## 1

#### Biotech industry strong now.

Cancherini et al. 4/30 [(Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company), “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide>] TDI

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues.

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have [more than 250 vaccine candidates in their pipelines](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/on-pins-and-needles-will-covid-19-vaccines-save-the-world), along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the [top dozen pharma companies](https://www.mckinsey.com/business-functions/m-and-a/our-insights/a-new-prescription-for-m-and-a-in-pharma) having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A [recent report](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives) from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

#### IPR key to innovation.

Bacchus 20 [(James, member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. He was a founding judge and was twice the chairman—the chief judge—of the highest court of world trade, the Appellate Body of the World Trade Organization in Geneva, Switzerland) "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines," Cato Institute, 12-16-2020, https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines] TDI

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for … profitability in decision‐​making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”[16](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref16)

This view is myopic. Subordinating IP rights temporarily to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.[17](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref17) To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs?

With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded.

Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion.

The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”[18](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref18) The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor[to innovation] is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐​based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation.

In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.[19](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref19)

As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”[20](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref20) This fault line is much on display in the WTO rules on IP rights. These rules recognize that “intellectual property rights are private rights” and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade‐​related intellectual property rights.”[21](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref21) Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror.

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

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

#### Bioterror causes extinction, bioweapons uniquely appeal to terrorists.

Krstić '17 [Marko; January 2017; assistant professor of microelectronics and physics at the University of Belgrade, PhD in Electrical Engineering and Computer Science from the University of Belgrade; "Tendency of using chemical, biological, radiological and nuclear weapons for terrorist purposes," Military Technical Courier, Vol. 65, No. 2, p. 481-498] SC SD

