## Biotech

#### **U.S dominance over biotech now BUT Misguided policy cedes control to China.**

Gupta 6/11 [“As Washington Ties Pharma's Hands, China Is Leaping Ahead.”, Gaurav Gupta, *Opinion | America Risks Ceding Its Biotech Dominance to China | Barron's*, Barrons, 11 June 2021, www.barrons.com/articles/as-washington-ties-pharmas-hands-china-is-leaping-ahead-51623438808., *Gaurav Gupta, a physician, is the founder of the biotechnology investment firm Ascendant BioCapital.]//Lex AKu*

There should be no doubt that we are living at the dawn of a golden age of biomedical innovation. The American scientific engine that produced Covid-19 vaccines in record time was fueled by a convergence of advances in genomics, biomarkers, data science, and manufacturing years in the making. The first Food and Drug Administration approvals of a host of new product formats—oligonucleotide, bispecific, oncolytic virus, CAR-T, and lentivirus/AAV—all took place within the last decade. These represent an unprecedented expansion of the armamentarium that physicians have at their disposal to treat and cure disease. In the last few years, 47% of all new medicines were invented by U.S. biopharma companies, with homegrown startups driving the majority of innovation. The bulk of the remainder were developed by foreign companies specifically for the U.S. market. An indirect benefit of these trends is that most novel therapeutics undergo clinical development and early commercial launch here in the U.S. The rest of the world understands that the American patient has earlier and broader access to groundbreaking therapies via these mechanisms. Indeed, the past decade is filled with examples of medical “firsts” for American patients: the first cure for Hepatitis C, the first gene therapy for blindness, the first immunotherapy for cancer. Future rewards will be greater still if we preserve our current system of incentivizing and protecting The remarkable innovation capacity of our biopharmaceutical industry ought to be a source of national pride. Yet while “Made in America” is the global standard for medicines in development today, misguided policy risks ceding our scientific prowess to other countries in the future. This is particularly true in the case of China, where biotechnology has become a strategic pillar for the health of its people and economy. From 2016 to 2020, the market capitalization of all Chinese biopharma companies increased exponentially from $1 billion to over $200 billion. China saw over $28 billion invested in its life sciences sector in 2020, double the previous year’s amount. Returns on China’s investment are already arriving. The FDA approved a drug developed in China for the first time ever in 2019. While China’s innovation capacity currently remains behind America’s, my experiences as a biopharma professional make it clear they are doing everything they can to catch up and catch up fast. In fact, when I speak to Chinese biotechnology executives, they boast that they can run clinical trials faster than their U.S. counterparts. The danger of misguided policies that disincentivize pharmaceutical innovation in the U.S. is effectively driving that same innovation to China. If we close off the market in the U.S. at the same time that China is opening its market to innovative new products, then we will see companies choose to first launch impactful novel medicines in China, based on clinical trials conducted in China. Because the FDA rarely accepts data generated entirely outside the U.S., this relocation of research capacity will negatively affect Americans’ access to cutting-edge therapies. The biotechnology field is advancing rapidly. Promising technologies such as targeted protein degradation and gene editing are perhaps not far from being developed into impactful medicines, and the U.S. risks these technologies being mastered by Chinese companies.

#### The plan chills American biomed innovation and cedes control to China.

Paulsen 7/9 [ERIK PAULSEN: We can save the world with our vaccines — without surrendering our IP to China," Bakersfield Californian, https://www.bakersfield.com/opinion/erik-paulsen-we-can-save-the-world-with-our-vaccines-without-surrendering-our-ip-to/article\_b0b87692-df61-11eb-9a13-d7fa02eefaee.html]//Lex AKu

