing aside, the Biden Administration surely knows that a TRIPS waiver for COVID-19 related IP will likely be futile. Scaling up production, as Klain alluded to, has proven to be the main challenge to manufacturing larger quantities of vaccine.[4] Waiving TRIPS would do nothing to address this constraint. **Waiving TRIPS would** instead encourage IP abuse and distort **market forces** and **innovation**. TRIPS Provisions The TRIPS agreement is an international trade agreement among all 164 members of the WTO. It is one of three founding and central components of the WTO, along with the General Agreement on Tariffs and Trade (GATT) and the General Agreement on Trade in Services (GATS). The purpose of the TRIPS agreement is to unify trade **and** provide **increased certainty** in international economic relations. Among other things, TRIPS specifically: Provides minimum IP protections and standards that apply to all WTO members; Outlines enforcement actions that countries can undertake to remedy violations of the above standards; and Establishes dispute settlement procedures to allow countries to negotiate an end to disagreements. TRIPS does, however, allow for compulsory licensing where in a public health emergency, a country may copy patented drugs without the permission of the original

manufacturer with WTO approval. Proposal to Waive TRIPS The recent proposal submitted by India and South Africa and signed on by over 100 developing countries would waive four specific protections of COVID-19 vaccines and related medical products and services: Copyrights; Patents; Trademarks; and Undisclosed information procedures. The first three protections allow companies to prevent foreign companies from copying their products. They require the original company to disclose information about the product, however. Foreign companies are free to study the disclosed information of the patent but cannot copy it unless given a licensing agreement from the original company. Contrarily, companies can choose not to get patents for their products and instead keep their information secret. The fourth protection prevents the theft of trade secrets of foreign companies. While TRIPS has been waived previously, if approved, this would be the **broadest waiver** since the agreement's enactment in 1995.[5] TRIPS and Manufacturing Capacity The primary justification for waiving TRIPS is that IP protections cause underutilized manufacturing capacity. By removing TRIPS, developing nations could copy patented drugs and use their own manufacturers to produce vaccines, thereby increasing access. This rationale, however, is flawed. Adar Poonawalla, CEO of the Serum Institute of India—currently the largest producer of COVID-19 vaccine doses in the world—has argued that access to IP is not limiting vaccine production, rather it is the time involved in scaling up manufacturing capacity.[6] It should also be noted that Moderna has already pledged not to enforce its own COVID-19 vaccine patents during the pandemic.[7] In addition, COVID-19 vaccines such as those produced by Pfizer and Moderna use emerging and very complex technologies and processes. These technologies and processes are essential to producing and increasing scale of COVID-19 vaccines. They are not published in patents but rather kept as trade secrets. The fourth protection mentioned above only prevents theft of trade secrets; it does not allow or disallow a company from keeping trade secrets. Waiving TRIPS therefore does nothing to speed up vaccine production even if there were excess manufacturing capacity, as manufacturers would not receive the essential trade secrets they would need. The issue at present is not underutilized manufacturing capacity, rather scaling up production has been the largest difficulty of vaccine manufacturing. It takes anywhere from 60 to 120 days to produce a single batch of vaccines. Even with manufacturing challenges, between 9.5 and 13.5 billion doses of COVID-19 vaccines are projected to be produced in 2021. Eleven billion doses would be sufficient to vaccinate 70 percent of the world population and reach heard immunity, assuming 2-dose vaccinations.