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#### Biotech R&D is set for high growth and investment now

NASDAQ 8/9 [NASDAQ is a stock market index that includes almost all stocks listed on the Nasdaq stock exchange. Along with the Dow Jones Industrial Average and S&P 500, it is one of the three most-followed stock market indices in the United States. This article was written by NASDAQ contributors and published on CNBC. The editorial staff of CNBC did not contribute to the creation of this study.) “Why the Nasdaq Biotechnology Index is poised for a run of sustainable growth” CNBC, NASDAQ, 8/9/2021, <https://www.cnbc.com/advertorial/2021/08/09/why-the-nasdaq-biotechnology-index-is-poised-for-a-run-of-sustainable-growth-.html>] RM

Between the recent bio innovation success stories in the battle against Covid-19 and the technology-driven advances ushering in new efficiencies for research and development (R&D), **the biotech industry has never been more relevant**.

As home to more than 265 companies, the pioneering Nasdaq Biotechnology Index (NBI) has long been committed to providing healthcare’s innovators with access to the capital they need to keep moving forward. Now, investors have access to the Index’s companies through a new ETF, the Invesco Nasdaq Biotechnology ETF (IBBQ).

Launched in 1993, in the wake of the original “biotech revolution” led by the discovery of recombinant DNA, NBI® remains the most representative index in the space. In fact, 98% of all U.S. listed biotech companies are listed on Nasdaq. When considering the massive growth taking place in the sector, it’s no surprise that NBI has outperformed both the S&P 500 (SPX) and Health Care Select Sector Index (IXVTR) in certain market environments.

According to Mark Marex, Index R&D Senior Specialist for Nasdaq who recently compiled an in-depth report on the NBI, global events and digital acceleration have contributed to the Index’s recent strong performance; and Nasdaq’s dedication to maintaining a true benchmark for technology-driven healthcare innovation has provided a framework for growth.

Building the ideal benchmark

Given the existence of pureplay biotech firms, hybrid biopharmaceutical companies, and less R&D-intensive pharmaceutical manufacturers, creating a single benchmark that truly captures the biotech sector and the symbiotic relationships among its players is no easy task.

One of the unique aspects of NBI, versus biotech-focused indexes created by other index providers, is its subsector classifications split between Biotechnology and Pharmaceuticals. As of June 30, 2021, ICB (FTSE Russell’s Industry Classification Benchmark) classified 222 NBI companies as Biotechnology and 47 as Pharmaceuticals. The resulting split by index weight is approximately 65% and 35%, respectively, which illustrates the major difference between the two groups: Pharmaceutical companies tend to be much larger than Biotechnology firms.

This split within a single index provides advantages for investors: While offering some exposure to more established pharmaceutical companies, it also includes R&D-heavy biotech firms that over time may transition into biotech-driven pharma companies. That’s exactly what happened this year when NBI’s largest company, Amgen (AMGN / $144Bn), was reclassified by ICB from Biotechnology to Pharmaceuticals. By retaining firms as they straddle the two classifications over the course of their lifecycle, NBI presents potential growth advantages when compared with index providers that focus rigidly on one classification versus the other.

Home to world-changing breakthroughs

Nasdaq’s vision for the Index has served it well, **both in terms of its longevity and its current role as a champion of the companies paving the way for a post-pandemic world through their technological advances and life-saving treatments**. The broad reach of NBI constituents across multiple fronts in the fight against Covid-19, for example — from diagnosis to vaccines and treatment —demonstrates the strength of its core approach.

NBI companies including Gilead and Regeneron made headlines for their successes during the pandemic with antiviral therapeutics and antibody-based therapeutics for high-risk patients. But it’s the stunning success of m-RNA vaccine technology from Moderna and BioNTech, two NBI companies, that most clearly showcase the home run potential among the biotech entrepreneurs in the space.

And while NBI is currently up 8.2% YTD on a price-return basis (as of June 30) **versus a broader market gain of 14.4% by SPX**, the S&P Biotechnology Select Industry Index (SPSIBI) is down 3.7%.

It’s worth noting that in 2020, NBI outperformed SPX with a price gain of 25.7% versus 16.3%, respectively. This shows the resilience of the NBI and the inherent strength of its current mix of companies.

The possibilities of accelerated R&D

As a whole, the life-changing work being done by NBI constituents requires enormous amounts of R&D. In 2020, R&D expenses for the entire group totaled $68.5Bn, nearly 31% of these companies’ revenue totals. Two-thirds of NBI’s firms reported R&D expenses that exceeded their revenues

For several NBI companies, however, these massive investments provided tangible benefits in the fight against Covid-19. Undoubtedly, years of back-end work and minimal profits ultimately helped deliver the very products that are now driving historic returns. Psychologically, their breakthroughs demonstrated the enormous potential of science and technology to serve humankind.

Looking ahead, **revolutions in Mapping and Engineering processes, boosted by rapid advancements in Machine Learning and Artificial Intelligence, are fostering a true fusion of Biology and Technology that could transform the traditionally costly and labor-intensive R&D function**. Some research estimates these advances could reduce the failure rate of drugs by up to 45% and shorten drug trials by up to 50%. The result could be even more breakthroughs, performed much more efficiently, greatly increasing the returns on biopharmaceutical R&D.

Even a conservative interpretation of the above numbers would significantly reduce R&D costs and boost the market capitalization of therapeutics companies from the current $2Tn up to $9Tn as soon as 2024, according to estimates from ARK Financial.

Meanwhile, increasingly cost-effective human genomics could revolutionize several other industries, from agriculture to biofuels.

By any measure, there is much to be excited about across the spectrum of biotech — especially coming out of a global pandemic. And while no person, nor index, can truly predict what the future holds, chances are strong that companies sitting within NBI will have a hand in leading the way.

“**For investors**, the Index already serves as a fascinating lens through which to view human society’s scientific and technological advancements,” says Mark Marex. “To me, it’s very exciting to ponder what the researchers, scientists, and business leaders in this space will accomplish next.”

#### IPR protections are key to sustain healthcare investments and manufacturing. Independently, it’s key to broader vaccine production.

Roberts 6/25/21 [James M. Roberts is a Research Fellow for Economic Freedom and Growth at the Heritage Foundation. Roberts' primary responsibility as one of The Heritage Foundation's lead experts in economic freedom and growth is to edit the Rule of Law and Monetary Freedom sections of [Index of Economic Freedom](https://www.heritage.org/index/). An influential annual analysis of the economic climate of countries throughout the world, the Index is co-published by Heritage and The Wall Street Journal.) “Biden’s OK of Global Theft of America’s Intellectual Property is Wrong, Dangerous.” 6/25/2021, The Heritage Foundation, Commentary—Public Health] RM

Last month, President Biden advocated removing international intellectual property rights (IPR) protections for American-made COVID-19 vaccines.

**Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes**.

The best way to prevent and treat new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production.

Three U.S. companies—Pfizer, Moderna, and Johnson & Johnson—created and manufactured the world’s most effective mRNA COVID vaccines in record time. An increasing majority of Americans have now been inoculated, but much of the developing world remains in desperate need of vaccines. Americans naturally want to help. The question is how.

Last month, President Biden advocated removing international intellectual property rights (IPR) protections for American-made COVID-19 vaccines. This, he said, would help make the vaccines more plentiful and available in needy countries. **It’s a short-sighted approach and doomed to fail.**

Mr. Biden wants to waive the World Trade Organization’s “Trade-Related Aspects of Intellectual Property Rights” (TRIPS) agreement for U.S. vaccines and let foreign countries issue “compulsory licenses“ allowing their domestic pharmaceutical companies to manufacture the medicines without adequately compensating the companies that invented them.

Practically speaking, countries such as India and South Africa are unlikely to manufacture the vaccines. They lack an advanced infrastructure for cold supply-chain distribution and many other crucial resources required by these products’ capital-intensive, state-of-the-art manufacturing process.

