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#### 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](https://www.efpia.eu/media/554521/efpia_pharmafigures_2020_web.pdf) were invented by U.S. biopharma companies, with [homegrown startups](https://www.cbo.gov/publication/57126) 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](https://www.bloomberg.com/news/articles/2021-03-01/xi-mobilizes-china-for-tech-revolution-to-cut-dependence-on-west). China saw over [$28 billion](https://www.bioworld.com/articles/506978-china-sees-five-year-highs-in-life-sciences-investments-and-partnering) 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](https://www.sciencemag.org/news/2019/12/chinese-scientist-who-produced-genetically-altered-babies-sentenced-3-years-jail) of international standards, and the U.S. national security community believes China is [pushing ahead](https://www.nbcnews.com/politics/national-security/china-has-done-human-testing-create-biologically-enhanced-super-soldiers-n1249914) 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.

#### 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.

#### China will leapfrog the US through biotech primacy

Cumbers 20 [John Cumbers, “I am the founder and CEO of SynBioBeta, the leading community of innovators, investors, engineers, and thinkers who share a passion for using synthetic biology to build a better, more sustainable universe. I publish the weekly SynBioBeta Digest, host the SynBioBeta Podcast, and wrote “What’s Your Biostrategy?”, the first book to anticipate how synthetic biology is going to disrupt virtually every industry in the world. I also founded BetaSpace, a space settlement innovation network and community of visionaries, technologists, and investors accelerating the industries needed to sustain human life here and off-planet. I’ve been involved with multiple startups, I am an operating partner and investor at the hard tech investment fund Data Collective, and I'm a former bioengineer at NASA. I earned my PhD in Molecular Biology, Cell Biology, and Biochemistry from Brown University and am originally from the UK.”) “China’s Plan To Beat The U.S. In The Trillion-Dollar Global Bioeconomy” Forbes, 2/3/2020] RM

The report, entitled “Safeguarding the Bioeconomy,” looks at how research and innovation in the life sciences is driving rapid growth in agriculture, biomedical science, information science and computing, energy, and other sectors of the U.S. economy. This economic activity—collectively referred to as the bioeconomy—presents many opportunities to create jobs, improve the quality of life, and continue to drive the U.S. economy as a whole.

The report says that while the U.S. has been a leader in advancements in the biological sciences, other countries are actively investing in and expanding their capabilities in this area—and the U.S.’s lead is beginning to slip.

Four reasons everyone should care about the U.S. bioeconomy

It might be easy for some to dismiss the report out of hand as a bunch of alarmist professors lobbying for more research money. But when you consider all the ways that biotechnology powers the economy and impacts our daily lives, it becomes clear that this is about something more:

The economy: at $1 trillion in value, the U.S. bioeconomy represents hundreds of thousands of quality, high-paying jobs for Americans.

Health & medicine: innovators in the bioeconomy are making next-generation therapies for cancer and diabetes, tackling emerging diseases like Coronavirus, and even increasing human longevity.

Food & farming: biotechnology is not only making agriculture more sustainable, it’s also bringing to market new and improved crops that are more nutritious, more affordable, and more delicious.

The environment: humanity’s health and well-being depend on our ability to stop and reverse climate change, and we can’t do it without biological solutions that treat carbon not as a waste product, but as the starting point for chemicals and materials that today use petroleum.

Considering all this, it doesn’t seem like an overstatement when the report authors say that U.S. competitiveness in the bioeconomy is key to maintaining the economic health and security of the country.

The very real risks to the U.S. bioeconomy

There are many things that can go wrong, causing the U.S. to lose its current edge in the global bioeconomy. Some of these are economic risks, and others present serious national security risks. All of them are related to a failure of our government to act now. Here’s a sampling of the risks to U.S. leadership at the frontiers of tech and bio:

Insufficient government R&D investment. Money for basic research and development builds the foundations of the bioeconomy. We learn, achieve new results, and create new applications. Investments that help develop enabling tools, technologies, and standards have the potential to maintain the U.S. bioeconomy competitive in a global bioeconomy.

Ineffective or inefficient regulations. Regulatory uncertainty stifles creative new approaches that may have unknown paths, long delays, or that might be prohibited by later changes.

Inadequate workforce. The U.S.’s K-12 education system may not prepare students to study STEM subjects at the university and postgraduate level, hindering the quality of workers. A skilled workforce gives U.S. companies the best talent to choose from, and it also encourages international firms to establish research and production facilities here.

Ineffective or inefficient intellectual property protections. Uncertainty over what is patentable could discourage innovators who are considering whether and how to bring their innovations to market. Patent eligibility is also important to venture capitalists and private equity investors when considering whether to invest in biotechnology companies.

Cybersecurity. As biological engineering depends more and more on massive datasets, the emerging bioeconomy now exists at the intersection of information science and biotechnological science. The bioeconomy’s growing reliance on software, networking, and computer hardware tools yields the same cyber vulnerabilities present in any other sector, including hacking, sabotage, breached privacy, or theft of intellectual property.

Biosafety and biosecurity risks. The tools of today’s bioeconomy are enabling new capabilities that can generate concerns regarding traditional biothreats. These can include the accidental or intentional creation or release of dangerous or lethal pathogens. Such biothreats can harm humans, animals, plants, agriculture, the environment, and materials.

Risks from climate change. Food and feed crops, biofuels crops, and crops used with bio-based fermentation products are susceptible to temperature and water stresses, as well as insects and pathogens that migrate with changing weather patterns.

China: the biotech elephant in the room

I’ve written previously written how the Chinese government is already making substantial investments in its bioeconomy. Here are three scary statistics, courtesy of Greg B. Scott of the ChinaBio Group:

China is out-investing the U.S. China’s private investors poured $14.4 billion into its bioeconomy in 2019. That compares to the United States’ more meager investment of $10.4 billion.

China is building a bigger bioeconomy workforce. China graduates about 8-10 million students each year. In the U.S., that number is closer to 400,000. Many Chinese students graduating from U.S. institutions stay here, but they are increasingly returning home to start highly innovative companies.

China is investing in itself. Historically, China has invested heavily in foreign companies, tech, and debt. Now we’re seeing an uptick in China-to-China investments—the country no longer needs to look abroad to find plenty of good biotech opportunities.

Chinese investments have led to centers of excellence in the regional technology hub of Shenzhen, including the Institute of Synthetic Biology at the Shenzhen Institute of Advanced Sciences (SIAT) and BGI Genomics. Shenzhen will compete for technological and economic leadership with U.S. regional biotech powerhouses such as San Francisco/Silicon Valley and Boston/Cambridge in the years to come.

Many of China’s long-standing challenges—environment, food, water, waste management, and rapid innovation to retain its global manufacturing competitiveness—are areas where synthetic biology is seen as a key technology for the future. In other words, synthetic biology is not just an academic pursuit for China. Rather, its leaders are thinking proactively about how biological engineering can be used to address the country’s strategic national interests—while U.S. leadership stands idly by.

What do we do?

So what can U.S. policymakers do to protect the U.S. bioeconomy and ensure continued technological and economic leadership in biology for the next twenty years?