The studies of a few cases of earlier CBRN actions have led experts to identify the key characteristics **of** terrorist groups **that could potentially have an interest to** use **these** weapons. It is thought that conservatism is inherent in terrorist organizations, but it must not be forgotten that **some terrorists are inclined to** innovations **in** weapons **and** tactics**, as well as to** taking risks **in actions or in the choice of weapons.** Many experts agree that most terrorist organizations want to use proven methods to achieve desired effects. Innovations, especially in the field of CBRN weapons, often indicate **terrorists are likely to be led by other factors rather than by pure curiosity and desire to experiment**. For some individuals, repression and democratic and strong rule of law are positive determinants of the emergence of CBRN actions which points to a new and more complex global security environment with an increasing risk of terrorists trying to perform a CBRN attack. It is a frightening fact that **a** single **terrorist or isolated terrorist group could improvise a** biological weapon **or use other ways to spread** anthrax, smallpox **or other biological agents and thereby cause** mass casualties and destroy the health care system of a state. CBRN weapons are secretly shipped to terrorists or hostile governments and represent a significant and growing threat to many countries. Although the threat of CBRN attacks is widely recognized as the central issue of national security, most analysts assume that the primary danger is a threat of the military use of these weapons in conventional wars with traditional military means while the threat of covert attacks, which includeterrorism**, is rashly and unfairly neglected**. Covert attacks are difficult to deter or prevent and CBRN weapons suitable for this type of attack are available to a growing number of enemy states and groups. At the same time, restrictions on their use appear to be diminishing, and so-called new terrorists do not always escalate and become apparent only by using unconventional weapons. These **weapons** are easily spread or transmitted from person to person, **have a** high mortality rate **and a potential impact on public health,** causing mass casualties that can crush health systems and cause public panic and social disruption, thus requiring special efforts to suppress them. When assessing the threat of CBRN weapons, we should take into account the change in capacity to carry out terrorist attacks that are on the rise among countries and non-government elements. Analysts believe that the fear of chemical and biological terrorist attacks is excessive, they point out that, in the past, very few attacks involved these weapons, and even those few attempts that have occurred were mostly thwarted by the authorities. A relative ease with which biological weapons can be obtained, along with other current changes and turbulences in the world, sets the stage for another type of warfare in the 21st century. The potential for CBRN terrorism has widely grown since 11 September, when some of these materials were used. The danger of terrorist use of nuclear weapons and other weapons of mass destruction represents a very serious threat for many countries; **if a terrorist group could gain access to this weapon, it is** highly likely it would use it, or threaten to use it. Although there is very little information on terrorists and their ability to come into possession of nuclear weapons or on their intentions to get them, the risk of CBRN weapons has certainly increased since the terrorists started to become more familiar with these agents and their harmful consequences. Discovering the nature of the threat of biological weapons, as well as the appropriate response to them requires an emphasis on the biological characteristics of these instruments of war and terror. Preparing for a terrorist attack may seem daunting and there are a small number of people with practical experience and a good knowledge of CBRN weapons, because until recently there was no need to own them. In the past, most of the planning regarding emergency response to terrorism concentrated on the concerns of open attacks (bombing). However, the threats of CBRN weapons are taken seriously, especially in the USA, where media, fascinated by new weapons of mass destruction, encourage a growing fear for public safety. Terrorists who have significant human and material resources are much more likely to realize their intentions than lone perpetrators or small terrorist groups. A CBRN terrorism threat is certainly a matter of concern; however, terrorists will face many obstacles in the implementation of an attack of this kind. This includes the acquisition of materials and preparation for spreading them as well as a selection and a survey of a chosen objective and a correct dose required to achieve a desired effect. The growing threat of CBRN terrorism Terrorism can be defined as a deliberate act of violence intended to cause damage, but also to create an appropriate political and ideological situation, so that the use of these non-traditional weapons of terror outside the context is obvious, and the goals will not be military, but civilian ones (Bioterrorism, chemical weapons, and radiation terrorism, nd). Toxic substances, regardless of whether they are of animal, vegetable or mineral origin, were used throughout the history for political assassinations and sabotage; despite the risk of severe penalties, the prospects for success favoured the use of toxic substances. Such use has always been reduced, however, since only a small number of people had access to substances and possessed the ability of learn how to use them (Pascal, 1999). CBRN weapons are rightly viewed with a special sense of horror, their effects can be devastating and indiscriminating, and they take the most stringent toll among the most vulnerable population, non-combatants (e.g. a biological attack cannot be detected sufficiently fast after the disease spreads through the population). Moreover, chemical **and** biological **weapons are a particularly** attractive alternative for groups that do not have the ability to produce nuclear weapons, and this risk raises complex but important ethical issues (London, 2003). The common name for CBRN terrorism which causes the death of a large number of people, large scale damage and a strong echo worldwide is post-industrial or hyper-terrorism. This means that non-state elements possess and dispose of assets that were previously held only by states, but unlike them, which often fear reprisals after WMD attacks, terrorists, having no geographical location, are ready to use WMD with much less scrupulousness and fear (Kurmnik, Ribnikar, 2003). Some authors have described the factors that make chemical, biological, radiological and nuclear terrorist attacks in many ways unique and demanding, such as an element of surprise, invisible agents, ordnance, the risk of repetition and new types of risks (Ruggiero, Voss, 2015). In the past 30 years, the use of CBRN weapons has become a major concern for many nations around the world. The public has become insensitive to traditional terrorist attacks that seem to be a less efficient way for terrorist organizations to achieve their goals. What causes shock and fear is actually presenting the properties of weapons which can be used by terrorist organizations to enhance their efforts and the effectiveness of attacks. CBRN