But the Biden policy is bad for many other reasons.

Developing breakthrough medications takes tremendous ingenuity and immense financial investments. **It’s an extraordinarily high-risk endeavor, and the prospect of making a profit is what convinces private companies to undertake those risks.**

Signaling that the United States will not fight to defend their intellectual property rights **actively undermines innovation and manufacturing** in American health care and medicines.

It also erodes patient protections by undermining quality control. Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes. Already there are reports of ineffective and even dangerous counterfeit COVID-19 vaccines being sold around the world.

Those pushing to break U.S. pharmaceutical patents say they want to do so for altruistic reasons. Consequently, they also insist that the prices for the medications be set far below their actual value.

But history shows us that forcing private companies to provide vaccines at an “affordable price,” regardless of the cost to the companies, actually impedes the manufacture of high-quality vaccines. Moreover, it inhibits the **future development of vaccines** needed to meet as-yet-unknown diseases.

Washington first imposed vaccine price controls as part of Hillary Clinton’s 1993 healthcare-for-all crusade. As the Wall Street Journal later noted, it was a body blow to the U.S. vaccine industry. Ironically, government-decreed prices left the companies unable to produce enough vaccines to meet Mrs. Clinton’s admittedly admirable goal of universal immunization of children. Since then, U.S. firms have largely eschewed the vaccine market because they could not recoup their R&D and manufacturing costs and earn enough profit to fund future innovation.

Ultimately, **compulsory licensing legalizes the theft of intellectual property**. Recognizing this, senators from both sides of the aisle have joined with other government officials and industry leaders to call on the administration to reverse this bad decision.

The U.S. patent protection system has served the nation well since its founding.  **It is and has been a bulwark of American prosperity**, but the strength of that protection has been weakening in the past few decades. **Compulsory licensing contributes to the erosion** of that protection.

As the U.S. and the rest of the world emerge from the pandemic, it is clear that more innovative medicines and vaccines will be needed for future protection from viruses and other emerging biological threats.

**The best way to prevent and treat those new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production**.

That way, U.S.-manufactured vaccines can be made available to all Americans quickly. And governments can subsidize their export and sale to other countries far more effectively and less expensively than through compulsory licensing schemes.

Meanwhile, let’s hope Mr. Biden listens to the more reasonable and less-agenda driven voices in this debate and reverses course on the TRIPS waiver.

#### COVID was a precursor to deadlier pandemics—vaccine production will determine everything.

Lander 8/4/21 [Eric Lander, President Biden’s Science Advisory and Director of the White House Office of Science and Technology Policy) “Opinion: As bad as Covid-19 has been, a future pandemic could be even worse—unless we act now” 8/4/21, The Washington Post] RM

[Coronavirus](https://www.washingtonpost.com/coronavirus/?itid=lk_inline_manual_3) vaccines can end the current pandemic if enough people choose to protect themselves and their loved ones by getting vaccinated. But in the years to come, we will still need to defend against a pandemic side effect: collective amnesia.

As public health emergencies recede, societies often quickly forget their experiences — and **fail to prepare for future challenges**. For pandemics, such a course would be disastrous.

**New infectious diseases have been emerging at an accelerating pace,** and they are spreading faster.

Our federal government is responsible for defending the United States against future threats. That’s why President Biden has asked Congress to fund his plan to build on current scientific progress to keep new infectious-disease threats from turning into pandemics like covid-19.

As the president’s science adviser, I know what’s becoming possible. For the first time in our history, we have an opportunity not just to refill our stockpiles but also to transform our capabilities. However, **if we don’t start preparing now for future pandemics, the window for action will close.**

Covid-19 has been a catastrophe: The toll in the United States alone is [more than 614,000 lives](https://www.washingtonpost.com/graphics/2020/national/coronavirus-us-cases-deaths/?itid=lk_inline_manual_11) and has been estimated to exceed [$16 trillion](https://jamanetwork.com/journals/jama/fullarticle/2771764), with disproportionate impact on vulnerable and marginalized communities.

But a future pandemic could be even worse — unless we take steps now.

It’s important to remember that the virus behind covid-19 is far less deadly than the 1918 influenza. The virus also belongs to a well-understood family, coronaviruses. It was possible to design vaccines within days of knowing the virus’s genetic code because 20 years of [basic scientific research](https://science.sciencemag.org/content/372/6538/109.full) had revealed which protein to target and how to stabilize it. And while the current virus spins off variants, its mutation rate is slower than that of most viruses.

**Unfortunately, most of the 26 families of viruses that infect humans are less well understood or harder to control**. We have a great deal of work still ahead.

The development of [mRNA vaccine technology](https://www.washingtonpost.com/health/2020/12/06/covid-vaccine-messenger-rna/?itid=lk_inline_manual_17) — thanks to more than a decade of foresighted basic research — was a game-changer. It shortened the time needed to design and test vaccines to less than a year — far faster than for any previous vaccine. And it’s been surprisingly effective against covid-19.

Still, there’s much more to do. We don’t yet know how mRNA vaccines will perform against other viruses down the road. And **when the next pandemic breaks out, we’ll want to be able to respond even faster.**

Fortunately, the scientific community has been developing a bold plan to keep future viruses from becoming pandemics.

Here are a few of the goals we should shoot for:

The capability to design, test and approve safe and effective vaccines within 100 days of detecting a pandemic threat (for covid-19, that would have meant May 2020); manufacture enough doses to supply the world within 200 days; and speed vaccination campaigns by replacing sterile injections with skin patches.

Diagnostics simple and cheap enough for daily home testing to limit spread and target medical care.

Early-warning systems to spot new biological threats anywhere in the world soon after they emerge and monitor them thereafter.

We desperately need to strengthen our public health system — from expanding the workforce to modernizing labs and data systems — including to ensure that vulnerable populations are protected.

And we need to coordinate actions with our international partners, because pandemics know no borders.

These goals are ambitious, but they’re feasible — provided the work is managed with the seriousness, focus and accountability of NASA’s Apollo Program, which sent humans to the moon.

Importantly, these capabilities won’t just prepare us for future pandemics; they’ll also improve public health and medical care for infectious diseases today.

Preparing for threats is a core national responsibility. That’s why our government invests heavily in missile defense and counterterrorism. We need to similarly protect the nation against biological threats, which range from the ongoing risk of pandemics to the possibility of deliberate use of bioweapons.

Pandemics cause massive death and disruption. From a financial standpoint, they’re also astronomically expensive. If, as might be expected from [history](https://www.cfr.org/timeline/major-epidemics-modern-era) and current trends, we suffered a pandemic of the current scale every two decades, the annualized cost would exceed $500 billion per year. Investing a much smaller amount to avert this toll is an economic and moral imperative.

The White House will put forward a detailed plan this month to ensure that the United States can fully prepare before the next outbreak. It’s hard to imagine a higher economic or human return on national investment.

#### Ecosystem sensitivity from climate change means future pandemics will cause extinction—assumes COVID

Supriya 4/19 [Lakshmi Supriya got her BSc in Industrial Chemistry from IIT Kharagpur (India) and a Ph.D. in Polymer Science and Engineering from Virginia Tech (USA). She has more than a decade of global industry experience working in the USA, Europe, and India. After her Ph.D., she worked as part of the R&D group in diverse industries starting with semiconductor packaging at Intel, Arizona, where she developed a new elastomeric thermal solution, which has now been commercialized and is used in the core i3 and i5 processors. From there she went on to work at two startups, one managing the microfluidics chip manufacturing lab at a biotechnology company and the other developing polymer formulations for oil extraction from oil sands. She also worked at Saint Gobain North America, developing various material solutions for photovoltaics and processing techniques and new applications for fluoropolymers. Most recently, she managed the Indian R&D team of Enthone (now part of MacDermid) developing electroplating technologies for precious metals.) “Humans versus viruses - Can we avoid extinction in near future?” News Medical Life Sciences, 4/19/21, https://www.news-medical.net/news/20210419/Humans-versus-viruses-Can-we-avoid-extinction-in-near-future.aspx] RM

Expert argues that human-caused changes to the environment can lead to the emergence of pathogens, not only from outside but also from our own microbiome, which can pave the way for large-scale destruction of humans and **even our extinction**.