Straight from the top. China has made clear its ambition to become a global tech superpower, with President Xi Jinping calling science and technology one of the main battlefronts of the economy. The U.S. administration needs to step up its game, too. President Trump recently declared January 2020 to be National Biotechnology Month, citing “boundless possibilities for economic growth, national security, healthcare, manufacturing, and agriculture.” That’s the right sentiment—now we need real action.

New legislation. Late last year, the U.S. House of Representatives passed the Engineering Biology Research and Development Act of 2019, which would direct the Office of Science and Technology Policy (OSTP) to implement a national research strategy for engineering biology. The explicit goal: maintain U.S. science, technology, and economic leadership in synthetic biology. The bill now resides in the Senate and awaits committee action. Legislative leadership is now needed to give this bill the appropriations necessary to give it real teeth, and then put it squarely on the President’s desk.

Investing for returns. The Human Genome Project is said to have returned $141 for every dollar invested by taxpayers. While “Big Science” yields tremendous benefits for everyone, it doesn’t happen without federal funding. In 2019, politically courageous Republicans and Democrats came together to produce a 2020 final spending bill that is kind to science, in essence ignoring President Trump’s proposed cuts and instead giving increases to each of the NIH, NSF, NASA, and DOE’s Office of Science. But the U.S. isn’t even in the top ten for R&D spending as a percentage of GDP, while China continues to close in on the U.S., meaning that the U.S. is no longer the uncontested global leader in science.

Leading the global bioeconomy: Have some courage

There are many things the U.S. could do to protect the American bioeconomy. But above all else, policymakers need to come together and demonstrate the kind of courage and vision needed to be a world leader. Science and technology know no partisan lines. Everybody wants healthy lives, clean water, and good jobs. Federal initiative and assistance are needed to bring these benefits to everyone living in the U.S..

Today, the American synthetic biology industry may be unprepared for the global competition it will face, lacking initiative and leadership at the highest levels of government. But this could change quickly. If a country like the U.S. makes engineering biology a national priority, anything is possible in the new bioeconomy.

#### Heg solves arms races, land grabs, rogue states, and great power war

Brands 18 [Hal, Henry Kissinger Distinguished Professor at Johns Hopkins University's School of Advanced International Studies and a senior fellow at the Center for Strategic and Budgetary Assessments." American Grand Strategy in the Age of Trump." Page 129-133]

Since World War II, the United States has had a military second to none. Since the Cold War, America has committed to having overwhelming military primacy. The idea, as George W. Bush declared in 2002, that America must possess “strengths beyond challenge” has featured in every major U.S. strategy document for a quarter century; it has also been reflected in concrete terms.6

From the early 1990s, for example, the United States consistently accounted for around 35 to 45 percent of world defense spending and maintained peerless global power-projection capabilities.7 Perhaps more important, U.S. primacy was also unrivaled in key overseas strategic regions—Europe, East Asia, the Middle East. From thrashing Saddam Hussein’s million-man Iraqi military during Operation Desert Storm, to deploying—with impunity—two carrier strike groups off Taiwan during the China-Taiwan crisis of 1995– 96, Washington has been able to project military power superior to anything a regional rival could employ even on its own geopolitical doorstep.

This military dominance has constituted the hard-power backbone of an ambitious global strategy. After the Cold War, U.S. policymakers committed to averting a return to the unstable multipolarity of earlier eras, and to perpetuating the more favorable unipolar order. They committed to building on the successes of the postwar era by further advancing liberal political values and an open international economy, and to suppressing international scourges such as rogue states, nuclear proliferation, and catastrophic terrorism. And because they recognized that military force remained the ultima ratio regum, they understood the centrality of military preponderance.

Washington would need the military power necessary to underwrite worldwide alliance commitments. It would have to preserve substantial overmatch versus any potential great-power rival. It must be able to answer the sharpest challenges to the international system, such as Saddam’s invasion of Kuwait in 1990 or jihadist extremism after 9/11. Finally, because prevailing global norms generally reflect hard-power realities, America would need the superiority to assure that its own values remained ascendant. It was impolitic to say that U.S. strategy and the international order required “strengths beyond challenge,” but it was not at all inaccurate.

American primacy, moreover, was eminently affordable. At the height of the Cold War, the United States spent over 12 percent of GDP on defense. Since the mid-1990s, the number has usually been between 3 and 4 percent.8 In a historically favorable international environment, Washington could enjoy primacy—and its geopolitical fruits—on the cheap.

Yet U.S. strategy also heeded, at least until recently, the fact that there was a limit to how cheaply that primacy could be had. The American military did shrink significantly during the 1990s, but U.S. officials understood that if Washington cut back too far, its primacy would erode to a point where it ceased to deliver its geopolitical benefits. Alliances would lose credibility; the stability of key regions would be eroded; rivals would be emboldened; international crises would go unaddressed. American primacy was thus like a reasonably priced insurance policy. It required nontrivial expenditures, but protected against far costlier outcomes.9 Washington paid its insurance premiums for two decades after the Cold War. But more recently American primacy and strategic solvency have been imperiled.

THE DARKENING HORIZON For most of the post–Cold War era, the international system was— by historical standards—remarkably benign. Dangers existed, and as the terrorist attacks of September 11, 2001, demonstrated, they could manifest with horrific effect. But for two decades after the Soviet collapse, the world was characterized by remarkably low levels of great-power competition, high levels of security in key theaters such as Europe and East Asia, and the comparative weakness of those “rogue” actors—Iran, Iraq, North Korea, al-Qaeda—who most aggressively challenged American power. During the 1990s, some observers even spoke of a “strategic pause,” the idea being that the end of the Cold War had afforded the United States a respite from normal levels of geopolitical danger and competition. Now, however, the strategic horizon is darkening, due to four factors.

First, great-power military competition is back. The world’s two leading authoritarian powers—China and Russia—are seeking regional hegemony, contesting global norms such as nonaggression and freedom of navigation, and developing the military punch to underwrite these ambitions. Notwithstanding severe economic and demographic problems, Russia has conducted a major military modernization emphasizing nuclear weapons, high-end conventional capabilities, and rapid-deployment and special operations forces— and utilized many of these capabilities in conflicts in Ukraine and Syria.10 China, meanwhile, has carried out a buildup of historic proportions, with constant-dollar defense outlays rising from US$26 billion in 1995 to US$226 billion in 2016.11 Ominously, these expenditures have funded development of power-projection and antiaccess/area denial (A2/AD) tools necessary to threaten China’s neighbors and complicate U.S. intervention on their behalf. Washington has grown accustomed to having a generational military lead; Russian and Chinese modernization efforts are now creating a far more competitive environment.

#### Independently, China uses biotech offensively—uncertainty means you should err negative

Kania and Vonrndick 19 [Elsa Kania is an Adjunct Senior Fellow with the Technology and National Security Program at the Center for a New American Security. She is also a Ph.D. candidate in Harvard University’s Department of Government. Her views are her own. Wilson VornDick consults on national security, emerging technologies, and China for Duco and Rane.) “Weaponizing Biotech: How China's Military Is Preparing for a 'New Domain of Warfare'” Defense One, Commentary, China, Biowarfare, 8/14/2019] RM

We may be on the verge of a brave new world indeed. Today’s advances in biotechnology and genetic engineering have exciting applications in medicine — yet also alarming implications, including for military affairs. China’s national strategy of military-civil fusion (军民融合) has highlighted biology as a priority, and the People’s Liberation Army could be at the forefront of expanding and exploiting this knowledge.