[8] TRIPS and Compulsory Licensing Separate from a broad IP waiver, TRIPS includes a compulsory licensing process. Foreign manufacturers are free to ask a patentee for a voluntary licensing agreement to manufacture a product. This process can be long, however, and the patentee can ultimately refuse. When this happens, TRIPS allows the manufacturer through its national government to grant a compulsory license provided the manufacturer has first sought a voluntary licensing agreement. This compulsory license is issued by that national government to the manufacturer to produce a patented drug without the original patentee's permission. Each compulsory license must apply to a specific product. It is important to note that TRIPS does not have a governing body which oversees this process. At the same time, if a country grants an internationally unpopular compulsory license, it will face economic, political, and retaliatory ramifications from other governments and private firms, so governments must weigh these costs. In addition, if a country declares a national emergency or other circumstances of extreme urgency, TRIPS allows a foreign manufacturer to immediately apply for a compulsory license, skipping the process to apply for a voluntary license. A TRIPS waiver, like the one suggested for COVID-19-related IP, is therefore entirely unnecessary—even if IP protections were an obstacle to vaccine access. In the case of COVID-19, compulsory licensing would not, however, address the real issues related to scaling manufacturing capacity. The Vagueness of the Proposed TRIPS Waiver Under the broad language of the proposed TRIPS waiver, any drugs that have use for patients with COVID-19, including those that **predate the pandemic**, could lose patent protection. Thus, a foreign company could produce a specific drug under the auspices of COVID-19 but sell it for another disease. Moreover, the foreign company would not have to provide any financial compensation to the company from whom they took the IP. The proposal's language is so broad that other patented medical products beyond pharmaceutical drugs such as masks, non-pharmaceutical **chemical compounds**, and respirators would also be subject to the waiver. It is also noteworthy that the vaccines developed by Pfizer, Moderna, and Johnson & Johnson are not currently approved by the Indian government for use in India, due to regulatory obstacles related to localized clinical trials. Effectively then, India is pointing to IP protections as an obstacle to obtaining vaccines they have not even approved for use in their country.[9] At the same time, a concerted global effort is underway to ensure access to COVID-19 vaccines in all countries. The WHO, Gavi (previously the Global Alliance for Vaccines and Immunization), and the Coalition for Epidemic Preparedness Innovations have partnered to establish the COVAX initiative, designed specifically to distribute vaccines to the developing world. COVAX is projected to distribute at least 2 billion vaccines by the end of 2021.[10] Johnson & Johnson has further announced plans to distribute 500 million vaccines to developing nations starting in mid-2021, in addition to those it already allocated to other nations.[11]TRIPS and Innovation The TRIPS agreement and its IP protections were created to increase unity and certainty in the global economy. The economic certainty provided by **IP protections preserve competitiveness** and **increase value**—i.e., IP protections provide incentives to companies to **create new and groundbreaking technologies**. In terms of the COVID-19 pandemic, perhaps it is these incentives that encouraged companies to produce vaccines quickly and successfully. **Without IP protections**, companies could not reap the rewards of their efforts. Waiving TRIPS would weaken the market forces that encourage innovation. Combined with the broad language of the TRIPS waiver, the **loss of innovation** would happen in **many industries and sectors of the global economy**. Conclusion The proposal to waive TRIPS is based on the misperception that IP protections serve as barriers to COVID-19 vaccine production. In fact, the difficulty of scaling up production is the key challenge. Waiving TRIPS will do nothing to increase vaccine production, represents poor policy toward IP, and will create a whole new set of **trade policy challenges**. A better approach is to build upon current global vaccine partnerships while ensuring that companies can secure their supply chains. Such efforts would increase access to vaccines while avoiding the potentially widespread and long-term problems associated with waiving IP protections provided by TRIPS.