Whenever there is a change in any system, it will cause other changes to reach a balance or equilibrium, generally at a point different from the original balance. Although this principle was originally posited by the French chemist Henry Le Chatelier for chemical reactions, this theory can be applied to almost anything else.

In an essay published on the online server Preprints\*, Eleftherios P. Diamandis of the University of Toronto and the Mount Sinai Hospital, Toronto, argues that changes caused by humans, to the climate, and everything around us will lead to changes that may have a dramatic impact on human life. Because our ecosystems are so complex, we don’t know how our actions will affect us in the long run, so humans generally disregard them.

Changing our environment

Everything around us is changing, from living organisms to the climate, water, and soil. Some estimates say about half the organisms that existed 50 years ago have already become extinct, and about 80% of the species may become extinct in the future.

As the debate on global warming continues, according to data, the last six years have been the warmest on record. Global warming is melting ice, and sea levels have been increasing. The changing climate is causing more and more wildfires, which are leading to other related damage. At the same time, increased flooding is causing large-scale devastation.

One question that arises is how much environmental damage have humans already done? A recent study compared the natural biomass on Earth to the mass produced by humans and found humans produce a mass equal to their weight every week. This human-made mass is mainly for buildings, roads, and plastic products.

In the early 1900s, human-made mass was about 3% of the global biomass. Today both are about equal. Projections say by 2040, the human-made mass will be triple that of Earth’s biomass. But, slowing down human activity that causes such production may be difficult, given it is considered part of our growth as a civilization.

Emerging pathogens

Although we are made up of human cells, we have almost ten times that of bacteria just in our guts and more on our skin. These microbes not only affect locally but also affect the entire body. There is a balance between the good and bad bacteria, and any change in the environment may cause this balance to shift, especially on the skin, the consequences of which are unknown.

Although most bacteria on and inside of us are harmless, gut bacteria can also have viruses. If viruses don’t kill the bacteria immediately, they can incorporate into the bacterial genome and stay latent for a long time until reactivation by environmental factors, when they can become pathogenic. They can also escape from the gut and enter other organs or the bloodstream. Bacteria can then use these viruses to kill other bacteria or help them evolve to more virulent strains.

An example of the evolution of pathogens is the cause of the current pandemic, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Several mutations are now known that make the virus more infectious and resistant to immune responses, and strengthening its to enter cells via surface receptors.

The brain

There is evidence that the SARS-CoV-2 can also affect the brain. The virus may enter the brain via the olfactory tract or through the angiotensin-converting enzyme 2 (ACE2) pathway. Viruses can also affect our senses, such as a loss of smell and taste, and there could be other so far unkown neurological effects. The loss of smell seen in COVID-19 could be a new viral syndrome specific to this disease.

Many books and movies have described pandemics caused by pathogens that wipe out large populations and cause severe diseases. In the essay, the author provides a hypothetical scenario where a gut bacteria suddenly starts producing viral proteins. Some virions spread through the body and get transmitted through the human population. After a few months, the virus started causing blindness, and within a year, large populations lost their vision.

Pandemics can cause other diseases that can threaten humanity’s entire existence. **The COVID-19 pandemic brought this possibility to the forefront**. If we continue disturbing the equilibrium between us and the environment, we don’t know what the consequences may be and **the next pandemic could lead us to extinction.**

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#### Text: The People’s Republic of China should offer Chinese developed vaccines and medical technology related to COVID-19 to the world for free

#### The CP massively ramps up Chinese “vaccine diplomacy” which solves the case

Juecheng and Yuwei 8-13-21

(Zhao and Hu, https://www.globaltimes.cn/page/202108/1231387.shtml)

One of China’s most valued contributions to the global fair accessibility to COVID-19 vaccines is to enable more developing countries to hone their ability to produce vaccines by themselves, Zha Daojiong, professor of International Political Economy from Peking University, who closely studies the global vaccine equitable allocation framework, told the Global Times in a recent exclusive interview. Sharing his insights on widely discussed “vaccine nationalism,” “wavering vaccine intellectual property,” and “COVAX operation challenges,” Zha believes that China is advocating negotiations among countries on equitable global distribution of vaccines from a humanitarian, and global perspective. China has vowed to make efforts to provide the world with 2 billion doses of COVID-19 vaccines this year and donate $100 million to COVAX to promote global vaccine provision. This commitment comes amid the rampaging Delta variant, which is bringing more challenges for developing countries to access vaccines and combat the pandemic while the West continues to drag its heels in fulfilling its promises. The promise was made at the first meeting of a forum on international cooperation on COVID-19 vaccines held on August 5. Zha suggested that the forum, alongside the Initiative for Belt and Road Partnership on COVID-19 Vaccine Cooperation, reflect China’s efforts to support long-term cooperation in the vaccine industry globally. However, some Western media have labeled China and Russia as the pioneers of the global "vaccine diplomacy" campaign. The choice of vaccines by countries has become the epitome of global geopolitics.   Foreign comments on China using "vaccine diplomacy" in a narrow geopolitical sense reflect the real competition among COVID-19 vaccine providers, Zha told the Global Times. Due to China’s mature vaccine technologies, longer shelf life and lower requirement for storage and transportation, Chinese made vaccines are a more preferable choice for many developing countries with relatively weak vaccination infrastructure . This has been reflected in the approval of Chinese vaccines in more than 100 countries. But the phenomenon of “vaccine nationalism” was never absent in the decision by governments to choose vaccines, Zha suggested. “For example, some countries and regions would include geopolitical factors in choosing vaccines. These countries would reject certain vaccines. Moreover, some media outlets refuse to accept the fact that the professional assessment of vaccine efficacy is also a scientific process. Instead, they made comments on potential vaccines based on their geopolitical interests. This is also a kind of “vaccine nationalism”. Voices blaming “vaccine nationalism” have long been present in developed countries. For instance, Zha recalled how, during the H1N1 pandemic of 2009 which affected more than 200 countries and regions for more than a year, certain developed countries bought out entire stocks of vaccines against H1N1 once they were developed. Though some of those countries had promised to donate vaccines to others after they met their vaccination needs, the virus had long disappeared before their donations were made. Therefore, many in other nations lost the opportunity of a timely vaccination. Providing assistance from one country to another in the field of infectious or non-infectious diseases is often referred to as "health diplomacy." Some international public health research literature support "health diplomacy" because cooperation in this field is conducive to the improvement of political, economic and diplomatic relations, Zha said. China has taken important steps to close the global vaccine gap, including the acceleration of large-scale production, boosting fair distribution, and licensing local production in more countries.