The Biden administration gave Beijing a gift when it endorsed a petition before the World Trade Organization to force the American developers of Covid-19 vaccines and therapeutics to relinquish their intellectual property rights to these medicines. The Chinese government seeks to take over in biotech, a sector where U.S. innovators lead. Biotech is included in its “Made in China 2025” plan, which lists 10 sectors that China aims to dominate. The government intends to force anyone doing business in China in those spheres to hand over know-how. Surrendering IP protections on biomedical technology has dire consequences. Foremost, it guts the foundation of biomedical innovation, which takes huge investments spanning many years to bear fruit. IP protections assure innovators that they can recover those investments and make a profit. Losing IP protection would have a chilling effect on investments in the sector. Equally injurious to America, the IP waiver would allow China to become a biotech powerhouse by piggybacking on American innovation. A waiver on IP for Covid-19 vaccines would accelerate the timeline for “Made in China 2025.” The mRNA technology, which undergirds the Pfizer-BioNTech and Moderna vaccines has uses beyond this pandemic. It has the potential to take on cancers and other diseases. With the waiver, China and others will be emboldened to use the once-proprietary mRNA know-how for broader research and applications. Is this in America’s interest? Mark Cohen, an expert on Chinese IP theft, recently told the Washington Post that the waiver would deliver “a competitive advantage to countries that are increasingly viewed as our adversaries, at taxpayer expense.” Beyond the damage that an mRNA giveaway will inflict on US R&D investments, the waiver sends a signal that America could agree to force American innovators to part with trade secrets every time there’s a global crisis. That attitude will arrest biopharmaceutical innovation. Small biotech firms spearhead 70 percent of the R&D pipeline, relying heavily on private investors to fund that work. If investors know that innovators may have to give away their discoveries in a global crisis, they’ll deploy their money elsewhere. That’ll make it even harder to draw the R&D investments needed to address infectious diseases, including drug-resistant infections and viruses. America is benefitting greatly from the early access to COVID-19 treatments and vaccines, saving lives and speeding economic recovery. Preserving U.S. leadership in biomedical innovation includes preserving the incentives that helped make it the world’s leader. A final downside of the waiver is the ability for American firms to find a cure for the next pandemic. Among the greatest threats is bacteria resistant to our current arsenal of antibiotics that becomes a pandemic-inducing superbug. Already, the market for new antimicrobials is broken. Only a handful of biotechs have them in development, and many have gone bankrupt trying to commercialize one. “A lot of people have rightly said we need to start thinking about preparing for the next pandemic now,” noted Craig Garthwaite, a healthcare-business professor at Northwestern University. “Suspending IP for vaccine manufacturers would send exactly the wrong signal for the future.” For the sake of patients everywhere, American IP rights must stay protected. It’s the only way to keep China at bay and American innovators at work.

#### Biotech leadership key to future military primacy.

Moore 21 [(Scott Moore is a political scientist and administrator at the University of Pennsylvania and the author of a forthcoming book, “How China Shapes the Future,” on China’s role in public goods and emerging technologies.) 8-8-2021, "In Biotech, the Industry of the Future, the U.S. Is Way Ahead of China," Lawfare, https://www.lawfareblog.com/biotech-industry-future-us-way-ahead-china]//Lex AKu

A continuing refrain from Washington in recent years has been that the United States is falling behind China in the development of critical emerging technologies. In some fields, this may be true. But not in biotechnology. To be sure, China’s biotech sector is growing at a torrid pace, and some of its firms are becoming leaders in certain areas, such as cancer treatment. Yet the U.S. retains a dominant position in research, development and commercialization, accounting for almost half of all biotech patents filed from 1999 to 2013. The triumph of its biotechnology industry during the coronavirus pandemic, producing two highly effective vaccines using an entirely new approach based on messenger RNA, and in record time, shows that the U.S.’s competitive edge in biotechnology remains largely intact. And that has important implications as Washington gears up for a sustained period of geopolitical competition with Beijing. Biotech is such a critical area for technological competition between the U.S. and China because it is transforming fields from medicine to military power. The great advances of the 19th century, like chemical fertilizers, resulted from mastering chemistry. In the 20th century, mastery of physics led to nuclear energy—and, more ominously, nuclear weapons. In the 21st century, biology offers a similar mix of peril and promise. This was illustrated dramatically by the award of the 2020 Nobel Prize for the discovery of an enzyme system known as CRISPR-Cas9, which allows an organism’s genomes to be edited with high precision. It is a transformational breakthrough. But while CRISPR shows great promise in the development of new cures for long-untreatable diseases, it could also lead to a whole new generation of deadly bioweapons. That’s a prospect that increasingly alarms U.S. intelligence officials. In 2016, then-Director of National Intelligence James Clapper warned Congress that “[r]esearch in genome editing conducted by countries with different regulatory or ethical standards than those of western countries probably increases the risk of the creation of potentially harmful biological agents or product