2 impacts:

1. Medical innovation specifically is key to address future pandemics---extinction.

Engelhardt 8 (H. Tristram, 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, "Innovation and the Pharmaceutical Industry: Critical Reflections on the Virtues of Profit," https://www.amazon.com/Innovation-Pharmaceutical-Industry-Reflections-Conflicts/dp/0980209447) (Taiwan)

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 industries.

2. Innovation is an impact filter---it encompasses AND outweighs every existential threat.

Dylan **Matthews 18**. Co-founder of Vox, citing Nick Beckstead @ Rutgers University. 10-26-2018. "How to help people millions of years from now." Vox. https://www.vox.com/future-perfect/2018/10/26/18023366/far-future-effective-altruism-existential-risk-doing-good brett

If you care about improving human lives, you should overwhelmingly care about those quadrillions of lives rather than the comparatively small number of people alive today. The 7.6 billion people now living, after all, amount to less than 0.003 percent of the population that will live in the **future**. It's reasonable to suggest that those **quadrillions** of future people have, accordingly, **hundreds of thousands of times** more moral weight than those of us living here **today** do. That's the basic argument behind Nick Beckstead's 2013 Rutgers philosophy dissertation, "On the overwhelming importance of shaping the far future." It's a glorious mindfuck of a thesis, not least because Beckstead shows very convincingly that this is a conclusion any plausible moral view would reach. It's not just something that weird utilitarians have to deal with. And Beckstead, to his considerable credit, walks the walk on this. He works at the Open Philanthropy Project on grants relating to the far future and runs a charitable fund for donors who want to prioritize the far future. And arguments from him and others have turned "long-termism" into a very vibrant, important strand of the effective altruism community. But what does prioritizing the far future even mean? The most **literal** thing it could mean is preventing human **extinction**, to ensure that the species persists as long as possible. For the long-term-focused effective altruists I know, that typically means identifying concrete threats to humanity's continued existence — like unfriendly artificial intelligence, or a pandemic, or global warming/out of control geoengineering — and engaging in activities to prevent that specific eventuality. But in a set of slides he made in 2013, Beckstead makes a compelling case that while that's certainly **part** of what caring about the far future entails, approaches that address **specific threats** to humanity (which he calls "**targeted**" approaches to the far future) have to **complement** "**broad**" approaches, where instead of trying to **predict** what's going to kill us all, you just **generally try to keep civilization running as best it can**, so that it is, as a whole, well-equipped to deal with **potential** extinction events in the **future**, not just in 2030 or 2040 but in 3500 or 95000 or even 37 million. In other words, caring about the far future **doesn't mean just paying attention to low-probability risks of total annihilation**; it also means **acting on pressing needs now**. For example: **We're** going to be **better prepared** to prevent extinction from **AI** or a **supervirus** or **global warming** if society as a whole makes **a lot of scientific progress**. And a significant bottleneck there is that the vast majority of humanity doesn't get high-enough-quality education to engage in scientific research, if they want to, which reduces the odds that we have enough trained scientists to come up with the breakthroughs we need as a civilization to survive and thrive. So maybe one of the **best things** we can do for the **far future** is to improve school systems — here and now — to harness the group economist Raj Chetty calls "lost Einsteins" (**potential innovators** who are thwarted by poverty and inequality in rich countries) and, more importantly, the hundreds of millions of kids in developing countries dealing with even worse education systems than those in depressed communities in the rich world. What if living ethically for the far future means living ethically now? Beckstead mentions some other broad, or very broad, ideas (these are all his descriptions): Help make **computers faster** so that people everywhere can work more efficiently Change **i**ntellectual **p**roperty law so that technological innovation can happen more quickly Advocate for open borders so that people from poorly governed countries can move to

better-governed countries and be more productive Meta-research: improve **incentives** and **norms** in **academic work** to better advance human knowledge Improve education Advocate for political party X to make future people have values more like political party X ”If you look at these areas (economic growth and technological progress, access to information, individual capability, social coordination, motives) a lot of everyday good works contribute,” Beckstead writes. “An implication of this is that a lot of everyday good works are good from a broad perspective, even though hardly anyone thinks explicitly in terms of far future standards.” Look at those examples again: It’s just a list of what normal altruistically motivated people, not effective altruism folks, generally do. Charities in the US love talking about the lost opportunities for innovation that poverty creates. Lots of smart people who want to make a difference become scientists, or try to work as teachers or on improving education policy, and lord knows there are plenty of people who become political party operatives out of a conviction that the moral consequences of the party’s platform are good. All of which is to say: Maybe effective altruists aren’t that special, or at least maybe we don’t have access to that many specific and weird conclusions about how best to help the world. If the far future is what matters, and generally trying to make the world work better is among the best ways to help the far future, then effective altruism just becomes plain ol’ do-goodery.*

3

Counterplan text: the member nations of the WTO ought to increase intellectual property protections for CRISPR gene editing technology

CRISPR gene editing patents control who can use the technology otherwise infinite actors have access. The question of who owns the technology is unresolved