#### Successful vaccine diplomacy is key to overall Chinese Soft Power

Huang, PhD, 3-11-21

(YANZHONG HUANG is Senior Fellow for Global Health at the Council on Foreign Relations, a Professor at Seton Hall University’s School of Diplomacy and International Relations, and Director of the school’s Center for Global Health Studies. https://www.foreignaffairs.com/articles/china/2021-03-11/vaccine-diplomacy-paying-china )

Vaccines have had a place in diplomacy since the Cold War era. The country that can manufacture and distribute lifesaving injections to others less fortunate sees a return on its investment in the form of soft power: prestige, goodwill, perhaps a degree of indebtedness, even awe. Today the country moving fastest toward consolidating these gains may be China, under President Xi Jinping, who proclaimed last May that Chinese-made vaccines against COVID-19 would become a “global public good.” Since that time, top officials have promised many developing countries priority access to Chinese vaccines, and the Chinese Foreign Ministry has announced that the country is providing free vaccines to 69 countries and commercially exporting them to 28 more. China’s competitors worry that where Beijing’s inoculations go, its influence will follow. But the field of COVID-19 vaccination is still a largely uncharted one and scattered with barriers, whether logistical, scientific, psychological, or geopolitical. China’s path through this labyrinth is neither obvious nor assured. The country faces stiffening competition from Russia and India. Now the United States, too, has entered the global stakes for equitable distribution of safe and effective vaccines. China has yet to prove that it can fulfill the role it has taken on or win the trust of those it has offered to aid. CHINA'S STAKE The Chinese government dislikes the term “vaccine diplomacy.” The implication that China would distribute vaccine doses in order to broaden its global political influence is a “sinister” one, according to the official Xinhua News Agency. Rather, the Chinese government contends that “in promoting cooperation in combating the pandemic, China does not seek any geopolitical goals or have any economic interest considerations, and it has never attached any political strings.” Xi has further stressed that by distributing necessary goods in a crisis, China is merely acting as a responsible great power should. In this regard, China may seek to succeed with vaccines where it failed with masks: last spring, quality-control issues and clumsy propaganda tarnished the country’s efforts to supply medical products to the developed world. Now China is looking to showcase its global health leadership to lower- and middle-income countries, where it is distributing vaccines. But Beijing surely has additional foreign policy objectives in mind. China began its vaccine development projects early last spring, and state media made quite clear that through them, China hoped to demonstrate its technological prowess and the superiority of its authoritarian model of governance. “We are not lagging behind the United States as far as the technology is concerned,” a Chinese virologist told the state-backed Global Times. Another scientist highlighted China’s “system advantages”: “The United States is no match for China in terms of concentrating power to accomplish big things.” Indeed, unlike in the United States, vaccine development in China was a highly state-driven process. The Chinese government simultaneously pushed several technological approaches, including inactivated vaccines, mRNA vaccines, and adenovirus vector vaccines. It mobilized at least 22 institutes and firms to work on 17 vaccine development projects. And until last summer, China was leading the global race in vaccine development. It developed a vaccine (Ad5-nCoV) as early as February 2020, started Phase 1 clinical trials on March 16, and published results of the trials in late May. General Chen Wei, the face of China’s vaccine development operation, celebrated such achievements as “an embodiment of our country’s S&T progress, an embodiment of China’s great-power image and responsibility, and, even more, a contribution to humankind.” Behind such lofty goals lie commercial objectives, too. Health-related development assistance has long offered Chinese pharmaceutical companies a low-cost means of expanding their market share in the developing world. In March 2020, President Xi explicitly linked the shipment of medical supplies overseas to the “Health Silk Road,” now an important component of the Belt and Road Initiative. Xiaofeng Liang, a former deputy director of the Chinese Center for Disease Control and Prevention, has publicly called for prioritizing BRI countries for access to Chinese vaccines. But the opportunity hardly ends there. Prior to the COVID-19 pandemic, few Chinese pharmaceutical companies had received World Health Organization prequalification to supply medical products to international organizations and donor funds. In 2019, China’s share in the value of UN-procured medical products was only 1.9 percent, compared with 21.9 percent for India. Chinese media lamented that of the 155 WHO-prequalified vaccines, only four were from China, compared with 44 from India. Indeed, Indian pharmaceutical firms produced more than 60 percent of the vaccines sold worldwide. The huge global demand for COVID-19 vaccines and “vaccine nationalism” in wealthy nations have created a great opportunity for China to break into a market that Indian and Western pharmaceutical firms have long dominated. If the vaccine were priced at $10 per dose with a 40 percent net profit margin, even a 15 percent share of the vaccine market in lower- and middle-income countries would generate total sales of $10.8 billion and a profit of $4.32 billion for the Chinese economy. In reality, Chinese vaccines are often priced higher than $10.

#### Chinese leadership stops global secessionist conflict

Griffiths 16 **-** Senior Lecturer in the Department of Government and International Relations at the University of Sydney (Ryan, States, Nations, and Territorial Stability: Why Chinese Hegemony Would Be Better for International Order, Security Studies, 25:3, 519-545, DOI: 10.1080/09636412.2016.1195628)

I began the article by claiming that the Pax Sinica would be better for international order. In making this claim I define “better” in narrow terms emphasizing territorial stability, which can be assessed in several ways. How often do either external aggressors or internal separatists shift sovereign borders through violence? What is the frequency of secessionist civil war? How much international discord is there on the topic of secession and recognition? This is the ledger I use when comparing the Pax Sinica with the post-1945 American-led order. There are many other factors, to be sure, and critics might point to a number of ways in which Chinese hegemony would be worse. For example, they may question the support for human rights under Chinese leadership. I do not argue that Chinese hegemony would be better in all ways—there are pros and cons to any order—but I contend that there are net benefits where territorial stability is concerned. Analyzed under these terms the key differences between the American order and the imagined Chinese order have to do with the politics of secession and sovereign recognition. International order matters because it determines diplomatic practices and shapes behavior. It sets the rules of the game. The American-led order over the last seventy years has attempted to balance the norms of territorial integrity and self-determination by establishing rules for what nations are eligible for independence. But, as Fabry notes, that is an enormously challenging project because developing clear rules that separate the lucky from the unlucky requires that states derive agreed-upon criteria in a constitutive process.73 Given the politics and conflicting principles of international life (and the evolving nature of normative arguments), inconsistency, ambiguity, and accusations of hypocrisy are unavoidable. The resulting political space creates uncertainty for states and nationalist movements over when self-determination applies and when it should be subordinated to territorial integrity. Incidents like the Ukrainian crisis cast a shadow over separatist crises elsewhere. The leadership in Azerbaijan detects double standards in American policy, wondering why it “punishes Russia for annexing Crimea, but not Armenia for similar behavior in Karabakh.”74 Such uncertainly can makes states feel vulnerable, as it has in Azerbaijan, change the incentives for key actors, and increase the chance of conflict. Secessionist civil war is a common feature of contemporary times. Scholars estimate that at least half of the civil wars since 1945 have involved secessionism, and Barbara F. Walter argues that secessionism is the chief source of violence in the world today.75 Erica Chenowith and Maria Stephan find that secessionism is one of the few (if only) forms of political protest where violent tactics are more effective than nonviolent.76 Meanwhile, Tanisha Fazal and I identify fifty-five secessionist movements as of 2011 and record that many of these movements feel they have a reasonable chance of gaining independence in light of the somewhat flexible practices surrounding recognition.77 Given the strategic environment in which secessionists operate, where violence can be effective and where sovereignty is thought to be obtainable, it should come as no surprise that conflict is common. In regard to territorial stability, the concern of contemporary times is not traditional territorial conquest, but the threat posed by state fragmentation.78 This is where Chinese hegemony ought to improve international order.

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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.

#### 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.

### WTO

#### **Alt causes to WTO cred—rules ignored, protectionism, no dispute settlement, lack of US commitment.**

Schott 20 [Jeffrey J. Schott is a senior fellow at the Peterson Institute for International Economics. He is a member of the State Department’s Advisory Committee on International Economic Policy and was previously cochairman of the Trade and Environment Policy Advisory Committee for the U.S. Trade Representative. 5-4-2020 The WTO is Dead ... Long Live the WTO Milken Institute Review https://www.milkenreview.org/articles/the-wto-is-dead-long-live-the-wto] SW 9-5-2021

When 123 nations signed the accord creating a truly global body to oversee international commerce in 1994, the new World Trade Organization was hailed as a major step toward a modern, rules-based regime that would advance the effort of global open trade. What a difference, alas, a quarter-century made.