The PLA’s keen interest is reflected in strategic writings and research that argue that advances in biology are contributing to changing the form or character (形态) of conflict. For example:

In 2010’s War for Biological Dominance (制生权战争), Guo Jiwei (郭继卫), a professor with the Third Military Medical University, emphasizes the impact of biology on future warfare.

In 2015, then-president of the Academy of Military Medical Sciences He Fuchu (贺福初) argued that biotechnology will become the new “strategic commanding heights” of national defense, from biomaterials to "brain control" weapons. Maj. Gen. He has since become the vice president of the Academy of Military Sciences, which leads China’s military science enterprise.

Biology is among seven "new domains of warfare" discussed in a 2017 book by Zhang Shibo (张仕波), a retired general and former president of the National Defense University, who concludes: “Modern biotechnology development is gradually showing strong signs characteristic of an offensive capability,” including the possibility that “specific ethnic genetic attacks” (特定种族基因攻击) could be employed.

The 2017 edition of Science of Military Strategy (战略学), a textbook published by the PLA’s National Defense University that is considered to be relatively authoritative, debuted a section about biology as a domain of military struggle, similarly mentioning the potential for new kinds of biological warfare to include “specific ethnic genetic attacks.”

These are just a few examples of an extensive and evolving literature by Chinese military scholars and scientists who are exploring new directions in military innovation.

Following these lines of thinking, the PLA is pursuing military applications for biology and looking into promising intersections with other disciplines, including brain science, supercomputing, and artificial intelligence. Since 2016, the Central Military Commission has funded projects on military brain science, advanced biomimetic systems, biological and biomimetic materials, human performance enhancement, and “new concept” biotechnology.

Gene Editing

Meanwhile, China has been leading the world in the number of trials of the CRISPR gene-editing technology in humans. Over a dozen clinical trials are known to have been undertaken, and some of these activities have provoked global controversy. It’s not clear whether Chinese scientist He Jiankui, may have received approval or even funding from the government for editing embryos that became the world’s first genetically modified humans. The news provoked serious concerns and backlash around the world and in China, where new legislation has been introduced to increase oversight over such research. However, there are reasons to be skeptical that China will overcome its history and track record of activities that are at best ethically questionable, or at worst cruel and unusual, in healthcare and medical sciences.

But it is striking how many of China’s CRISPR trials are taking place at the PLA General Hospital, including to fight cancer. Indeed, the PLA’s medical institutions have emerged as major centers for research in gene editing and other new frontiers of military medicine and biotechnology. The PLA’s Academy of Military Medical Sciences, or AMMS, which China touts as its “cradle of training for military medical talent,” was recently placed directly under the purview of the Academy of Military Science, which itself has been transformed to concentrate on scientific and technological innovation. This change could indicate a closer integration of medical science with military research.

In 2016, an AMMS doctoral researcher published a dissertation, “Research on the Evaluation of Human Performance Enhancement Technology,” which characterized CRISPR-Cas as one of three primary technologies that might boost troops’ combat effectiveness. The supporting research looked at the effectiveness of the drug Modafinil, which has applications in cognitive enhancement; and at transcranial magnetic stimulation, a type of brain stimulation, while also contending that the “great potential” of CRISPR-Cas as a “military deterrence technology in which China should “grasp the initiative” in development.

AI + Biotech

The intersection of biotechnology and artificial intelligence promises unique synergies. The vastness of the human genome — among the biggest of big data — all but requires AI and machine learning to point the way for CRISPR-related advances in therapeutics or enhancement.

In 2016, the potential strategic value of genetic information led the Chinese government to launch the National Genebank (国家基因库), which intends to become the world’s largest repository of such data. It aims to “develop and utilize China’s valuable genetic resources, safeguard national security in bioinformatics (生物信息学), and enhance China’s capability to seize the strategic commanding heights” in the domain of biotechnology.

The effort is administered by BGI, formerly known as Beijing Genomics Inc., which is Beijing’s de facto national champion in the field. BGI has established an edge in cheap gene sequencing, concentrating on amassing massive amounts of data from a diverse array of sources. The company has a global presence, including laboratories in California and Australia.

U.S. policymakers have been concerned, if not troubled, by the company’s access to the genetic information of Americans. BGI has been pursuing a range of partnerships, including with the University of California and with the Children’s Hospital of Philadelphia on human genome sequencing. BGI’s research and partnerships in Xinjiang also raise questions about its linkage to human rights abuses, including the forced collection of genetic information from Uighurs in Xinjiang.

There also appear to be links between BGI’s research and military research activities, particularly with the PLA’s National University of Defense Technology. BGI’s bioinformatics research has used Tianhe supercomputers to process genetic information for biomedical applications, while BGI and NUDT researchers have collaborated on several publications, including the design of tools for the use of CRISPR.

Biotech’s Expansive Frontier

It will be increasingly important to keep tabs on the Chinese military’s interest in biology as an emerging domain of warfare, guided by strategists who talk about potential “genetic weapons” and the possibility of a “bloodless victory.” Although the use of CRISPR to edit genes remains novel and nascent, these tools and techniques are rapidly advancing, and what is within the realm of the possible for military applications may continue to shift as well. In the process, the lack of transparency and uncertainty of ethical considerations in China’s research initiatives raise the risks of technological surprise.

### CP – Pandemics

#### States should:

#### shore up surveillance and reporting for infectious diseases,

#### fund, train, and personnel the GOARN,

#### create localized programs to reach underprivileged communities,

#### cross-train health workers in practice scenarios, and

#### enforce post-pandemic reviews.

#### The Executive Branch of the United States Federal Government should use the Defense Production Act to mandate federal orders for national stockpiles of medical supplies and vaccinations.

#### We solve for future pandemics

Radcliff and Clendenin 3/8 [[Tiffany A. Radcliff](https://theconversation.com/profiles/tiffany-a-radcliff-1129662), Associate Dean for Research and Professor of Health Policy and Management, Texas A&M University, [Angela Clendenin](https://theconversation.com/profiles/angela-clendenin-1000624), Instructional Assistant Professor of Epidemiology and Biostatistics, Texas A&M University) “5 strategies to prepare now for the next pandemic,” The Conversation: COVID-19 Section, 3/8/21, <https://theconversation.com/5-strategies-to-prepare-now-for-the-next-pandemic-154317>] RM

**1. Shore up the systems already in place**

The identification in February 2021 of a new outbreak of Ebola in Guinea showed how critical surveillance and reporting are for rapidly responding to and containing infectious disease.

We bring the expertise of academics to the public.

The process generally works like this: Once an astute clinician diagnoses a disease that is on the watch list of the World Health Organization and the Centers for Disease Control and Prevention, she reports the case to local health authorities to investigate. The information gets passed up the chain to the state, federal and international levels.

Clinicians, public health practitioners and labs all around the world send disease reports to groups like the WHO’s Global Outbreak Alert and Response Network. It aggregates all that data and helps identify outbreaks of new infectious diseases and their pandemic potential.