terrorism is often a synonym for weapons of mass destruction, although this form of terrorism and related incidents do not require attacks and inflicting harm to large numbers of people they do not even require deadly attacks at all. The number of studies on this type of terrorism is limited due to the lack of available data on this terrorism type. There is a very small number of databases of CBRN incidents, and even the existing ones have relatively little to do with them and they are compared to conventional terrorism (Jesse, 2012). Some experts emphasize the factors that promote such attacks and these factors include the availability of information and expertise, increased frustration of terrorists, demonization of the target population, as well as a millennial, apocalyptic or messianic vision. Experts also differ in opinion when it comes to possible perpetrators of CBRN incidents, and include religious fundamentalists and cults1 as possible perpetrators of such attacks, especially when these groups address to ethereal audience, emphasizing the hatred of unbelievers (Ivanova, Sandler, 2007). Concerns about super terrorism which involves the use of CBRN weapons are mainly focused on what terrorists can do in the context of our social reality, with an emphasis on terrorist motivations, initiatives and limitations. When considering which terrorist groups may be inclined to commit CBRN terrorism, it is important to recognize the spectrum of these acts, as well as to analyze the following categorization: (a) massive casualty events produced by conventional weapons; (b) CBRN scams; (c) conventional attack on a nuclear facility; (d) limited-scale chemical or biological attack or a radiological dispersion; (e) large scale chemical or biological attack or a radiological dispersion; and (f) CBRN strikes (super terrorism) that can lead to thousands of victims. In addition to the motivation and willingness to inflict mass casualties in any way, terrorists must have technical and financial capabilities to come into possession of material and acquire skills for these types of weapons and materials and carry out a successful attack. Chemical and biological weapons can pose a risk to terrorists thus deterring them from using such weapons (Post, 2005, pp.148-151). The possibility that terrorists use chemical or biological substances may increase over the next decade, according to US intelligence agencies. According to CIA2, an interest among non-state actors, including terrorists**, for biological and chemical materials is real and growing, and** the number of potential perpetrators is increasing. The agency also noted that many of these groups had developed an international network and did not need to rely on state sponsors for financial and technical support. However, it is believed that it is less likely that terrorists would choose chemical and biological weapons over conventional explosives, because these weapons are difficult to control and their results are unpredictable (Condesman, Burke, 2001). The risk of CBRN weapons is growing since terrorists are better acquainted with these agents and their potential for causing harm3. These agents possess desirable characteristics as **weapons** of terror; they **are biologically invisible to the naked eye,** odorless **and potentially** lethal **in the form of particles**; natural organisms are so readily available, and can be "camouflaged" in natural disasters and used to spread fear and various diseases. Chemical agents quickly attack the critical physiological centers of the body, disabling or killing the victim. Biological and chemical weapons require the application of huge amounts of resources and result in different effects, causing fear and panic in the contaminated areas. Often referred to as "weapons of mass destruction", but, in medical terms, they are weapons of potential mass casualties because they can lead to massive death toll in the absence of preventive measures and timely response (Meyer, Spinella, 2014, pp.645-656). "Bioterrorism is the intentional use of microorganisms or toxins derived from living organisms used for hostile purposes intended to cause disease or death in man, animals and plants, on which they depend". The threat of bioterrorist attacks is real, and each individual is a potential terrorist, when terrorists are "invisible" prior to an attack which also can be "invisible" in the form of causing infectious diseases or epidemics. Citizens who are not aware they are infected are potential safety hazard and so-called dangerous bodies (Mijalković, 2011). In the last ten years, the issue of CBRN weapons has attracted the attention of experts, but a list of priorities by the heads of states has never been established. Biological weapons almost became forgotten after they had been banned by the 1972 Convention on Biological Weapons. A significant attention was paid to them during the 90s of the last century. The important thing is that biological weapons attract much less attention than other similar weapons, but probably represent the greatest danger, and in addition to their use in war, they are available as instruments of terror in peace. Some countries showed willingness to use such weapons against defenseless populations to achieve strategic objectives, and in this regard, some analysts believe that those who attacked the World Trade Center in 1993 applied cyanide on their bombs (this was not confirmed, but a large amount of cyanide was found in possession of the perpetrators). Such a group will prove to be less inefficient, because if terrorists decide to shock and surprise the government by inflicting enormous damage, CBRN weapons will become more attractive and more accessible (Bettis, 1998). Motives and forms of behavior of individuals and groups who acquired or used CBRN weapons have existed since long ago and there is no doubt that modern society is vulnerable to such attacks (Tucker, 2000). Fear of biological terrorism is certainly greater than the fear of the conventional forms of terrorism; some of these fears are justified and some are often exaggerated. Some agents are really very contagious and deadly, and if used properly, have a potential to result in casualties similar to those in a nuclear attack. Perhaps the scariest aspect of biological weapons is that the body is attacked without warning, people are afraid of the threat as it is invisible, and cannot be heard or felt. The history of warfare, terrorism and crime involving biological agents in the last century is considerably less dangerous and more deadly than the history of conventional warfare (Parachini, 2001). Today, some states and some terrorist groups can more easily overcome technological barriers due to the increased flow of information and access to previously unavailable technologies. Along with nuclear and chemical weapons, biological weapons are part of an unholy trinity of weapons of mass destruction (Davis, Johnson-Winegar, 2000, pp.15-28). The **society is now faced with the threat of an** apocalyptic and asymmetric war **scenario** in which kamikaze attackers are able to arm themselves with WMD4 without even having to have a "physical" weapon to create fear; they probably still prefer simple, proven methods: a stampede in an enclosed place, or just an explosive device, which will kill many people5 (Palmer, 2004, pp.3-9). Early detection and response to biological or chemical terrorism are crucial to solving this problem (U.S. Congress House, 2003, p.117).