Now the WTO is increasingly seen as sclerotic. Its rules badly need updating and the dispute-settlement process is breaking down. Multilateral trade talks have collapsed; efforts to conclude even modest deals at the upcom-ing June 2020 meeting of trade ministers seem unlikely. Indeed, it’s no exaggeration to say that the WTO faces an existential crisis. Here, I offer some perspective on what has gone wrong and how to make it right in the face of widespread skepticism that a global rules-based trade system remains viable.

Grim Realities

There’s no getting around the fact that the WTO’s rules are widely abused or flat-out ignored. Even after the heralded U.S.-China trade deal was announced in January, the U.S. and China continue to violate WTO obligations on a grand scale, with about $425 billion of two-way merchandise trade still subject to duties that violate WTO obligations of both countries. Rules on subsidies, intellectual property and investment, last updated in the 1990s, are inadequate and in-complete, allowing countries to circumvent their market-access commitments with financial support for domestic firms and farmers, and to encourage the misappropriation of foreign technology.

Equally alarming, the exemption to the WTO rules allowing trade restrictions for compelling reasons of national security protection has been grossly misapplied by U.S. officials to protect domestic steel, aluminum and possibly auto producers — and by Japan and Korea to justify high-tech trade restrictions. If countries continue to brazenly invoke national security rationales to justify plain and simple protectionism, commitments to open markets that are central to WTO obligations will become increasingly worthless.

At the same time, the WTO’s dispute-settlement process, which has helped to resolve almost 600 cases since 1995, has been seriously impaired by the idling of its Appellate Body (AB). All countries have the right to appeal dispute-panel decisions, which are then held in abeyance pending completion of the appeal. But since last December, the AB has been reduced to only one member out of the normal complement of seven. That’s because U.S. officials have blocked the appointments of AB members until other WTO countries approve changes in dispute procedures demanded by the United States.

Now, since three members are needed to form a panel to hear appeals, the whole appeals process has been placed in suspended animation. The situation has broad-ranging implications for the multilateral trading system. Preventing new appeals of panel rulings will, of course, allow disputing parties to block implementation of the rulings. This will encourage unilateral actions by countries strong enough to pressure partners and will discourage new rule-making negotiations because of uncertainty that rules will be enforced.

What Would It Take?

Can the WTO system be put back on track? Doing so would require the recognition that its rulebook, along with the process of resolving disputes about those rules, needs substantial renovation. It also requires the recognition that the world’s key problems require global solutions, in which the top traders — the U.S., the European Union, Japan and China — work together in common cause.

That’s a tough row to hoe, especially given current U.S.-China and U.S.-EU frictions. But it is doable, if WTO members reorder their priorities and focus on narrow, pragmatic solutions. To see a way forward, it makes sense to digress a moment to see how we got here.

Throughout the postwar era, the United States led the charge to strengthen the multilateral trading system and to lower barriers to trade and investment. U.S. negotiators led by example: U.S. tariff cuts accounted for a large share of the liberalization undertaken in the first four rounds of postwar negotiations under the General Agreement on Tariffs and Trade, when tariffs were high to protect industrial recovery in war-decimated economies. U.S. officials opened and led all eight GATT rounds of more or less successful reform — plus the Doha Round (named after the city in which it was started), the first multilateral trade negotiation of the WTO era.

Almost the entire WTO rulebook was crafted in the period 1947-1994, when trans- Atlantic nations dominated world trade and China’s footprint was barely noticeable. Since then, technological developments have transformed the way we produce, transport, market and finance goods and services. The Doha Round, begun in late 2001, was meant to make WTO rules more relevant for 21st-century economies. In the event, the giant package of trade reforms developed in the Doha Round, so close to completion in 2008, was felled by the slingshot blows of India and a few other countries seeking special protection for their farmers and industries. WTO rules have been virtually unchanged since then, with the Trade Facilitation Agreement (2013) and updates to the Government Procurement Agreement (2014) the only modest changes.

The WTO’s prospects are not bright. In particular, it’s unclear whether the United States is willing to invest in a multilateral effort.

As I am writing this, the WTO’s prospects are not bright. In particular, it’s unclear whether the United States is willing to invest in a multilateral effort. Under the Trump administration, the United States, the lead architect of the postwar trading system, has been quick to criticize flaws in WTO agreements but half-hearted in its commitment to reform. The president has made no secret of his preference to deal with trading partners and allies one on one, where they are more likely to accept U.S. demands in deference to broader strategic relations.

Why is the WTO so unpopular in Washington these days? Simply put, President Trump believes past U.S. administrations paid too much and got too little in return from U.S. trading partners in previous multilateral trade agreements.

His complaints target several interrelated problems. First, largely for historical reasons alluded to above, U.S. tariffs are frozen in the WTO at lower levels than for other major trading nations. Trump is particularly galled that European auto tariffs are four times higher than U.S. auto tariffs. But under existing WTO rules, if U.S. officials want to raise these “bound” tariffs, they have to offer other WTO members something in return.

Second, too many countries avoid WTO tariff obligations, most notably by invoking special exemptions for developing countries. Any WTO member can self-designate as a developing country — as Singapore and South Korea have done in the past. And third, WTO rules weren’t designed for big economies (think China) that feel free to intervene in markets to achieve government goals. Nor were they built to accommodate the big-data world of digital trade.

Accordingly, the White House wants past WTO deals redone, with an updated rulebook to address Chinese industrial policies (especially support for state-owned enterprises). It wants a freer hand for U.S. officials to raise tariffs under WTO antidumping, safeguards and national security exceptions (where Trump’s current tariffs against China, Europe and others plainly violate current WTO norms). And it wants the removal of most developing- country trade preferences in current and prospective trade deals.

U.S. trade officials don’t want U.S. policies to be subject to binding enforcement of WTO rules. Defanging the AB permanently would enable them to achieve that result.

#### Biden’s “multilateralism” hasn’t changed anything—it’s even worse

Baschuk 21 [Bryce Baschuk, World Trade Reporter, Bloomberg LP Biden Picks Up Where Trump Left Off in Hard-Line Stances at WTO February 22, 2021 <https://www.bloomberg.com/news/articles/2021-02-22/biden-picks-up-where-trump-left-off-in-hard-line-stances-at-wto>] 9/5/2021

President Joe Biden’s administration dashed hopes for a softer approach to the World Trade Organization by pursuing a pair of his predecessor’s strategies that critics say risk undermining the international trading system.

The U.S. delegation to the WTO, in a statement Monday obtained by Bloomberg, backed the Trump administration’s decision to label Hong Kong exports as “Made in China” and said the U.S. cites national-security exemption in Hong Kong dispute U.S. blocks new appellate members, citing systemic concerns

WTO had no right to mediate the matter because the organization’s rules permit countries to take any action to protect their “essential security interests.” “The situation with respect to Hong Kong, China, constitutes a threat to the national security of the United States,” the U.S. delegation said. “Issues of national security are not matters appropriate for adjudication in the WTO dispute-settlement system.”

Prior to 2016, WTO members generally steered clear of defending their trade actions on the basis of national security because doing so could encourage other nations to pursue protectionist policies that have little or nothing to do with hostile threats.

Steel Tariffs

That changed in 2018, when the Trump administration triggered a cold war-era law to justify tariffs on foreign imports of steel and aluminum. In response, a handful of U.S. trade partners, including Canada, the EU, and China filed disputes at the WTO and a ruling in those cases is expected later this year.

Since then, more nations -- including Saudi Arabia, India, Russia and others -- have cited the WTO’s national-security exemption in regional trade fights, leading trade experts to warn that such cases could erode the organization’s ability to mediate disputes.

The Biden administration on Monday said the U.S. has consistently argued that national-security disputes are not subject to WTO review because it would infringe on a member’s right to determine what is in its own security interests.

In spite of the U.S. objection, the WTO granted Hong Kong’s dispute inquiry and will establish a panel of experts to deliberate the matter and render a decision, which could take two to three years.