If a pathogen does make it past local monitors and starts to spread, governments have emergency management systems in place to respond. These incident command structures provide a framework to respond to crises that range from infectious disease to natural disaster to terrorist attack.

In the U.S., various federal agencies have different responsibilities. They monitor emerging infectious diseases, establish a strategic national stockpile of resources and support the states in their preparedness and response. Responsibility for the emergency response lies with each state – that’s in the U.S. Constitution – so they have flexibility in how they implement everything on a local level.

One practical way to be prepared for a future pandemic is to ensure that all these systems and structures remain stable. That means maintaining funding, training and personnel for a rapid global response even when no pandemic threats are visible on the horizon.

2. Prepare the public to do its part

Effective pandemic response requires a clear, consistent voice and an actionable message that reflects best practices based on sound science. Messaging and data that clearly explain how each individual has an important role in curbing the pandemic – and that it might evolve as the pandemic unfolds over time – are critical.

The message to stay home and “flatten the curve” to avoid overwhelming health care resources with COVID-19 cases was an essential early public health message that resonated with many Americans who were not designated as essential workers. However, once initial shutdown orders were lifted and new treatments emerged**, there was general confusion about the safety of public gatherings**, particularly since guidance varied by state or locality.

Guidance is also most effective if it’s tailored to different audiences. In the South, distrust of testing and vaccination efforts by government and health care providers is directly linked to language barriers and immigration concerns. One strategy to reach diverse and often underserved populations is to rely on leaders in the local faith community to help deliver public health messages.

Preparedness requires an “all of community approach” **that engages everyone in the planning stages, especially those from underserved or vulnerable populations**. Building relationships now can improve access to information and resources when the next disaster strikes, helping ensure equity and agility in response.

Science and risk communication scholars have started talking about the best ways people can manage the flood of information during a pandemic. Lessons from what’s been called the infodemic of COVID-19 news – some trustworthy but some certainly not – can inform new strategies for sharing reliable info and fostering trust in science.

a

Participants at a tabletop exercise in Texas that envisioned an Ebola virus disease outbreak. The USA Center for Rural Health Preparedness, CC BY-ND

**3. Get coordinated and practice**

Emergency managers and health care leaders have long recognized that a coordinated response by diverse teams is critical for public health emergencies.

Tabletop exercises that simulate real emergencies help officials prepare for crises of all types. Like a fire drill, they bring together community stakeholders to walk through a hypothetical disaster scenario and hash out roles and responsibilities. These practice sessions include people who work in public health, emergency management and health care, as well as federal, tribal, state and local front-line responders.

Practice scenarios must also include the reality of “stacked disasters,” like a hurricane or winter storm that puts even more stress on the disaster response system.

These exercises enable a community to test parts of the overall emergency management plan and determine gaps or areas to strengthen. Ongoing testing and training to the plan ensures everyone is as ready as they can be.

Beyond this training, health care professionals could be cross-trained to back up specialized clinical staff, who may need support over the course of a long pandemic.

The COVID-19 pandemic delivered lessons about infrastructure and supply chains. **Strategic investments can shore up existing strategic national stockpiles of supplies and vaccinations for the future**. If necessary, **the president can use the Defense Production Act to order private companies to prioritize federal orders.**

4. Polish the playbook

After every major disaster response, all of the different groups involved – law enforcement, EMS, fire, emergency management, public health, search and rescue and so on – conduct what are called “after action reviews.” They can improve plans for the next time around.

For instance, after the 2009 influenza pandemic, the Department of Health and Human Services found that while CDC communication efforts were widely successful, some non-English-speaking populations missed important messages. The after action review noted that distrust in the government increased when vaccine supplies did not meet public expectations. In turn, officials could plan exercises to test and tweak approaches for next time.

A thorough review of the response to the current COVID-19 pandemic at all levels will identify gaps, challenges and successes. **Those “After Action” findings need to be integrated into future planning to improve preparedness and response for the next pandemic.**

seated operators in front of telephone switchboard

A previous pandemic hastened the end of switchboard operators. Which technologies will get a boost after this one? Stevens/Topical Press Agency/Hulton Archive via Getty Images

5. Build on the new normal

Back when the 1918 H1N1 influenza pandemic unfolded, few Americans had a telephone. Quarantine rules led more households to use phones and hastened research that reduced reliance on human telephone operators. Similarly, no doubt COVID-19 triggered some rapid changes that will last and help the U.S. be ready for future events.

It’s been easier to adapt to the necessary lifestyle changes due to this pandemic thanks to the ways technology has changed the workplace, the classroom and the delivery of health care. Business analysts predict the quick move to video teleconferencing and remote work for offices in 2020 will be lasting legacies of COVID-19. A multidisciplinary team here at Texas A&M is tracking how robotics and automated systems are being used in pandemic response in clinical care, public health and public safety settings.

Some of the sudden, dramatic changes to norms and behaviors, like the use of face masks in public, may be among the easiest strategies to keep in place to fend off a future pandemic from a respiratory virus. Just as telephone systems continued to improve over the last 100 years, ongoing innovation that builds on rapid adoption of technologies around COVID-19 will help people adjust to sudden lifestyle changes when the next pandemic strikes.

<https://foreignpolicy.com/2021/04/14/pandemic-treaty-who-tedros-china-transparency-inspections-data-covid-19-coronavirus/>

<https://www.vox.com/future-perfect/22397914/vaccine-mrna-adenovirus-manufacturing-process-investment>

### 301 - DA

#### The aff violates section 301 of the trade act deeming it illegitimate

Roberts 6/9 [James M. Roberts is Research Fellow for Economic Freedom and Growth in the Center for International Trade and Economics, of the Kathryn and Shelby Cullom Davis Institute for National Security and Foreign Policy, at The Heritage Foundation. Gavin Zhao of the Heritage Young Leaders Program assisted in the preparation of this report. June 9, 2021 “Biden’s Wink at Global Theft of U.S. Vaccine Patents Is Bad for America and the World” [https://www.heritage.org/economic-and-property-rights/report/bidens-wink-global-theft-us-vaccine-patents-bad-america-and-the //gord0](https://www.heritage.org/economic-and-property-rights/report/bidens-wink-global-theft-us-vaccine-patents-bad-america-and-the%20//gord0) link is being weird af but it works!]