Mischel 4/27 Fiona Mischel, April 27, 2021, Synbiobeta. Who owns CRISPR in 2021? It's even more complicated than you think. Fiona Mischel is the Editor-in-Chief of SynBioBeta. She frequently covers sustainability, CRISPR research, food and agriculture technology, and biotech for space travel. https://synbiobeta.com/who-owns-crispr-in-2021-its-even-more-complicated-than-you-think/ //AHS

The question of **who owns CRISPR**, the genetic editing tool expected to transform modern medicine, **is a confusing mess of legal battles**, obscure naming conventions, and subtle variations in molecular form and function. **The entities that eventually own the patent** rights to these tools **will** almost certainly **control who can use it, how it's used, and how much it costs**. The original CRISPR patent battle between UC Berkeley and the MIT-Harvard Broad Institute has not been pretty. Patent fights rarely are, but the debate of who owns CRISPR-Cas9 has been especially heated. It's not surprising. Since CRISPR is billed as the future of medicine, **the ability to own and license** some part of the tool **is critical** for a slew of companies founded on the original CRISPR-Cas9 technology. But who owns CRISPR in 2021 is significantly more complicated than it was just a few years ago. **As more companies, researchers, and academic institutions file patent applications** for subtly different CRISPR molecules, it's no longer possible to narrow down the intellectual property rights to just two or three big players.

It's a medicine

Bergman 19 Mary Todd Bergman, Harvard University, January 9, 2019. Perspectives on Gene Editing. https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/

Medicine is at a turning point, on the cusp of major change as disruptive technologies such as gene, RNA, and cell therapies enable scientists to approach diseases in new ways. The swiftness of this change is being **driven by innovations such as CRISPR gene editing**, which makes it possible to correct errors in DNA with relative ease. Progress in this field has been so rapid that the dialogue around potential ethical, societal, and safety issues is scrambling to catch up. This disconnect was brought into stark relief at the Second International Summit on Human Genome Editing, held in Hong Kong in November, when exciting updates about emerging therapies were eclipsed by a disturbing announcement. He Jiankui, a Chinese researcher, claimed that he had edited the genes of two human embryos, and that they had been brought to term. There was immediate outcry from scientists across the world, and He was subjected to intense social pressure, including the removal of his affiliations, for having allegedly disregarded ethical norms and his patients' safety. Yet as I. Glenn Cohen, faculty director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, has said, gene editing comes in many varieties, with many consequences. Any deep ethical discussion needs to take into account those distinctions. Human genome editing: somatic vs. germline The germline editing He claimed to have carried out is quite different from the somatic gene therapies that are currently changing the frontiers of medicine. While somatic gene editing affects only the patient being treated (and only some of his or her cells), germline editing affects all cells in an organism, including eggs and sperm, and so is passed on to future generations. The possible consequences of that are difficult to predict. Somatic gene therapies involve modifying a patient's DNA to treat or cure a disease caused by a genetic mutation. In one clinical trial, for example, scientists take blood stem cells from a patient, use CRISPR techniques to correct the genetic mutation causing them to produce defective blood cells, then infuse the "corrected" cells back into the patient, where they produce healthy hemoglobin. The treatment changes the patient's blood cells, but not his or her sperm or eggs. Germline human genome editing, on the other hand, alters the genome of a human embryo at its earliest stages. This may affect every cell, which means it has an impact not only on the person who may result, but possibly on his or her descendants. There are, therefore, substantial restrictions on its use. Germline editing in a dish can help researchers figure out what the health benefits could be, and how to reduce risks. Those include targeting the wrong gene; off-target impacts, in which editing a gene might fix one problem but cause another; and mosaicism, in which only some copies of the gene are altered. For these and other reasons, the scientific community approaches germline editing with caution, and the U.S. and many other countries have substantial policy and regulatory restrictions on using germline human genome editing in people. But many scientific leaders are asking: When the benefits are believed to outweigh the risks, and dangers can be avoided, should science consider moving forward with germline genome editing to improve human health? If the answer is yes, how can researchers do so responsibly? CRISPR pioneer Feng Zhang of the Broad Institute of Harvard and MIT responded immediately to He's November announcement by calling for a moratorium on implanting edited embryos in humans. Later, at a public event on "Altering the Human Genome" at the Belfer Center at Harvard Kennedy School (HKS), he explained why he felt it was important to wait: "The moratorium is a pause. Society needs to figure out if we all want to do this, if this is good for society, and that takes time. If we do, we need to have guidelines first so that the people who do this work can proceed in a responsible way, with the right oversight and quality controls." Aside from the safety risks, human genome editing poses some hefty ethical questions. For families who have watched their children suffer from devastating genetic diseases, the technology offers the hope of editing cruel mutations out of the gene pool. For those living in poverty, it is yet another way for the privileged to vault ahead. One open question is where to draw the line between disease treatment and enhancement, and how to enforce it, considering differing attitudes toward conditions such as deafness. Robert Truog, director of the Center for Bioethics at Harvard Medical School (HMS), provided context:"This question is not as new as it seems. Evolution progresses by random mutations in the genome, which dwarf what can be done artificially with CRISPR. These random mutations often cause serious problems, and people are born with serious defects. In addition, we have been manipulating our environment in so many ways and exposing ourselves to a lot of chemicals that cause unknown changes to our genome. If we are concerned about making precise interventions to cure disease, we should also be interested in that. "To me, the conversation around Dr. He is not about the fundamental merits of germline gene editing, which in the long run will almost certainly be highly beneficial. Instead, it's about the oversight of science. The concern is that with technologies that are relatively easy to use, like CRISPR, how does the scientific community regulate itself? If there's a silver lining to this cloud, I think it is that the scientific community did pull together to be critical of this work, and took the responsibility seriously to use the tools available to them to regulate themselves."When asked what the implications of He's announcement are for the emerging field of precision medicine, **Richard Hamermesh**, **faculty co-chair of the Harvard** Business School/Kraft **Precision Medicine Accelerator, said**: "Before we start working on embryos, we have a long way to go, and