Appellate-Body Paralysis

At the same meeting, the Biden administration said it would not agree to appoint new members to the WTO’s appellate body, a seven-member panel of experts who until 2019 had the final say on trade disputes involving billions of dollars worth of international commerce.

The Biden administration said it could not do so because the U.S. “continues to have systemic concerns” with the functioning of the appellate body as have all previous administrations over the past 16 years.

Though the statement was not entirely unexpected, it confirms America’s bipartisan frustration with the functioning of the WTO appellate body and the new administration’s willingness to block new panelists until changes can be agreed.

Once Katherine Tai is confirmed as the U.S. Trade Representative, her office “looks forward to working with” WTO Director-General Ngozi Okonjo-Iweala to tackle the problems with WTO dispute settlement, including the unresolved issues over appellate-body overreach, USTR spokesman Adam Hodge said in an email. “These are long-standing, bipartisan concerns that we hope our trading partners will work with us to address,” he said.

The Trump administration broke precedent when it refused to consider any nominees to fill vacancies on the panel until there weren’t enough to sign off on new rulings. As a result, the WTO’s dispute-settlement system has been critically damaged because WTO members are now free to veto any adverse dispute rulings by appealing them into a legal void created by the appellate body’s paralysis.

### India

#### No link - India COVID crisis already peaked – their UQ is from May

Ellyatt 21

Holly Ellyatt, 7-21-2021, “After being ravaged by the delta Covid variant, how is India doing now?,” CNBC, [https://www.cnbc.com/2021/07/23/coronavirus-how-india-is-doing-now-after-delta-variant-spread.html //](https://www.cnbc.com/2021/07/23/coronavirus-how-india-is-doing-now-after-delta-variant-spread.html%20//) AW

The situation is still bad, data shows, but not as bad as it was when the second wave peaked in the country, when daily new cases were more than 400,000. On May 7, [India reported a staggering 414,188 new infections](https://www.cnbc.com/2021/05/14/india-covid-crisis-cases-rise-but-remain-below-may-7-peak.html) and several thousand deaths.

Fortunately, [cases have declined significantly since then](https://pib.gov.in/PressReleasePage.aspx?PRID=1737607). On Thursday, India reported 41,383 new coronavirus infections and 507 new deaths, the Indian Health Ministry tweeted.

#### No indo-pak war—history, international mediation, rationality, and dramaturgy

Ganguly 19 [Sumit, Distinguished Professor of Political Science and Rabindranath Tagore Chair in Indian Cultures and Civilizations at Indiana University, Bloomington] “Why the India-Pakistan Crisis Isn’t Likely to Turn Nuclear” [https://www.foreignaffairs.com/articles/india/2019-03-05/why-india-pakistan-crisis-isnt-likely-turn-nuclear 3-5-19](https://www.foreignaffairs.com/articles/india/2019-03-05/why-india-pakistan-crisis-isnt-likely-turn-nuclear%203-5-19) RE

Worried analysts now fear that, since India and Pakistan have breached the informal norm against using air power across the border, they will be unable to prevent further escalation. Hawkish publics in both countries are calling for retaliation. Can the politicians exercise restraint?

THE LESSONS OF HISTORY

No one can say for sure, but history suggests that there is cause for optimism. During the Kargil War, India worked to contain the fighting to the regions around Pakistan’s original incursions and the war concluded with no real threat of nuclear escalation.

Less than two years later, the two countries plunged into crisis once again. In December 2001, five terrorists from the Pakistan-based groups Lashkar-e-Tabia and Jaish-e-Mohammed attacked the parliament building in New Delhi with AK-47s, grenades, and homemade bombs, killing eight security guards and a gardener. In response, India launched a mass military mobilization designed to induce Pakistan to crack down on terrorist groups. As Indian troops deployed to the border, terrorists from Pakistan struck again. In May 2002, three men killed 34 people in the residential area of an Indian army camp in Kaluchak, in Jammu and Kashmir. Tensions spiked. India seemed poised to unleash a military assault on Pakistan. Several embassies in New Delhi and Islamabad withdrew their nonessential personnel and issued travel advisories. The standoff lasted for several months, but dissipated when it became apparent that India lacked viable military options and that the long mobilization was taking a toll on the Indian military’s men and materiel. The United States also helped ease tensions by urging both sides to start talking. India claimed victory, but it was a Pyrrhic one, as Pakistan failed to sever its ties with a range of terrorist organizations.

Other nuclear states have also clashed without resorting to nuclear weapons. In 1969, China, then an incipient nuclear weapons state, and the Soviet Union, a full-fledged nuclear power, came to blows over islands in the Ussuri River, which runs along the border between the two countries. Several hundred Chinese and Soviet soldiers died in the confrontation. Making matters worse, Chinese leader Mao Zedong had a tendency to run risks and dismissed the significance of nuclear weapons, reportedly telling Indian Prime Minister Jawaharlal Nehru that even if half of mankind died in a nuclear war, the other half would survive and imperialism would have been razed to the ground. Yet despite Mao’s views, the crisis ended without going nuclear, thanks in part to the efforts of Soviet Prime Minister Alexei Kosygin, who took the first step by travelling to Beijing for talks.

There’s reason to believe that the current situation is similar. Pakistan’s overweening military establishment undoubtedly harbors an extreme view of India and determines Pakistan’s policy toward its neighbor. The military, however, is not irrational. In India, although Prime Minister Narendra Modi has a jingoistic disposition, he, too, understands the risks of escalation, and he has a firm grip on the Indian military.

Another source of optimism comes from what political scientists call the “nuclear revolution,” the idea that the invention of nuclear weapons fundamentally changed the nature of war. Many strategists argue that nuclear weapons’ destructive power is so great that states understand the awful consequences that would result from using them—and avoid doing so at all costs. Indian and Pakistani strategists are no different from their counterparts elsewhere. Even Pakistani Prime Minister Imran Khan, a political neophyte, underscored the dangers of nuclear weapons in his speech addressing the crisis last week. And Modi, for all his chauvinism, has scrupulously avoided referring to India’s nuclear capabilities.

The decision by India and Pakistan to allow their jets to cross the border represents a major break with the past. Yet so far both countries have taken only limited action. Their principal aim, it appears, is what the political scientist Murray Edelman once referred to as “dramaturgy”—theatrical gestures designed to please domestic audiences. Now that both sides have gone through the motions, neither is likely to escalate any further. Peering into the nuclear abyss concentrates the mind remarkably.

#### Removing IP would cause ineffective and unsafe vaccines

Brougher MPH 3/30/21

Joanna T. Brougher, Esq., Mph &amp; Andrew Kingsbury, 3-30-2021, "Calls for Compulsory Licensing and IP Waivers of COVID-19 Vaccines Ignore Technical Complexities," IPWatchdog, <https://www.ipwatchdog.com/2021/03/30/calls-compulsory-licensing-ip-waivers-covid-19-vaccines-ignore-technical-complexities/id=131617/> // AW