**\*IPR = Intellectual Property Rights**

The primary U.S. law used to protect American IPR internationally is Section 301 of the Trade Act of 1974.10 Public Law No. 93–618. ﻿ Through that statute, a congressionally mandated “Special 301” report is produced annually through which the United States Trade Representative (USTR) is “to identify foreign countries that deny adequate and effective protection of IPR or fair and equitable market access to U.S. persons that rely on IP protection.”11 A country listed in that report as a priority foreign country (PFC) has been found to engage in or permit onerous and egregious practices. Once a PFC has been so identified, the USTR must open a Section 301 investigation, which may lead to some form of trade sanctions for IPR violations. As the Office of the USTR notes, the Special 301 report documents address (among other things): a wide range of concerns that limit innovation and investment, including: (a) the deterioration in the effectiveness of IP protection and enforcement and overall market access for persons relying on IP in a number of trading partner markets; [and] (b) reported inadequacies in trade secret protection in countries around the world, as well as an increasing incidence of trade secret misappropriation.12 The theft by actors in foreign countries of the trade secrets in patented pharmaceutical products made by American companies constitutes a Special 301 violation. Waiving patent protection also opens the door to the overseas production of *counterfeit* vaccines that could be ineffective—even deadly. As the authors of a study commissioned by the National Institutes of Health report: Counterfeit drugs pose a public health hazard, waste consumer income, and reduce the incentive to engage in research and development and innovation.… [C]ounterfeit drugs may raise concerns among consumers about safety and may reduce patient medication adherence. ﻿ Although the amended TRIPS Article 31bis14)﻿ says that the pharmaceutical companies whose patents have been infringed through compulsory licensing should be remunerated, it leaves the decision as to when and how much compensation should be paid to the patent holders up to the WTO-member government that is demanding the compulsory license. Since the amended TRIPS agreement is vague and does not prescribe a definite timeline or formula to calculate the amount of remuneration, in practice the compulsory licensing amounts to the legalized theft of patent holder’s intellectual property. Bipartisan Opposition to TRIPS Waiver The Biden Administration’s policy is a bad one for many reasons. It signals to the world that the United States will not fight to defend the intellectual property rights of American companies. That means the Administration is *actively* undermining innovation and manufacturing in one of the American economy’s most vital and leading-edge sectors—health care and medicines.

#### Decks executive control

Coffield 81 [Shirley A. Coffield, UNC School of Law, “Using Section 301 of the Trade Act of 1974 as a Response to Foreign Government Trade Actions: When, Why, and How”, 6 N.C. J. INT'L L.381 (1981). [https://scholarship.law.unc.edu/cgi/viewcontent.cgi referer=https://search.yahoo.com/&httpsredir=1&article=1144&context=ncilj](https://scholarship.law.unc.edu/cgi/viewcontent.cgi%20referer=https://search.yahoo.com/&httpsredir=1&article=1144&context=ncilj) //gord0]

Section 301 of the Trade Act of 19741 is the primary U.S. statute providing authority for the President to take action against unfair trade practices of other governments which adversely affect U.S. commerce,either in goods or services. For the most part, the implementation of the statute has focused on attempts to eliminate the acts, practices, or poli-cies of foreign governments that adversely affect U.S. exports. The stat-ute is also used to combat violations of international agreements by foreign governments which may affect imports into the United States as well as exports, and it contains special provisions for the treatment of violations of the MTN agreement on subsidies and countervailingduties.2Section 301 is not a substitute for, nor an alternative to, other U.S. statutes that address specific unfair trade practices, such as the anti-dumping laws,3 the 337 statute,4 or, except under specifically provided procedures, the countervailing duty statute.5 Unlike these statutes, a sec-tion 301 proceeding is not an APA proceeding, and the flexibility pro-vided the President and the United States Trade Representative (USTR)v makes it a more political statute. Section 301 was shaped quite deliber-ately to give the Executive the tools to use diplomatic and economic pres-sure to achieve a more "equitable" world trading system, to the benefit of U.S. commerce. In its amended form, section 301 takes on an expanded and more critical role as the primary statute to enforce U.S. rights under newly negotiated trade agreements as well as under general GATT6 provisions. For this reason, the future use of section 301 will be an important indica-tor of both the United States' commitment to the multilateral trade rules and its ability to resolve trade disputes on a bilateral basis before resort-ing to the more fragile multilateral mechanisms. This article will examine the provisions of sections 301-306 of the Trade Act of 1974, as amended by the Trade Agreements Act of 1979.7The development of this trade action will be reviewed, and the mechan-ics for a private petition will be outlined. Then, the article will describe the petitioner's interface with the Office of the USTR as well as the fed-eral government's roles and objectives. Throughout, practical advice onsensitive areas of the process will be provided to enable the petitioner toprepare a well-conceived strategy to achieve the desired results. Background While the roots of present section 301 may be found in much prior federal legislation,8 the major provisions now present in the statute were first incorporated into legislation in the Trade Act of 1974.9 That legisla-tion gave the President broad authority to retaliate against unreasonable and unjustifiable import restrictions of other countries that affect U.S. commerce. As enacted in 1975, section 301 allows the President to deny or mod-ify the benefits of trade agreement concessions or to impose duties or other import restrictions on the products and services of any country that is found to be unjustifiably'° or unreasonably burdening or restricting U.S. commerce. Congress gave administration of the procedures to the Office of the Special Representative for Trade Negotiations (STR). i2The purpose of section 301 is quite clear: the United States is to use this retaliatory authority vigorously as leverage to get other countries to eliminate unfair trade practices that affect U.S. commerce,'3 including both product exports and services.14 The practices noted in the legisla-tive history as unfair include discriminatory rules of origin, government procurement, licensing systems, quotas, exchange controls, restrictive business practices, discriminatory bilateral agreements, variable levies, border tax adjustments, discriminatory road taxes, horsepower taxes, other taxes which discriminate against imports,15 certain product stan-dards, and many other practices that were documented by the U.S. In-ternational Trade Commission (USITC),'6 and subsidies identified intheir principal forms by the Senate Finance Committee.17

#### Exec Flex in all instances creates fluid politics that uniquely solves nuclear terror

Yoo 7, [The one and only John Yoo is Professor of Law at UC-Berkeley, Exercising Wartime Powers, hir.harvard.edu/article/?a=1369 //recut gord0]

Take the threat posed by the Al Qaeda terrorist organization. Terrorist attacks are more difficult to detect and prevent than conventional ones. Terrorists blend into civilian populations and use the channels of open societies to transport personnel, material, and money. Although terrorists generally have no territory or regular armed forces from which to detect signs of an impending attack, WMDs allow them to inflict devastation that once could have been achievable only by a nation-state. To defend itself from this threat, the United States may have to use force earlier and more often than when nation-states generated the primary threats to US national security. The executive branch needs the flexibility to act quickly, possibly in situations wherein congressional consent cannot be obtained in time to act on the intelligence. By acting earlier, the executive branch might also be able to engage in a more limited, more precisely targeted, use of force. Similarly, the least dangerous way to prevent rogue nations from acquiring WMDs may depend on secret intelligence gathering and covert action rather than open military intervention. Delay for a congressional debate could render useless any time-critical intelligence or windows of opportunity. The Constitution creates a presidency that is uniquely structured to act forcefully and independently to repel serious threats to the nation. Instead of specifying a legalistic process to begin war, the Framers wisely created a fluid political process in which legislators would use their appropriations power to control war. As the United States confronts terrorism, rogue nations, and WMD proliferation, we should look skeptically at claims that radical changes in the way we make war would solve our problems, even those stemming from poor judgment, unforeseen circumstances, and bad luck.