## 2

**US dominance is secured in biotech now, but China’s closing the gap fast – that allows geopolitical and economic advantages**

Scott **Moore** **2020** [(Director of the Penn Global China Program at the University of Pennsylvania. Previously, Moore was a Young Professional and Water Resources Management Specialist at the World Bank Group, and Environment, Science, Technology, and Health Officer for China at the U.S.) “China’s Role In The Global Biotechnology Sector And Implications For U.S. Policy” https://www.brookings.edu/wp-content/uploads/2020/04/FP\_20200427\_china\_biotechnology\_moore.pdf]TDI

EXECUTIVE SUMMARY Even by the standards of emerging technologies, **biotechnology has the potential to utterly transform geopolitics, economics**, and society in the 21st century. Yet while the United States has long been the world leader in most segments of the global biotechnology sector, **China is fast becoming a significant player**. This brief assesses the implications of China’s changing role in biotechnology for the United States, which span national security, data security, and economic competitiveness. On current trends the United States is likely to remain the world leader in most biotechnology areas. **However, the gap between China and the U.S. is narrowing in the biotechnology sector,** and U.S. policymakers must boost public investment, liberalize immigration and foreign student visa policies, and enact regulatory reforms to ensure America remains competitive. At the same time, areas like vaccine development and regulation of emerging technologies like synthetic biology present rich opportunities for Sino-U.S. cooperation. INTRODUCTION Thanks to extensive government funding for biomedical research, an unparalleled ability to translate basic research into commercial products and applications, and strong intellectual property protections, the United States has been the dominant global player in developing and commercializing biotechnology for decades.1 This dominance is reflected in the fact that United States accounted for almost half of all biotechnology patents filed worldwide from 1999 to 2013.2 However, in the intervening years, and just as in the case of artificial intelligence and other emerging technologies, other nations, including South Korea and Singapore, have invested heavily in developing their biotechnology sectors and industries. These efforts pale, however, in comparison to those of China, and the sheer size and scale of the Chinese biotechnology industry pose a range of economic, security, and regulatory issues for American policymakers. The determination of China’s one-party state to become a leading player in biotechnology is reflected by the rapid growth in investment in the sector. Some estimates claim that collectively, **China’s** central, local, and provincial **governments have invested over $100 billion in life sciences** research and development. Regardless of the true figure, official encouragement has led to a torrid place of investment. In just the two-year period from 2015 to 2017, venture capital and private equity investment in the sector totaled some $45 billion.3 The value of commercial deals concluded in the fields of biology, medicine and medical machine technology, meanwhile increased from 25.8 billion renminbi (RMB), or $3.6 billion, in 2011 to over 75 billion RMB ($10.6 billion) in 2017.4 Annual research and development expenditures by Chinese pharmaceutical firms, the foundation of the biotechnology sector, rose from some 39 billion RMB in 2014 ($5.5 billion) to over 53 billion RMB (US$7.5 billion) by 2017. Expenditure on new product development among these firms, an important indicator of future growth potential, increased from just over 40 billion RMB ($5.6 billion) to almost 60 billion ($8.4 billion).5 By Western standards, some of these figures are still low. Swiss drugmaker Roche, the world leader in biotechnology research and development, spent some $11 billion in 2018 alone.6 As these figures suggest, the development of China’s biotechnology sector paints a nuanced picture for U.S. policymakers. On one hand, the sector’s rapid growth, and high-level commitment to continued investment, means that China will inevitably become an increasingly important player in the global biotechnology sector, **with implications for national security, economic competitiveness, and regulation**. An executive from In-Q-Tel, the U.S. government’s inhouse national security venture capital fund, warned Congress in a November 2019 hearing, for example, that China “intends to own the biorevolution… and they are building the infrastructure, the talent pipeline, the regulatory system, and the financial system they need to do that.”7 The CEO of European drugmaker AstraZeneca has similarly opined that “Much of [China’s] innovation in the last three to four years has been ‘me too,’ but now on the horizon we can see firstin-class innovation.”8 Yet on the other hand, while China’s biotechnology sector will almost certainly continue to grow in scale, sophistication, and competitiveness, there is little reason to believe on current trends that the United States will lose its edge in the sector. Indeed, the biggest risk to the global competitiveness of the U.S. biotechnology industry likely comes from the prospect of declining public investment and reduced mobility for world-class researchers and industry professionals. Moreover, the COVID-19 crisis underscores both the importance of continued investment in biotechnology and the many challenges to promoting effective international cooperation on global health security. This brief first examines the key policies and actors in China’s biotechnology sector, then offers an assessment of the sector’s current capabilities and future trends, and finally further explores the implications of developments in Chinese biotechnology for U.S. policy.

**The aff’s waiving of IP doesn’t solve but it does give away sensitive national security information that allows China to lead ahead in biotech**

Josh **Rogin 4-8**. [(Washington Post Columnist covering National Security Issues.) “Opinion: The wrong way to fight vaccine nationalism” https://www.washingtonpost.com/opinions/global-opinions/the-wrong-way-to-fight-vaccine-nationalism/2021/04/08/9a65e15e-98a8-11eb-962b-78c1d8228819\_story.html ] TDI