While seeking compulsory licensing or IP waivers may seem an attractive solution to address technological disparities across human populations, these mechanisms ignore some of the more technical hurdles to increasing accessibility to vaccination. This post will first briefly explain what compulsory licensing and IP waivers are and then examine three possible causes for why compulsory licenses and IP waiver are not a feasible solution to the current COVID-19 pandemic. Compulsory Licensing One of the agreements that countries must ratify upon joining the World Trade Organization (WTO) is the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement was negotiated in 1994 to harmonize intellectual property laws across different countries and to establish minimum standards for protecting and enforcing intellectual property rights for all WTO member countries. There are several provisions under TRIPS that allow governments to provide for limitations to intellectual property rights. In [Article 31](https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_oth.pdf), for instance, TRIPS allows governments to order domestic manufacturers to make a patented product without permission from the patent holder. This practice is known as compulsory licensing. Article 31 permits countries to engage in compulsory licensing if there is a “case of a national emergency or other circumstances of extreme urgency,” or in cases of “public non-commercial use.” Under these circumstances, the country is first required to negotiate with, or seek approval from, the patent holder of the drug, but if the negotiations fail, is ultimately just permitted to manufacture patented products, such as essential medicines, for its domestic market. For countries that cannot manufacture drugs themselves, and who would thus not be able to issue compulsory licenses under Article 31, Article 31bis was created to permit a developed country to export a generic drug under a compulsory license to a less developed country. IP Waivers Contrary to compulsory licensing, IP waivers simply ask that countries be exempt from the provisions of TRIPS that require countries to protect and enforce patent rights to COVID-19 treatments and vaccines. In October 2020, [India and South Africa petitioned the WTO](https://www.ipwatchdog.com/2021/01/02/india-south-africas-covid-vaccine-proposal-wto-patent-waiver-must-considered-compulsory-licensing/id=128652/) for a temporary waiver from specific provisions of the TRIPS Agreement that could essentially put entire realms of existing intellectual property law on hold at the international level until widespread vaccination has become globally implemented. Perhaps unsurprisingly, this proposal was met with strong resistance from developed nations while developing and less developed nations were more welcoming towards it. In March 2021, the proposal failed to pass resolution at the WTO. Covid-19 Vaccines are New What these proposals fail to take into account is the nature of the Pfizer and Moderna vaccines. The efficacy of both of these proposals turns on a country’s internal technological capabilities to recreate and administer the vaccine. The Pfizer and Moderna vaccines, however, are not typical vaccines. Whereas traditional vaccines functioned by introducing parts of a virus — or a weakened form of a virus — Pfizer’s and Moderna’s vaccines use messenger RNA to cause host cells to produce the protein themselves. These are the [first vaccines to utilize this type of technology](https://www.abc27.com/news/health/coronavirus/vaccination-frustration/digital-original-how-do-covid-19-vaccines-compare-to-other-vaccinations/). The novelty of these vaccines potentially degrades the utility of a compulsory license or IP waiver. For instance, remdesivir received a great deal of focus early in the pandemic. Bangladesh managed to recreate the drug without Gilead Science’s approval because it is exempt from Article 31 of TRIPS, and Bangladesh [was able to produce a sufficient supply for the country by the summer of 2020](https://patentlyo.com/patent/2021/01/shortages-compulsory-licensing.html) because information about the drug was available. Given the fact that Pfizer’s and Moderna’s vaccines represent a new form of vaccine, lacking technical information on how to make this new form of vaccine could lead the countries to create entirely ineffective vaccine replicas. These issues may be compounded by the fact that many vaccine manufactures [rely on trade secret protection more heavily](https://www.jdsupra.com/legalnews/trade-secret-protection-the-covid-19-37383/) following the [Ass’n for Molecular Pathology v. Myriad Genetics, Inc](https://www.leagle.com/decision/insco20130613e08). decision. These trade secrets can withhold critical scientific know-how that might be necessary for replicating a vaccine. Thus, the new technology behind these messenger RNA vaccines and the lack of accessibility to the related know-how might deter countries from attempting to manufacture them. Lack of Information Yet another more fundamental problem exists for replicating these vaccines. Not only do these vaccines represent a new form of vaccine, but information about these particular vaccines is simply unavailable. Even if the Pfizer and Moderna vaccines do not utilize any trade secrets, the discovery of these vaccines is fundamentally different than remdesivir’s timeline, which resulted in Bangladesh’s recreation of the drug. [A patent for remdesivir was filed as early as 2015](https://patents.google.com/patent/US20170071964A1/en), and thus the information had been publicly available for years. While the technology underlying mRNA vaccines has been in development for decades, there are likely specific technological hurdles associated with, for instance, the coronavirus, mass production and scale up, and delivery mechanisms that needed to be developed for this specific application of the legacy technology. This additional information will not be found in scientific journals or magazine articles, nor can it be found in any patent application, yet. Patents, moreover, can take up to 18 months from filing to be published. BioNTech made an [F-1 filing with the SEC](https://www.sec.gov/Archives/edgar/data/1776985/000119312520195911/d939702df1.htm) on July 21, 2020, in which it acknowledged its partnership with Pfizer to develop the vaccine. If this filling is at all indicative of when a patent could have been filed, then this would mean the patent may not be available to the public until late-2021–mid-2022. With Novelty Comes Difficulty The newness of these vaccines also creates problems due to the complexity in how these types of vaccines function and how to produce them. According to a [Wall Street Journal report](https://www.wsj.com/articles/mrna-covid-19-vaccines-are-fast-to-make-but-hard-to-scale-11614776401), manufactures say that vaccine production is difficult both “because some steps are difficult to scale up quickly or because they simply haven’t been done before.” Even Pfizer is [having difficulty obtaining](https://www.wsj.com/articles/pfizer-slashed-its-covid-19-vaccine-rollout-target-after-facing-supply-chain-obstacles-11607027787) the necessary materials for vaccine production. Here, the complexity of these vaccines demonstrates the potential futility of a compulsory license or IP waivers. Even if other countries could compel manufactures to license the underlying intellectual property and provided them with the information about how to do so, the complexity of manufacturing these types of vaccines could be a particularly high barrier to overcome. It’s Complicated Countries face roadblocks for producing a viable vaccine candidate based on Pfizer’s and Moderna’s vaccines. The new technology that utilizes messenger RNA vaccines, coupled with the lack of public information about these vaccines and the vaccines’ complicated nature, present significant hurdles to seeking compulsory licenses or IP waivers.

#### Any imperfection in LIC implementation leads to vaccine skepticism – low bar for offense and turns case

Trogen et al 20

Brit Trogen (Md, Ms1), David Oshinsky ( PhD), Arthur Kaplan (PhD) 1-28-2020, "Rushing a SARS-CoV-2 Vaccine: Potential for Harm," JAMA, <https://jamanetwork.com/journals/jama/fullarticle/2766651%20> // AW