civilization has to think long and hard about it. **There's no question that gene editing technologies** are potentially transformative and **are the ultimate precision medicine**. If you could precisely correct or delete genes that are causing problems — mutating or aberrant genes — that is the ultimate in precision. It would be so transformative for people with diseases caused by a single gene mutation, like sickle cell anemia and cystic fibrosis. Developing safe, effective ways to use gene editing to treat people with serious diseases with no known cures has so much potential to relieve suffering that it is hard to see how anyone could be against it.

It's easy to misuse CRISPR to make bio WMDs that threaten humanity

Cropper 20

Nicholas Cropper, April 29, 2020, American Security Project. Crispr is Making Bioweapons More Accessible. The American Security Project (ASP) is a nonpartisan organization created to educate the American public and the world about the changing nature of national security in the 21st Century. Accessed 9/1/2021 3:35 pm https://www.americansecurityproject.org/crispr-is-making-bioweapons-more-accessible/ //AHS

Synthetic biology collectively refers to the concepts, tools, and approaches used to modify or create biological organisms. The most recent breakthrough in synthetic biology is a genetic engineering technique known as CRISPR-Cas9. The first genetic engineering experiments took months to complete and cost millions of dollars to produce results that were often unsatisfying. **CRISPR**-Cas9 **has** changed the landscape, offering **a relatively simple, low cost, speedy genetic modification tool**. CRISPR-Cas9 has become **so democratized that anyone can get everything they need to perform a simple genetic alteration delivered** to their door **for less than $300**. It may seem exciting to have cutting edge biological tools available to everyone, but **lack of oversight** of these tools **could be a danger to humanity**. Warfare has moved away from conventional weapons and towards asymmetric operations in the 21st century. The **U.S.' adversaries, particularly non-state terror groups**, are looking for any opportunity to **use limited resources to inflict maximum damage** to the U.S. Advances in genetic engineering have offered them an opportunity to create **a low cost, low profile, potentially catastrophic weapon of mass destruction**; a bioweapon. Colonel Michael Ainscough highlighted the bioweapon threat in his paper for the USAF Air War College: "Biotechnology has made it possible **to inflict mass casualties** using only small-scale special operations that can evade detection in attempt to avoid retribution. In asymmetric warfare, biological weapons are seen as a 'great equalizer.'" The National Academy of Sciences has put together a framework for assessing the threat posed by a synthetic bioweapon. **CRISPR**-Cas9 has dramatically improved the usability of genetic engineering, lowering the barrier to entry for the average person both financially and technically. Much of the science **is available for** free on the internet, giving **anyone with an internet connection and determination** access to all of the knowledge necessary to successfully perform a genetic edit. Additionally, because CRISPR-Cas9 can be done in your kitchen, the operational footprint is quite small.