## Case

### Bioterror

#### no impact to bioterror.

Filippa Lentzos 14, PhD from London School of Economics and Social Science, Senior Research Fellow in the Department of Social Science, Health and Medicine at King’s College London, Catherine Jefferson, researcher in the Department of Social Science, Health, and Medicine at King’s College London, DPhil from the University of Sussex, former senior policy advisor for international security at the Royal Society, and Dr. Claire Marris, Senior Research Fellow in the Department of Social Science, Health and Medicine at King's College London, “The myths (and realities) of synthetic bioweapons,” 9/18/2014, http://thebulletin.org/myths-and-realities-synthetic-bioweapons7626

The bioterror WMD myth. Those who have overemphasized the bioterrorism threat typically portray it as an imminent concern, with emphasis placed on high-consequence, mass-casualty attacks, performed with weapons of mass destruction (WMD). This is a myth with two dimensions.

The first involves the identities of terrorists and what their intentions are. The assumption is that terrorists would seek to produce mass-casualty weapons and pursue capabilities on the scale of 20th century, state-level bioweapons programs. Most leading biological disarmament and non-proliferation experts believe that the risk of a small-scale bioterrorism attack is very real and present. But they consider the risk of sophisticated large-scale bioterrorism attacks to be quite small. This judgment is backed up by historical evidence. The three confirmed attempts to use biological agents against humans in terrorist attacks in the past were small-scale, low-casualty events aimed at causing panic and disruption rather than excessive death tolls.

The second dimension involves capabilities and the level of skills and resources available to terrorists. The implicit assumption is that producing a pathogenic organism equates to producing a weapon of mass destruction. It does not. Considerable knowledge and resources are necessary for the processes of scaling up, storage, and dissemination. These processes present significant technical and logistical barriers.

Even if a biological weapon were disseminated successfully, the outcome of an attack would be affected by factors like the health of the people who are exposed and the speed and manner with which public health authorities and medical professionals detect and respond to the resulting outbreak. A prompt response with effective medical countermeasures, such as antibodies and vaccination, can significantly blunt the impact of an attack.

#### No impact or solvency.

Pinker 18 Steven Arthur Pinker is a Canadian-American cognitive psychologist, Professor at Harvard University. [Enlightenment Now: The Case for Reason, Science, Humanism, and Progress, Viking, Penguin Group]//BPS

Start with the number of maniacs. Does the modern world harbor a significant number of people who want to visit murder and mayhem on strangers? If it did, life would be unrecognizable. They could go on stabbing rampages, spray gunfire into crowds, mow down pedestrians with cars, set off pressure-cooker bombs, and shove people off sidewalks and subway platforms into the path of hurtling vehicles. The researcher Gwern Branwen has calculated that a disciplined sniper or serial killer could murder hundreds of people without getting caught.42 A saboteur with a thirst for havoc could tamper with supermarket products, lace some pesticide into a feedlot or water supply, or even just make an anonymous call claiming to have done so, and it could cost a company hundreds of millions of dollars in recalls, and a country billions in lost exports.43 Such attacks could take place in every city in the world many times a day, but in fact take place somewhere or other every few years (leading the security expert Bruce Schneier to ask, “Where are all the terrorist attacks?”).44 Despite all the terror generated by terrorism, there must be very few individuals out there waiting for an opportunity to wreak wanton destruction. Among these depraved individuals, how large is the subset with the intelligence and discipline to develop an effective cyber- or bioweapon? Far from being criminal masterminds, most terrorists are bumbling schlemiels.45 Typical specimens include the Shoe Bomber, who unsuccessfully tried to down an airliner by igniting explosives in his shoe; the Underwear Bomber, who unsuccessfully tried to down an airliner by detonating explosives in his underwear; the ISIS trainer who demonstrated an explosive vest to his class of aspiring suicide terrorists and blew himself and all twenty-one of them to bits; the Tsarnaev brothers, who followed up on their bombing of the Boston Marathon by murdering a police officer in an unsuccessful attempt to steal his gun, and then embarked on a carjacking, a robbery, and a Hollywood-style car chase during which one brother ran over the other; and Abdullah al-Asiri, who tried to assassinate a Saudi deputy minister with an improvised explosive device hidden in his anus and succeeded only in obliterating himself.46 (An intelligence analysis firm reported that the event “signals a paradigm shift in suicide bombing tactics.”)47 Occasionally, as on September 11, 2001, a team of clever and disciplined terrorists gets lucky, but most successful plots are low-tech attacks on target-rich gatherings, and (as we saw in chapter 13) kill very few people. Indeed, I venture that the proportion of brilliant terrorists in a population is even smaller than the proportion of terrorists multiplied by the proportion of brilliant people. Terrorism is a demonstrably ineffective tactic, and a mind that delights in senseless mayhem for its own sake is probably not the brightest bulb in the box.48 Now take the small number of brilliant weaponeers and cut it down still further by the proportion with the cunning and luck to outsmart the world’s police, security experts, and counterterrorism forces. The number may not be zero, but it surely isn’t high. As with all complex undertakings, many heads are better than one, and an organization of bio- or cyberterrorists could be more effective than a lone mastermind. But that’s where Kelly’s observation kicks in: the leader would have to recruit and manage a team of co-conspirators who exercised perfect secrecy, competence, and loyalty to the depraved cause. As the size of the team increases, so do the odds of detection, betrayal, infiltrators, blunders, and stings.49 Serious threats to the integrity of a country’s infrastructure are likely to require the resources of a state. 50 Software hacking is not enough; the hacker needs detailed knowledge about the physical construction of the systems he hopes to sabotage. When the Iranian nuclear centrifuges were compromised in 2010 by the Stuxnet worm, it required a coordinated effort by two technologically sophisticated nations, the United States and Israel. State-based cyber-sabotage escalates the malevolence from terrorism to a kind of warfare, where the constraints of international relations, such as norms, treaties, sanctions, retaliation, and military deterrence, inhibit aggressive attacks, as they do in conventional “kinetic” warfare. As we saw in chapter 11, these constraints have become increasingly effective at preventing interstate war. Nonetheless, American military officials have warned of a “digital Pearl Harbor” and a “Cyber-Armageddon” in which foreign states or sophisticated terrorist organizations would hack into American sites to crash planes, open floodgates, melt down nuclear power plants, black out power grids, and take down the financial system. Most cybersecurity experts consider the threats to be inflated—a pretext for more military funding, power, and restrictions on Internet privacy and freedom.51 The reality is that so far, not a single person has ever been injured by a cyberattack. The strikes have mostly been nuisances such as doxing, namely leaking confidential documents or e-mail (as in the Russian meddling in the 2016 American election), and distributed denial-of-service attacks, where a botnet (an array of hacked computers) floods a site with traffic. Schneier explains, “A real-world comparison might be if an army invaded a country, then all got in line in front of people at the Department of Motor Vehicles so they couldn’t renew their licenses. If that’s what war looks like in the 21st century, we have little to fear.”52 For the techno-doomsters, though, tiny probabilities are no comfort. All it will take, they say, is for one hacker or terrorist or rogue state to get lucky, and it’s game over. That’s why the word threat is preceded with existential, giving the adjective its biggest workout since the heyday of Sartre and Camus. In 2001 the chairman of the Joint Chiefs of Staff warned that “the biggest existential threat out there is cyber” (prompting John Mueller to comment, “As opposed to small existential threats, presumably”). This existentialism depends on a casual slide from nuisance to adversity to tragedy to disaster to annihilation. Suppose there was an episode of bioterror or bioterror that killed a million people. Suppose a hacker did manage to take down the Internet. Would the country literally cease to exist? Would civilization collapse? Would the human species go extinct? A little proportion, please—even Hiroshima continues to exist! The assumption is that modern people are so helpless that if the Internet ever went down, farmers would stand by and watch their crops rot while dazed city-dwellers starved. But disaster sociology (yes, there is such a field) has shown that people are highly resilient in the face of catastrophe.53 Far from looting, panicking, or sinking into paralysis, they spontaneously cooperate to restore order and improvise networks for distributing goods and services. Enrico Quarantelli noted that within minutes of the Hiroshima nuclear blast, survivors engaged in search and rescue, helped one another in whatever ways they could, and withdrew in controlled flight from burning areas. Within a day, apart from the planning undertaken by the government and military organizations that partly survived, other groups partially restored electric power to some areas, a steel company with 20 percent of workers attending began operations again, employees of the 12 banks in Hiroshima assembled in the Hiroshima branch in the city and began making payments, and trolley lines leading into the city were completely cleared with partial traffic restored the following day.54