As the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) pandemic persists across the US and the world, the spotlight on vaccine science has never been more intense. Researchers across the globe are working rapidly to produce a potential vaccine, and 7 candidates are already in clinical trials.[1](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r1) Operation Warp Speed, the vaccine development project announced by President Trump, has advocated for a vaccine to be made available in the US by the beginning of 2021.[1](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r1) But for scientists and physicians, the term “warp speed” should trigger concern. Good science requires rigor, discipline, and deliberate caution. Any medical therapy approved for public use in the absence of extensive safeguards has the potential to cause harm, not only for COVID-19 prevention efforts and vaccine recipients, but also for public trust in vaccination efforts worldwide. Long before coronavirus disease 2019 (COVID-19), vaccine hesitancy and refusal were increasing.[2](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r2) In 2019, the World Health Organization listed vaccine refusal as one of the top 10 global health threats.[3](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r3) Pediatricians, in particular, frequently encounter resistance to childhood vaccinations, and as a result, outbreaks of measles and other vaccine-preventable illnesses, such as pertussis and influenza, have increased in recent decades.[4](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r4) Much of the distrust of vaccines (and, by extension, the physicians and scientists who promote them) is driven by widespread misinformation from both online sources and skeptical communities.[2](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r2),[4](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r4) The belief that vaccines cause harmful adverse effects like autism has persisted despite carefully designed research studies that have refuted such claims. When physicians promote vaccines, they do so knowing that the benefits far outweigh the minimal risks, and that each vaccine has been studied extensively to establish its safety profile. Yet vaccine opponents frequently accuse physicians and researchers of failing in this respect, citing financial or political interests as the motivation for promoting vaccines. As the search for a SARS-CoV-2 vaccine accelerates, physicians and **scientists who wish to maintain the public’s trust must not promote a vaccine that has either bypassed established safety standards or is open to a serious charge of having done so. There is grim historical precedent** for allowing expediency to rule vaccine development. In 1955, the inactivated polio vaccine developed by Jonas Salk was declared “safe, potent, and effective” following the largest public health experiment in the nation’s history, involving more than a million schoolchildren.[5](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r5) Within weeks, however, the miracle vaccine intended to end the scourge of polio stood accused of causing it. Years in development, the Salk vaccine had been rigorously tested in preparation for the massive trials. But the very success of these trials led to an understandable outcry for the immediate, but premature, public release of the vaccine. Five pharmaceutical companies were given Salk’s formula and left to produce the vaccine without significant oversight. As speed took precedence over caution, serious mistakes went unreported.[5](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r5) One company, Cutter Laboratories, distributed a vaccine so contaminated with live poliovirus that 70 000 children who received that vaccine developed muscle weakness, 164 were permanently paralyzed, and 10 died.[6](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r6) Not surprisingly, that incident forced the federal government to directly intervene. The legacy of this event is a regulatory landscape in which vaccines undergo thousands of tests to ensure their safety and effectiveness.[6](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r6) Yet on rare occasions, this vital evidence-based process of vaccine development and testing has still been ignored. In 1976, concerns about the emergence of a new swine flu strain reminiscent of the lethal 1918 version led President Gerald Ford to convene a panel that recommended a government-backed mass vaccination program.[7](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r7) Poorly conceived, the attempt to vaccinate the US population at breakneck speed failed in virtually every respect. Safety standards deteriorated as one manufacturer produced the incorrect strain. The vaccine tested poorly on children who, depending on the form of vaccine tested, either developed adverse reactions with high fevers and sore arms or did not mount an immune response at all. Reports emerged that the vaccine appeared to cause Guillain-Barré syndrome in a very small number of cases, a finding that remains controversial, but added to the early momentum of the antivaccine movement.[7](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r7) Once again, the pressure to rapidly distribute a vaccine undermined the scientific integrity of the process and damaged public trust. COVID-19 has created intense concern and uncertainty in the US and throughout the world. There are immense public and political pressures to develop a new vaccine, a process that typically takes years, not months. But as history warns, these pressures must not supplant rigorous scientific practice. Proceeding stepwise through the phases of clinical trials is the ethical standard for investigations involving human research participants. Adherence to the scientific method is the only way to safeguard against a SARS-CoV-2 vaccine that is ineffective, or worse, carries unacceptable adverse effects. Failing to abide by standards of safety and scientific rigor during the COVID-19 crisis will fuel the argument that physicians and scientists cannot be trusted. Vaccination rates, which are declining due to widespread concern about visiting clinicians’ offices, could further decrease. The US could see resurgences of many vaccine-preventable illnesses, and inevitably, massive increases in avoidable deaths and irreversible outcomes. There are, however, reasons to hope that these scenarios will not come to pass. In response to past failures, vaccine development in the US is subject to increased regulatory oversight designed to protect against substandard practices. Technological advances permit the rapid communication of adverse events in clinical trials, and the understanding of the genetic factors influencing immunologic responses has increased. To proactively address safety concerns, these and other safeguards should be clearly communicated to the public during the vaccine development process. Both the public and the scientific community want an effective and safe intervention to prevent COVID-19. The morbidity, mortality, and societal and financial devastation that SARS-CoV-2 has caused throughout the world will have wide-reaching consequences for almost every aspect of life for years to come. Nothing should dampen the ardor of researchers worldwide in the aggressive search for effective treatments. In this unprecedented crisis, novel trial designs, such as those that include challenge studies, should be carefully considered.[8](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r8) But what cannot and must not be allowed is for desperation to result in the suspension of scientific principles and ethical research values. Physicians should not administer inadequately vetted vaccines; researchers should not endorse them without sufficient data. The scientific community has only one chance at winning public acceptance of a SARS-CoV-2 vaccine. The likelihood of achieving that goal will depend on convincing evidence of vaccine safety and efficacy.

#### Both sides exercise restraint and purposely avoid escalatory action specifically over Kashmir.

Krepon, MA, 19

(Michael, InternationalStudies@JohnsHopkins, Co-Founder+DistinguishedFellow@StimsonCenter, 2-28, https://www.forbes.com/sites/michaelkrepon/2019/02/28/india-and-pakistan-are-trying-hard-to-avoid-a-nuclear-war-can-they-stumble-into-one/#1184c8be5a57)

First the obvious bad news: India and Pakistan have dialed up hostilities to the worst level since their 1999 war, when Pakistani troops crossed the Kashmir divide and Indian troops drove them back. There were perhaps 700 fatalities in that border war. This time around, a Kashmiri youth triggered hostilities by killing forty Indian troops in a suicide bombing. It’s widely believed that he had help from Pakistan’s Inter-Service Intelligence (ISI), because that’s what they do, and because the group claiming responsibility for the attack, Jaish e-Mohammad, is based in Pakistan. This crossed a red line for Indian Prime Minister Narendra Modi. In the run up to national elections, he authorized Indian Air Force jets to attack a target in Pakistan's Khyber Pasthunwa Province. This was a big deal -- the first time Indian jets attacked targets beyond Pakistan-controlled Kashmir since 1971. The stated target for the attack was a jihadi camp tied to Jaish and run by a relative of its leader, Masood Azhar, who was sprung from an Indian jail in 1991 in return for a hijacked Indian Airlines plane. Here things went haywire. Jihadi camps close to Indian-controlled Kashmir are fly-by-night enterprises; when tensions rise, people disappear into the night. Modi claimed a great success, but Pakistan used its media to demonstrate otherwise. Whether by design or a hurried targeting decision with Pakistani jets in hot pursuit, the pilot bombed forested land. Pakistani leaders, having promised a “befitting response,” sent combat aircraft to retaliate, but only within Indian-controlled Kashmir, where they say they purposely avoided hitting anything of consequence. These claims have not been rebutted by Indian officials. Tit for tat. But that wasn’t the end of it. The third move of any escalatory spiral is more important than the first two. Modi wasn’t about to accept tit for tat. He authorized more airstrikes and two Indian planes were shot down. One of the pilots is now being held in Pakistan, with a promise of quick release. What now? Pakistani Prime Minister is singing John Lennon’s tune, “Give Peace a Chance,” while Modi is facing a hard choice. The next move is his. If he sends more jets into the air, Pakistan will, too. Or he might choose a move that Pakistan will have difficulty countering. Or he can declare mission accomplished and move on. This sounds dangerous, and it certainly is. But believe it or not, both sides have acted with restraint -- so far. Striking at a target in Khyber Pasthunwa was an eye opener, but the real targets of Pakistani-supported militancy are in the heartland of Punjab Province. That’s where Jaish e-Mohammed and Lashkar e-Toiba, the two biggest terror outfits, have their compounds, seminaries, and training grounds. Strikes against these targets would be a whole new ball game. Pakistan has also shown restraint -- so far. It has studiously avoided hitting targets in India proper or striking against built up areas in India’s Kashmir. Most importantly, there are not yet reports of major troop movements and mobilization -- the kind of actions that we might expect if ground warfare is imminent along fighting corridors. This would be a major “tell,” because the most likely uses of nuclear weapons would result if the two armies clash. Likewise, there are no reports of missile movements as yet. This, too, would be cause for greater concern. In previous severe crises, Washington took the lead in crisis management. But Islamabad and New Delhi might not be able to count on the Trump administration to help orchestrate a stand down. Ironically enough, this might be another factor in reinforcing restraint. Even so, it wouldn’t hurt and might help if Secretary of State Mike Pompeo visits the region after his trip to Hanoi. Bottom line: For now, India and Pakistan are exercising necessary restraints. The last thing either government wants or needs is a mushroom cloud.