Americans will not be safe from covid-19 until the entire world is safe. That basic truth shows why vaccine nationalism is not only immoral but also counterproductive. But the simplest solutions are rarely the correct ones, **and some countries are using the issue to advance their own strategic interests**. The Biden administration must reject the effort by some nations to turn our shared crisis into their opportunity. As the inequities of vaccine distribution worldwide grow, a group of more than 50 developing countries led by India and South Africa is pushing the World Trade Organization to dissolve all international intellectual property protections for pandemic-related products, which would include vaccine research patents, manufacturing designs and technological know-how. The Trump administration rejected the proposal to waive the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for the pandemic when it was introduced in October. Now, hundreds of nongovernmental organizations and dozens of Democratic lawmakers are pushing the Biden administration to support the proposal. But many warn **the move would result in the United States handing over a generation of advanced research** — much of it funded by the U.S. taxpayer — **to** our country’s greatest competitors, above all **China**. In Congress, there’s justified frustration with the United States’ failure to respond to China’s robust vaccine diplomacy, in which Beijing has conditioned vaccine offers to pandemic-stricken countries on their ignoring security concerns over Chinese telecom companies or abandoning diplomatic recognition of Taiwan. There’s also a lot of anger at Big Pharma among progressives for profiting from the pandemic. “We are in a race against time, and unfortunately Big Pharma is standing in the way of speedily addressing this problem,” Rep. Jan Schakowsky (D-Ill.), who supports the effort to waive intellectual property protections, told me in an interview. “I think the real security issue is that while the United States balks in making sure that we help ourselves, that these adversaries will just jump right in.” Schakowsky argued that alternative measures for helping poor countries manufacture vaccines are simply not moving fast enough to save lives and that the United States has a duty to respond. House Speaker Nancy Pelosi (D-Calif.) personally conveyed her support for the waiver to President Biden, Schakowsky said. But Big Pharma is just one piece of the puzzle. Countries such as India and South Africa have been trying to weaken WTO intellectual property protections for decades. **The mRNA technology that underpins the Pfizer and Moderna vaccines was funded initially by the Defense Advanced Research Projects Agency and has national security implications.** Inside the Biden administration, the National Security Council has already convened several meetings on the issue. The waiver is supported by many global health officials in the White House and at the U.S. Agency for International Development, who believe the United States’ international reputation is suffering from its perceived “America First” vaccine strategy. On Wednesday, U.S. Trade Representative Katherine Tai spoke with WTO Director General Ngozi Okonjo-Iweala about the waiver issue. USTR is convening its own interagency meetings on the issue, which many see as a move to reassert its jurisdiction over WTO matters. If and when this does get to Biden’s desk, he will also hear from national security officials who believe that waiving TRIPS would result in the forced transfer of national security-sensitive technology to China, **a country that strives to dominate the biotechnology** ***field*** as part of its Made in China 2025 strategy. **Once countries such as China have this technology, they will apply their mercantilist industrial models to ensure their companies dominate these strategically important industries, potentially erasing thousands of U.S. jobs.** “We would be delivering a competitive advantage to countries that are increasingly viewed as our adversaries, at taxpayer expense, when there are other ways of doing this,” said Mark Cohen, senior fellow at the University of California at Berkeley Law School. **A preferable approach would be to build more vaccine-manufacturing capacity** in the United States and then give those vaccines to countries in need, said Cohen. The U.S. pharmaceutical industry would surely benefit, but **that’s preferable to being dependent on other countries when the next pandemic hits.** “If there’s anything that the pandemic has taught us, it’s that we need to have a robust supply chain, for ourselves and for the world generally,” Cohen said. What’s more, it’s not clear that waiving the TRIPS agreement for the pandemic would work in the first place. Bill Gates and others involved in the current vaccine distribution scheme have argued that it would not result in more vaccines, pointing out that licensing agreements are already successfully facilitating cooperation between patent-holding vaccine-makers and foreign manufacturers. Critics respond that such cooperation is still failing to meet the urgent needs in the developing world. Vaccine equity is a real problem, but waiving intellectual property rights is not the solution. If the current system is not getting shots into the arms of people in poor countries, we must fix that for their sake and ours. But the pandemic and our responses to it have geopolitical implications, whether we like it or not. **That means helping the world and thinking about our strategic interests at the same time.**

**China will convert biotechnology gains to military advantages, undermining US primacy – specifically true in the context of vaccines. It fractures the liberal order and turns the case**

Mercy A. **Kuo 2017** [(Executive Vice President at Pamir Consulting.) “The Great US-China Biotechnology and Artificial Intelligence Race” <https://thediplomat.com/2017/08/the-great-us-china-biotechnology-and-artificial-intelligence-race/>] TDI