Kills tens of millions and outweighs nukes

Markman 17 JD Markman, July 17, 2017, Yahoo! News. Jon Markman is an investment adviser, trader, columnist and author based in Seattle. https://www.yahoo.com/news/bioterrorism-could-kill-30-million-people-143248192.html //AHS

Thirty million people **dead in less than a year**. That's the grisly **forecast for a successful bioterrorist attack**. And **it's more likely than ever**, according to experts. Bill Gates made his fortune bringing personal computing to the world with Windows software. Lately he's been consumed with closing the window on the next global epidemic. **Advances in biotechnology mean** it is now incredibly easy to re-create **fast-moving, airborne pathogens**, like smallpox or the Spanish flu. Patented in 2014, **CRISPR**-Cas9, **is** a gene-editing technique that uses molecular scissors to precisely snip genetic code. It's a scientific marvel. With it, researchers have modified genes to help

blind people see, cure sickle cell disease in some patients and expedite the development of numerous new drug treatments. They have also been able to create antibiotic-resistant forms of E. coli. CRISPR-Cas9 is unregulated, inexpensive and somewhat of a cottage industry. In 2016, the Nuffield Council of Bioethics warned that "garage scientists" **might unwittingly create a modified organism that could kill millions.** Gates is thinking more strategically. His foundation works in developing nations. He understands the perils of bad actors in unstable environments. He's worried about biotechnology being weaponized. **A single infected person** strategically placed **in a busy airport could** ultimately **kill millions**. "The scariest thing is **something like the 1919** [Spanish] **flu**," Gates warned at a gathering at the Royal United Services Institute in London. **Modern travel coupled with** the fact that people have **no immunity** to that strain **would be an unstoppable, deadly combination**. His concern is well founded. In the developed world, **we worry about bad actors getting** their hands on **nuclear materials**. **Though tragic, a nuclear bomb would not kill 10 million** people. Gates reckons that **an infected traveler could be the starting point for** a human-to-human respiratory infection. And it would all begin with simple aches and sniffles. The Spanish Flu of 1919 killed **50 million** people.

The CP solves -- strong patents prevent rogue actors from using CRISPR as a weapon

Zettler et al 19 Zettler PJ, Guerrini CJ, Sherkow JS. Regulating genetic biohacking. Science. 2019 Jul 5;365(6448):34-36. doi: 10.1126/science.aax3248. PMID: 31273115; PMCID: PMC7004414. https://pubmed.ncbi.nlm.nih.gov/31273115/ //AHS

Genetic biohacking is also potentially subject to U.S. **laws** that are **enforced by** private rather than government actors. These may fill some of the gaps in public regulators' ambit (9). **Patent owners**, for example, **can impose ethical restrictions on** licensees, such as the Broad Institute's licenses for its **CRISPR** patents to Bayer (formerly Monsanto), with conditions that Bayer avoid research activities that are potentially harmful to public health, including tobacco research and germline editing (10). **Such license restrictions can**—and should—**be used to police** commercial manufacturers of **genome-editing** kits **and** reagents popular in biohacking communities, just as they have previously been used to **prevent activities that pose national security, environmental, or public health risks (**11). Even without a license in place, **patent owners can enforce restrictions** through threats of patent infringement litigation **against any recalcitrant biohackers or manufacturers** of biohacking products. A similar model was proposed as an attempt to restrict the use of "gene drive technology"—inheritable versions of CRISPR designed to drive a specific allele through generations of a population (12). Beyond patents, people injured by genetic biohacking materials could potentially bring tort law claims against biohackers and component suppliers to seek compensation for their injuries. A person injured while using a DIY CRISPR kit, for example, would likely be able to sue the seller of the kit—**a potentially strong deterrent to marketers of unsafe biohacking materials.**