### Drug Prices

#### No disease impact.

Halstead 19 John Halstead, doctorate in political philosophy. [Cause Area Report: Existential Risk, Founders Pledge, https://founderspledge.com/research/Cause%20Area%20Report%20-%20Existential%20Risk.pdf]//BPS

However, there are some reasons to think that naturally occurring pathogens are unlikely to cause human extinction. Firstly, Homo sapiens have been around for 200,000 years and the Homo genus for around six million years without being exterminated by an infectious disease, which is evidence that the base rate of extinction-risk natural pathogens is low.82 Indeed, past disease outbreaks have not come close to rendering humans extinct. Although bodies were piled high in the streets across Europe during the Black Death,83 human extinction was never a serious possibility, and some economists even argue that it was a boon for the European economy.84 Secondly, infectious disease has only contributed to the extinction of a small minority of animal species.85 The only confirmed case of a mammalian species extinction being caused by an infectious disease is a type of rat native only to Christmas Island. Having said that, the context may be importantly different for modern day humans, so it is unclear whether the risk is increasing or decreasing. On the one hand, due to globalisation, the world is more interconnected making it easier for pathogens to spread. On the other hand, interconnectedness could also increase immunity by increasing exposure to lower virulence strains between subpopulations.87 Moreover, advancements in medicine and sanitation limit the potential damage an outbreak might do.

#### Disease not widespread nor existential

Dr. Toby Ord 20, Senior Research Fellow in Philosophy at Oxford University, DPhil in Philosophy from the University of Oxford, The Precipice: Existential Risk and the Future of Humanity, Hachette Books, Kindle Edition, p. 124-126

Are we safe now from events like this? Or are we more vulnerable? Could a pandemic threaten humanity’s future?10

The Black Death was not the only biological disaster to scar human history. It was not even the only great bubonic plague. In 541 CE the Plague of Justinian struck the Byzantine Empire. Over three years it took the lives of roughly 3 percent of the world’s people.11

When Europeans reached the Americas in 1492, the two populations exposed each other to completely novel diseases. Over thousands of years each population had built up resistance to their own set of diseases, but were extremely susceptible to the others. The American peoples got by far the worse end of exchange, through diseases such as measles, influenza and especially smallpox.

During the next hundred years a combination of invasion and disease took an immense toll—one whose scale may never be known, due to great uncertainty about the size of the pre-existing population. We can’t rule out the loss of more than 90 percent of the population of the Americas during that century, though the number could also be much lower.12 And it is very difficult to tease out how much of this should be attributed to war and occupation, rather than disease. As a rough upper bound, the Columbian exchange may have killed as many as 10 percent of the world’s people.13

Centuries later, the world had become so interconnected that a truly global pandemic was possible. Near the end of the First World War, a devastating strain of influenza (known as the 1918 flu or Spanish Flu) spread to six continents, and even remote Pacific islands. At least a third of the world’s population were infected and 3 to 6 percent were killed.14 This death toll outstripped that of the First World War, and possibly both World Wars combined.

Yet even events like these fall short of being a threat to humanity’s longterm potential.15

[FOONOTE]

In addition to this historical evidence, there are some deeper biological observations and theories suggesting that pathogens are unlikely to lead to the extinction of their hosts. These include the empirical anti-correlation between infectiousness and lethality, the extreme rarity of diseases that kill more than 75% of those infected, the observed tendency of pandemics to become less virulent as they progress and the theory of optimal virulence. However, there is no watertight case against pathogens leading to the extinction of their hosts.

[END FOOTNOTE]

In the great bubonic plagues we saw civilization in the affected areas falter, but recover. The regional 25 to 50 percent death rate was not enough to precipitate a continent-wide collapse of civilization. It changed the relative fortunes of empires, and may have altered the course of history substantially, but if anything, it gives us reason to believe that human civilization is likely to make it through future events with similar death rates, even if they were global in scale.

The 1918 flu pandemic was remarkable in having very little apparent effect on the world’s development despite its global reach. It looks like it was lost in the wake of the First World War, which despite a smaller death toll, seems to have had a much larger effect on the course of history.16

It is less clear what lesson to draw from the Columbian exchange due to our lack of good records and its mix of causes. Pandemics were clearly a part of what led to a regional collapse of civilization, but we don’t know whether this would have occurred had it not been for the accompanying violence and imperial rule. The strongest case against existential risk from natural pandemics is the fossil record argument from Chapter 3. Extinction risk from natural causes above 0.1 percent per century is incompatible with the evidence of how long humanity and similar species have lasted. But this argument only works where the risk to humanity now is similar or lower than the longterm levels. For most risks this is clearly true, but not for pandemics. We have done many things to exacerbate the risk: some that could make pandemics more likely to occur, and some that could increase their damage. Thus even “natural” pandemics should be seen as a partly anthropogenic risk.

#### Lots of alt causes to inaccessibility -- Expertise, processes, bio samples, cell lines, distribution, and cost

Shultz and Stevens 1/14 Mark Schultz is the Goodyear Endowed Chair in Intellectual Property Law at the University of Akron School of Law, United States. Philip Stevens is Executive Director of Geneva Network., Geneva Network, "Why intellectual property rights matter for COVID-19 - Geneva Network - Intellectual Property Rights and Covid-19", January 14th, 2021, https://geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/ - BD

The real challenges

IP has underpinned the research and development that has led to the arrival of several game-changing vaccines. But the challenge does not end there. Perhaps the biggest hurdle is manufacturing billions of doses or new antibody treatments while maintaining the highest quality standards.

There’s more to it than starting a global manufacturing free for all by overriding or ignoring patents. A spokesperson for Regeneron, a manufacturer of a novel COVID-19 antibody treatment explained to The Lancet: “Manufacturing antibody medicines is incredibly complex and transferring the technology takes many months, as well as significant resources and skill. Unfortunately, it is not as simple as putting a recipe on the internet and committing to not sue other companies during the pandemic”.