Trans-Pacific View author Mercy Kuo regularly engages subject-matter experts, policy practitioners, and strategic thinkers across the globe for their diverse insights into the U.S. Asia policy. This conversation with Eleonore Pauwels – Director of Biology Collectives and Senior Program Associate, Science and Technology Innovation Program at the Wilson Center in Washington D.C. – is the 104th in “The Trans-Pacific View Insight Series.” Explain the motivation behind Chinese investment in U.S. genomics and artificial intelligence (AI). With large public and private investments inland and in the U.S., China plans to become the next AI-Genomics powerhouse, which indicates that these technologies will soon converge in China. China’s ambition is to lead the global market for precision medicine, **which necessitates acquiring strategic tech**nological and human capital in both genomics and AI. And the country excels at this game. A sharp blow in this U.S.-China competition happened in 2013 when BGI purchased Complete Genomics, in California, with the intent to build its own advanced genomic sequencing machines, therefore securing a technological knowhow mainly mastered by U.S. producers. There are significant economic incentives behind China’s heavy investment in the increasing convergence of AI and genomics. This golden combination will drive precision medicine to new heights by developing a more sophisticated understanding of how our genomes function, leading to precise, even personalized, cancer therapeutics and preventive diagnostics, such as liquid biopsies. By one estimate, the liquid biopsy market is expected to be worth $40 billion in 2017. Assess the implications of iCarbonX of Shenzhen’s decision to invest US$100 million in U.S.-company PatientsLikeMe relative to AI and genomic data collection. iCarbonX is a pioneer in AI software that learns to recognize useful relationships between large amounts of individuals’ biological, medical, behavioral and psychological data. Such a data-ecosystem will deliver insights into how an individual’s genome is mutating over time, and therefore critical information about this individual’s susceptibilities to rare, chronic and mental illnesses. In 2017, iCarbonX invested $100 million in PatientsLikeMe, getting a hold over data from the biggest online network of patients with rare and chronic diseases. If successful, this effort could turn into genetic gold, making iCarbonX one of the wealthiest healthcare companies in China and beyond. The risk factor is that iCarbonX is handling more than personal data, but potentially vulnerable data as the company uses a smartphone application, Meum, for customers to consult for health advice. Remember that the Chinese nascent genomics and AI industry relies on cloud computing for genomics data-storage and exchange, creating, in its wake, new vulnerabilities associated with any internet-based technology. This phenomenon has severe implications. How much consideration has been given to privacy and the evolving notion of personal data in this AI-powered health economy? And is our cyberinfrastructure ready to protect such trove of personal health data from hackers and industrial espionage? In this new race, will China and the U.S. have to constantly accelerate their rate of cyber and bio-innovation to be more resilient? Refining our models of genomics data protection will become a critical biosecurity issue. Why is Chinese access to U.S. genomic data a national security concern? **Genomics** and computing research **is inherently dual-use, therefore a strategic advantage in a nation’s security arsenal.** Using AI systems to understand how the functioning of our genomes impacts our health **is of strategic importance for biodefense.** This knowledge will lead to increasing developments at the forefront of medical countermeasures, **including vaccines**, antibiotics, and targeted treatments relying on virus-engineering and microbiome research. Applying deep learning to genomics data-sets could help geneticists learn how to use genome-editing (CRISPR) to efficiently engineer living systems, but also to treat and, even “optimize,” human health, **with potential applications in military enhancements**. A $15 million partnership between a U.S. company, Gingko Bioworks, and DARPA aims to genetically design new probiotics as a protection for soldiers against a variety of stomach bugs and illnesses. China could be using the same deep learning techniques on U.S. genomics data to better comprehend how to develop, patent and manufacture tailored cancer immunotherapies in high demand in the United States. Yet, what if Chinese efforts venture into understanding how to impact key genomics health determinants relevant to the U.S. population? **Gaining access to increasingly large U.S. genomic data-sets gives China a knowledge advantage into leading the next steps in bio-military research.** Could biomedical data be used to develop bioweapons? Explain. Personalized medicine advances mean that personalized bio-attacks are increasingly possible. The combination of AI with biomedical data and genome-editing technologies will help us predict genes most important to particular functions. Such insights will contribute to knowing how a particular disease occurs, how a newly-discovered virus has high transmissibility, but also why certain populations and individuals are more susceptible to it. Combining host susceptibility information with pathogenic targeted design, **malicious actors could engineer pathogens that are tailored to overcome the immune system or the microbiome of specific populations.**

**C/a their ev that maintenance of the ILO is key.**

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**The United States federal government should:**

**- substantially increase production and global distribution of the COVID-19 Vaccine, specifically providing all necessary vaccines to India and South Africa.**

**- cooperate with allies to achieve increased production and global distribution of the COVID-19 Vaccine.**

**The US should take the lead – otherwise, China and Russia will use vaccine diplomacy to advance foreign policy goals. The counterplan alone solves and reinvigorates US leadership.**