On-case

Top level: use innovation as an impact filter for the aff offense - high levels of innovation uniquely mitigate every threat to humanity which means our contention 1 controls whether they can access their offense. There is an increased risk of existential threat in every scenario if innovation declines so if you're voting to prevent extinction you have to negate

And Turn: Reducing IP doesn't solve and makes future pandemics worse

Bacchus 21 James Bacchus, June 30, 2021, The Cato Institute. Trade Is Good for Your Health: Freeing Trade in Medicines and Other Medical Goods during and beyond the COVID-19 Emergency. James Bacchus is Adjunct Fellow, Cato Institute, former U.S. Representative (D-FL), and former Chairman, World Trade Organization's Appellate Body. https://www.cato.org/policy-analysis/trade-good-health-freeing-trade-medicines-other-medical-goods-during-beyond-covid#executive-summary //AHS

In response to this widespread shortsightedness, India and South Africa, with the support of other developing countries, have sought — so far unsuccessfully — **a broad waiver of the WTO intellectual property rules** in relation to COVID-19 medicines. Although these WTO members are well-intentioned**, their waiver proposal aims at the wrong target.**[71] What **the world** faces is not an abuse of their rights by vaccine patent holders; it is a shortage of vaccine supply. **What is needed to speed the spread of COVID-19 vaccines worldwide is thus not a waiver of intellectual property rights but a rapid scaling up of vaccine production**. The antidote to vaccine nationalism is multilateralism, and this healing multilateralism must focus on increasing the capacity for vaccine production, accelerating production, and distributing doses of the vaccines throughout the world as quickly as possible.[72] What is more**, a waiver of intellectual property protections** for the inventors of the COVID-19 vaccines **would not have the intended effect and would also have undesirable consequences for future vaccine innovations.** It is not at all clear that, if these protections were waived by the WTO, that the vast majority of developing countries would have the immediate or imminent capacity — much less the technical know-how — to produce these cutting-edge biologic drugs. It is clear, however, that **waiving these protections could have a chilling effect on the development of additional COVID-19 vaccines and could reduce the incentives for innovators to produce vaccines for future pandemics**.

Lifting patents doesn't increase supply OR address distribution – decks solvency

Adler 7/20 David Adler, July 20, 2021, Foreign Policy. "To Vaccinate the World, Supply is Only Half the Issue." David Adler is a writer on economics and industrial policy, the author of several books, and the organizer of internationally recognized conferences on economic policy such as the Athens Economics Forum. https://foreignpolicy.com/2021/07/20/wto-trips-waiver-vaccine-equity-distribution-covid-pandemic/ //AHS