John-Arne Røttingen, chair of the WHO COVID-19 Solidarity trial, explains that technology transfer will be crucial to scaling up production, but voluntary mechanisms are better: “If you want to establish a biological production line, you need a lot of additional information, expertise, processes, and biological samples, cell lines, or bacteria” to be able to document to regulatory agencies that you have an identical product, he explains.

“Manufacturing antibody medicines is incredibly complex and transferring the technology takes many months. Unfortunately, it is not as simple as putting a recipe on the internet”

The TRIPS waiver, he says, is the “wrong approach” because COVID-19 therapeutics and vaccines are complex biological products in which the main barriers are production facilities, infrastructure, and know-how. “IP is the least of the barriers”, he says.

Then there is the problem of distributing the vaccines to billions of people in every country. Even with plentiful supplies, a range of issues need to be considered such as regulatory bottlenecks; supply chain, transport and storage; maintenance of the cold chain; adequately trained staff; data tracking; and vaccine hesitancy amongst the population.

The costs of the vaccine itself is only a small component of the total cost of delivering doses to millions of people. The UK, for example, has spent around £2.9bn on procuring vaccines, far less than the official estimate of £8.8bn to be spent on distributing and delivering them. Comparable costs will exist for all other countries, even if they are subsidised by Overseas Development Assistance. Even then, the combined costs of vaccination are dwarved by the other economic costs of the pandemic.

IP is part of the solution

Far from being a problem, IP has repeatedly proven itself to be part of the solution in fighting disease. It allows innovators to manage production scale-up by selecting and licensing technology to partners who have the skills and capacity to reliably manufacture large quantities of high-quality products, which they distribute at scale in low and middle-income countries. It would make no sense for IP owners to use it to withhold access, when they can profit from supplying all demand. IP licensing is the way this is done.

This is the model unfolding for COVID-19, with new manufacturing licensing deals such as those between AstraZeneca and the Serum Institute in India (1bn doses), China’s BioKangtai (200m doses), Brazil’s FioCruz, Russia’s R-Pharm and South Korea’s SK Bioscience. Collectively, such deals will see the manufacture of 2 billion doses by the end of 2021. The Serum Institute has also entered into manufacturing licenses with a number of developers of yet to be approved COVID-19 vaccines, as have several other Indian vaccine manufacturers. Many of these doses will be procured on a non-profit basis by new collective procurement bodies such as COVAX, for distribution to low and middle-income countries.

IP is important because it allows the innovator to control which partners manufacture the product, ensuring the quality of supplies, while maximising low-cost access for low and middle-income countries. It also allows the innovator to preserve its ability to recoup costs from richer markets, meaning the preservation of incentives for future R&D investment.

Voluntary licensing has worked well in the past, particularly for low and middle-income countries. A recent academic analysis of hepatitis C voluntary licenses published by The Lancet Global Health concluded that they have increased access to medicines at a considerably faster pace than alternative access models, by avoiding the need for lengthy patent disputes and bringing to bear inter-company competition and economies of scale.

But again, these licenses model were criticised by public health NGOs and other stakeholders, who called for the confiscation of IP rights via compulsory licensing. Time has shown such calls to be mistaken.

Conclusion

As of January 2021, there are three vaccines approved by stringent regulatory authorities with several more likely to follow in the coming months. Prices of COVID-19 vaccines vary between more expensive but complex to manufacture, and cheaper ones based on existing technologies. Companies are offering their vaccines at cost, with pooled procurement mechanisms such as COVAX ready to leverage their enormous purchasing power to drive economies of scale and bring prices down further for developing countries, many of which will have the cost of vaccination subsidised by Overseas Development Assistance.

Meanwhile, the existence of multiple vaccines means there is no COVID-19 vaccine “monopoly”, and minimal risk of premium pricing. In fact, there is a competitive marketplace in which manufacturers are incentivised to refine and improve their vaccines – vital given the new strains of the virus which constantly emerge.

Providing COVID-19 vaccines rapidly at scale is a pressing challenge for all countries but there is no evidence that overriding intellectual property rights will achieve more than the licensing agreements currently being forged between innovators and reputable vaccine manufacturers in countries like India and Brazil.

Manufacturing of COVID-19 vaccines is continuing at speed, and mechanisms are gearing up to ensure a rapid global role out. Forceable tech transfer and other forms of IP abrogation such as those proposed by India and South Africa at the WTO TRIPS Council would throw manufacturing supply chain planning, financing and distribution systems into chaos for little upside.

Instead of sowing division and creating major distractions at venues such as the WTO, opponents of IP should stop the rhetoric. The IP system has put us in a position to end the pandemic. We should allow it to continue doing its job.

#### Monopolies don’t exist

Shultz and Stevens 1/14 Mark Schultz is the Goodyear Endowed Chair in Intellectual Property Law at the University of Akron School of Law, United States. Philip Stevens is Executive Director of Geneva Network., Geneva Network, "Why intellectual property rights matter for COVID-19 - Geneva Network - Intellectual Property Rights and Covid-19", January 14th, 2021, https://geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/ - BD

Nevertheless, the emergence of several competing vaccines has shifted the debate. There are increasingly loud calls to suspend IP rights in order to promote affordable prices for low and middle-income countries, and to mandate forced transfer of know-how and technology in order to scale up global manufacturing . These calls have culminated in proposals at the WTO to implement a temporary suspension of certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including obligations regarding patent rights and the protection of undisclosed information on all COVID-19-related technologies.

Such extreme proposals are based on muddled thinking. Specifically, the political campaigns that underpin them mischaracterise IP rights as “monopolies” that allow companies to charge unaffordable prices.

One eminent scholar of patents, Prof. Edmund Kitch described the application of the term “monopoly” to patents as one of the “elementary and persistent errors in the economic analysis of Intellectual Property”. In reality, IP rights drive the emergence of competing products in the same category, putting a lid on the ability of manufacturers to charge premium prices.

Owning IP rarely gives control over a market and IP markets are often intensely competitive. In medicines, for instance, there are usually many substitutes and alternatives. For example, a patient needing a cholesterol drug has a host of statins from which to choose, both patented and generic. Similarly, patients with osteoporosis and their doctors can choose from Fosamax®, Actonel®, or Boniva®. Recent years have seen the emergence of competing shingle vaccines, increased competition in the lung cancer therapeutic space, and a slew of promising clinical trials and new drug launches in the under-served area of lung disease.

Each of the owners of patents in these products has a temporary exclusive right to their product; none of them has a monopoly over the market for this type of treatment.

The most spectacular demonstration of this point is the recent emergence of multiple competing hepatitis C cures, which have opened up a wide range of treatment options and placed downward pressure on prices

As Geoffrey Dusheiko and Charles Gore wrote in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”

Every step of the development of this new market in hepatitis C cures was accompanied by calls to override their IP by civil society and certain intergovernmental organizations. Had those calls been heeded, it is doubtful such a competitive market would exist today.

A similar story is unfolding in the COVID-19 vaccine space. Pharmaceutical market analysts predict competition will hold COVID-19 vaccine prices down even in the unlikely scenario of rights holders declining to license their IP to other manufacturers. “In two years’ time, there could be 20 vaccines on the market,” Emily Field, head of European pharmaceutical research at Barclays told the BBC. “It’s going to be difficult to charge a premium price.”