**Gayle et al 21**. [(HELENE GAYLE is President and CEO of the Chicago Community Trust and has served in global health and development roles with CARE, the Centers for Disease Control and Prevention, and the Bill & Melinda Gates Foundation. GORDON LaFORGE is a Senior Researcher at Princeton University and a lecturer at Arizona State University’s Thunderbird School of Global Management. ANNE-MARIE SLAUGHTER is CEO of New America and former Director of Policy Planning at the U.S. State Department) “America Can—and Should—Vaccinate the World,” Foreign Affairs, March 19, 2021. <https://www.foreignaffairs.com/articles/united-states/2021-03-19/america-can-and-should-vaccinate-world>] TDI

These initiatives come not a moment too soon. In tackling the **worst global crisis** of a lifetime, the **United States has so far been upstaged**. Russia and China have aggressively marketed and distributed their vaccines to foreign countries, **largely to advance foreign policy goals**. Russia is using the jab to bolster its image and investment prospects and to drive a wedge between EU countries. China is donating doses to gain leverage in territorial disputes and expand its influence under the Belt and Road Initiative. Both Moscow and Beijing have **moved to undercut the United States in its own backyard by supplying vaccines to Latin America.** The Biden administration is right to want to take the lead in vaccinating the world, for a host of reasons both self-interested and altruistic. But it should not fall into the trap of trying to beat Russia and China at their own game—handing out vaccines to specific countries based on their geostrategic importance and the amount of attention they are receiving from rival powers. Rather, **Biden should pursue** abroad the sort of “all in” unity approach that he has proclaimed at home. His administration should focus less on strategic advantage than on vaccinating the largest number of people worldwide in the shortest amount of time. In so doing, the United States would **concentrate on what the world’s peoples have in common—susceptibility to this and many other viruses**—regardless of the nature of their governments. ALL IN AND ALL OUT The United States has successfully mobilized its own and international resources to respond to regional crises in the past. In 2003, President George W. Bush started the U.S. President’s Emergency Plan for AIDS Relief, the largest global health program focused on a single disease in history. PEPFAR brought together U.S. agencies, private companies, and local civil society groups to help sub-Saharan Africa and Southeast Asia get the AIDS crisis under control, saving millions of lives. In 2004, a tsunami in the Indian Ocean caused more than 220,000 deaths and billions in damage, and the United States led an urgent, similarly inclusive humanitarian relief and recovery effort that rescued victims, hastened reconstruction, and built lasting goodwill in South and Southeast Asia. Biden can improve on Bush’s precedent by going global, and he has already taken steps toward doing so. Under President Donald Trump, the United States refused to participate in the COVID-19 Vaccine Global Access (COVAX) Facility, an international partnership that aims to guarantee COVID-19 vaccine access for the entire world. The Biden administration reversed this stance immediately and contributed $4 billion, making the United States the largest donor to the effort. Still, even if COVAX meets the ambitious target of delivering two billion doses to developing nations by the end of 2021, it will be able to vaccinate only 20 percent of those countries’ populations. Just imagine, however, what could happen if Washington were to treat COVID-19 as the equivalent of the enemy in a world war or the pandemic as a global version of the regional AIDS and Ebola epidemics of years past. Imagine, in other words, what all-out mobilization would look like if the **United States treated the COVID-19 pandemic like the global threat** that it is. The Biden administration is right to want to take the lead in vaccinating the world. Washington would lead a multilateral, whole-of-society effort to help COVAX vaccinate the world. The government would activate the military and call upon allies in the G-7 and NATO for a major assistance operation that speeds the flow of vaccine supplies and strengthens delivery systems. As it has pledged to do in the Quad summit deal, the U.S. government would use the State Department, U.S. Agency for International Development (USAID), Centers for Disease Control and Prevention (CDC), and other civilian agencies and development programs to help countries with their national vaccination programs. And it would enlist companies, nonprofits, and civil society organizations to help increase vaccine production, raise funding, and provide technical assistance to foreign counterparts. The U.S. government should undertake exactly such an effort, right now: an all-out response for an all-in global vaccination campaign. Such a campaign would advance U.S. economic and security interests and **reboot American global leadership** after years of decline. Rather than perpetuate the transactional, friend-by-friend vaccine diplomacy of China and Russia, a U.S.-led vaccine effort could **invigorate a new multilateralism** that is more pragmatic and inclusive than the twentieth-century international order and better adapted to tackling twenty-first-century global threats. Washington would do well to remember that if COVID-19 does come back, authoritarian governments will be able to lock down their populations more quickly and effectively than democracies will, so even in competitive terms, America’s best bet really is to eradicate the novel coronavirus. The United States has a momentous **opportunity to prove both that democracy can deliver** and that American ideals truly are universal. By offering a model of global cooperation that draws on a far wider range of resources than any one government can provide, the United States can lead a vaccine effort that builds on the strengths of its **open and pluralist society.** President Biden would demonstrate unequivocally that the United States is not only “back” but looking—and **leading—far ahead.**