These rollout **problems found in the United States are amplified** many times when it comes to global rollout. **The Biden administration discovered this first hand when it attempted to donate 80 million doses from domestic U.S. supply to the rest of the world in June but fell well short** of this target. White House press secretary Jen Psaki said, "what we found to be **the biggest challenge is not actually the supply**—we have plenty of doses to share with the world—**but** this is a herculean logistical challenge. And we've seen that as we've begun to implement." She pointed to the **distributional challenges associated with storing vaccines** at the proper temperature as well as the **need for needles and syringes**. As Psaki's comments show, **there is more to vaccinating the world than** just **increasing supply**. Even if there are vaccine shortages at this moment, limited vaccine supply may not be a binding constraint by year end. Serum Institute of India, the world's largest vaccine manufacturer, has announced it will begin exporting later this year, implying India should have adequate vaccine supply by then. Pfizer/BioNTech has pledged to deliver 2 billion doses to low- and middle-income countries. AstraZeneca is continuing to scale up production. Nonetheless, the Biden administration's signature international COVID-19 policy, **the TRIPS waiver, is a supply side move—but one unlikely to lead to any actual increase in supply**. This waves intellectual property protections for COVID-19 vaccines to further foreign production. **The U.K. and German governments have viewed it skeptically and can block it**. Also, as has been widely noted, **manufacturing involves trade secrets and supply chain issues that go well beyond intellectual property (IP) rights**. Less widely noted is the fact that the Johnson & Johnson, AstraZeneca, and Novavax vaccines have already been licensed to Indian manufacturers, so **it is not clear to what degree IP rights are really hindering additional foreign production**. Therefore, the TRIPS waiver can be seen as essentially a political or even theatrical gesture, well removed from the messy world of vaccine distribution and administration. It appealed to a domestic audience hostile to Big Pharma and an international audience of countries like India and South Africa whose industrial policies have long called for limitations on IP rights. The Biden administration's policies keep evolving, and newer proposals are likely to show more immediate results. The United States has pledged to buy 500 million U.S. produced doses of the Pfizer/BioNTech vaccine over the next year and donate them to low-income countries. Many financing initiatives have been announced. But U.S. **plans of how to tackle the critical last mile and get the vaccines into people's arms have not been as clearly fleshed out**, with the United States mostly taking a hands-off approach. Administering vaccines requires a global rollout plan. After all, as the truism goes, a global pandemic demands a global response. However, this phrase is open to interpretation, with vaccine nationalism typically cloaked in globalist rhetoric. Many in the United States are deeply uncomfortable with a U.S.-led pandemic effort and hear the statement to mean that globalist institutions should take the lead. In other countries, the phrase can mean something very different. For instance, when European Commission President Ursula von der Leyen floated the idea of a "vaccine export transparency mechanism" to block vaccine exports from the EU to the U.K., she said it was for the "global common good." These various meanings are somehow aligned in discouraging any U.S. unilateralism and pose challenges to a more active U.S. involvement in a global rollout.

TRIPS waiver and tech transfer must be done together to ensure equitable access – the waiver alone isn't enough

ASIL 5/27 Marc Eccleston-Turner and Michelle Rourke, American Society of International Law, May 27, 2021. "The TRIPS Waiver is Necessary, but it alone is not enough to solve equitable access to COVID-19 Vaccines." ASIL Insights, Volume 25, Issue 9. Marc Eccleston-Turner is a Lecturer of Global Health Law at Keele University. Michelle Rourke is the CSIRO Synthetic Biology Future Science Fellow at Griffith University,

Australia. The ASIL a nonprofit, nonpartisan, educational membership organization founded in 1906 and chartered by Congress in 1950. ASIL holds Special Consultative Status to the Economic and Social Council of the United Nations and is a constituent society of the American Council of Learned Societies. https://www.asil.org/insights/volume/25/issue/9 //AHS

Most notably **absent from contracts** concluded under the PIP Framework to date **is any commitments from manufacturers regarding transfer of technology**. This is despite the fact that **the importance of technology transfer for pandemic preparedness and procurement was stressed** in the reports of the PIP Framework's Advisory Group and the WHO Director-General during negotiations of the PIP Framework.[22] It is clear, therefore, that developed country Members of **the WTO need to provide a strong commitment to share know-how** and/or provide economic incentives to pharmaceutical companies based within their territories to actively engage in transfer of technology for COVID-19 vaccines. Doing so **would satisfy their Article 66 TRIPS obligations and demonstrate a clear commitment to fair and equitable vaccine access** for LMICs. A significant amount of the research and development funding for COVID-19 vaccines was paid for with public monies—either directly by developed country governments, or through public initiatives such as COVAX.[23] This fact alone highlights the limitations of arguments that the TRIPS waiver and associated measures would destroy free-market incentives for R&D investment. **Yet, it appears no government, while agreeing to heavily subsidize the COVID-19 vaccine R&D, sought to negotiate IP ownership, or impose obligations on manufacturers receiving this funding to actively engage in transfer of technology** to other manufacturers in order to expand any future manufacturing base. Ideally, **access to information and know-how ought to occur through the WHO hub system** (which could be expanded beyond mRNA technology), **rather than on a direct bilateral manufacturer-to-manufacturer basis**, to ensure maximum efficiency and maximum utility from the transfer. If we are to make progress on equitable access to vaccine, **the TRIPS waiver must be promptly passed by WTO Members**, **but until a workable solution to facilitate technology transfer** on vaccine technology can be found, **we remain at an impasse on equitable access to medicines**.