**That comparatively solves better – IP rights don’t hinder vaccine cooperation, but manufacturing capacity is the current constraint.**

Hans **Sauer 6-17** [(Deputy General Counsel, Biotechnology Industry Organization.) “Web event — Confronting Joe Biden’s proposed TRIPS waiver for COVID-19 vaccines and treatments” https://www.aei.org/wp-content/uploads/2021/06/210617-Confronting-Joe-Bidens-proposed-TRIPS-waiver.pdf?x91208&x91208] TDI

But contrary to what Lori said, **there are genuine real problems in the supply chain** that are **not caused by patents**, that are simply caused by the unavailability and the constraints on existing capacity. There is in this world such a thing as maxed-out capacity that just can’t be increased on a dime. It’s not all due to intellectual property. This is true for existing vaccines as well as for vaccine raw materials. There are trade barriers. There are export restrictions that we should all be aware of and that we need to work on. And there are very real political, I think, interests in finding an explanation for how we got to this place that absolve governments around the world from their own policy decisions that they made in the past. In the United States, again, it was the declared policy of the previous administration, as well as this one, that we would vaccinate healthy college kids and go all down the line and offer a vaccine to everybody who wants it before we start sharing any with grandmothers in Burkina Faso. That was the policy. You can agree with it or disagree with it, but that was policy. We had export restrictions in place before a lot of other countries did. And that, too, contributed to unequal access of vaccines around the world. Another thing that was predictable was that politicians and governments around the world who want to be seen as proactive, on the ball, in control, for a long time were actually very indecisive, very unsure about how to address the COVID problem, which has so many dimensions. Vaccines are only one of those. But with respect to vaccines, not many governments took decisive action, put money on the table, put bets on multiple horses, before we knew whether these vaccines would work, would be approved. And it was governments in middle-income countries who now, I think, justifiably are concerned that they’re not getting fast enough access, who didn’t have the means and who didn’t have the decision-making structure to place the same bets on multiple horses, if you will, that were placed in the relatively more wealthy, global North and global West. But there is, I think, a really good and, with hindsight, predictable explanation of how we got to this place, and I think it teaches us something about how to fix the problem going forward. **So why will the waiver not work**? Well, first of all, with complex technology like vaccines, Lori touched on it, reverse engineering, like you would for a small molecule drug, is much more difficult if not impossible. But it depends very much more than small molecule drugs on cooperation, on voluntary transfer of technology, and on mutual assistance. We have seen as part of the pandemic response an unprecedented level of collaborations and cooperation and no indication that IP has stood in the way of the pandemic response. **The waiver proponents have found zero credible examples of where IP has actually been an obstacle,** where somebody has tried to block somebody else from developing a COVID vaccine or other COVID countermeasure, right? It’s not there. **Second, the myth of this vast global capacity to manufacture COVID vaccines that somehow exists** **out there is unsubstantiated** and frankly, in my opinion, untrue. But there is no such thing as vast untapped, idle capacity that could be turned around on a dime to start making COVID vaccines within weeks or even months. This capacity needs to be built; it needs to be established. And at a time when time is of the essence to beat this pandemic, starting capacity-building discussions is helpful, but it won’t be the answer to beat this pandemic. It will be the answer if we do everything right to beating the next pandemic. And if we learn any lesson of this, and then I will stop, is that the COVID waiver as well as the situation in which we find ourselves — if anything, it’s a reminder that we definitely have to take global capacity-building more seriously than we did in the past. That is true for the global North, as well as for middle-income countries — all of whom have to dedicate themselves much more determinedly to pandemic preparedness. And there’s a need to invest both in preparedness and in public health systems that hasn’t happened in the wake of past pandemic threats. This is what we will need to do. We will need to reduce export restrictions, and we will need to rededicate ourselves to preparing for the next pandemic. As far as this pandemic goes, **there are 11 vaccines around the world that are already being shot into arms, only four of which come from the global North. How many more vaccines do we want?** I don’t know, maybe 11 is enough if we start making more of them. But there are manufacturers around the world who know how to do this — including in China, including in India, and including in Russia. All developed their homegrown vaccines, apparently without interference by IP rights, right? **So let’s make more of those. I think that’s going to be the more practical and realistic answer to solving the problem**. And we need to lean on governments to stop export controls and to dedicate themselves to more global equity.

**Case**