s.” Although Clapper didn’t name specific countries, it soon became clear that he was referring mainly to China. Four years later, his successor, John Ratcliffe, issued a far more pointed warning that “China has even conducted human testing on members of the People’s Liberation Army in hope of developing soldiers with biologically enhanced capabilities. There are no ethical boundaries to Beijing’s pursuit of power.” Such capabilities are almost certainly only speculative—but they underscore why biotech leadership is so important for national security as well as economic competitiveness. Beijing has long envied the United States’s dominant position in biotechnology and spent heavily to overtake it. Biotech has been a priority sector for state investment since the 1980s, and by one estimate Beijing had poured some $100 billion into the sector by 2018. Nowhere did it lavish more attention or invest more of its propaganda power than in developing a coronavirus vaccine. State media have spent months crowing that “China is working around the clock for breakthroughs in COVID-19 vaccines.” Yet despite this push, China’s vaccine program quickly took on a Potemkin air. In February 2020, barely two months after the onset of the pandemic and after a supposedly crash vaccine effort, a military doctor stood in front of a Chinese flag to receive what was billed as an experimental vaccine dose but was widely suspected to be a staged photo op. Now, having spent months talking up its two primary vaccine candidates to developing countries like Brazil and Indonesia, both of which have entered into purchase agreements with Chinese biotech firms, Chinese officials face severe mistrust among their nation’s overseas partners. For China’s leaders, the disappointing returns on their big bet on biotechnology look likely to cause them more headaches at home as well as abroad—there are already signs that affluent Chinese place more trust in foreign-developed coronavirus vaccines than the homegrown ones produced at such great expense. For U.S. officials, though, China’s relative underperformance in vaccine development presents an opportunity to reassert the United States’s leadership in biotechnology and public health and bolster the nation’s depleted soft power in the process. The Biden administration has already signaled it will reengage in multilateral bodies such as the World Health Organization. Yet the U.S. shouldn’t stop there. Washington should begin thinking now about how to emulate the success of the President’s Emergency Plan for AIDS Relief (PEPFAR)—which, though imperfect, is widely regarded as one of the most successful single public health interventions in history—to address growing disparities in access to coronavirus vaccines between countries. At the moment, vaccine supplies are controlled largely by rich countries, creating the risk of moral and public health failure if the gap persists. While COVID-19, the respiratory disease caused by the novel coronavirus, differs in many respects from AIDS, PEPFAR combined research, prevention, and access to therapeutics. Developing a comparable institutional structure to close the coronavirus vaccine access gap is the right thing to do—but it would also go a long way to restoring America’s battered global reputation. At the same time, the United States can’t afford to rest on its laurels in biotechnology, or any other field. Aside from China, other nations like Singapore and Israel have also invested heavily to develop their biotechnology sectors, with Israel in particular giving rise to a thriving biotech industry. U.S. public investment in basic scientific research and development has meanwhile been on the decline for decades, and there are worrying signs that America’s once world-beating innovation ecosystem is less productive, and less entrepreneurial, than it once was. Despite strengths in translational research, moreover, the frontiers of biology increasingly sit at the intersection with other disciplines like computer science, meaning that funding agencies, universities and other organizations need to break down disciplinary silos. Boosting support for biotechnology research, while reforming how that money is used, will go a long way toward shoring up the United States’s leading position in the global biotech sector. The U.S. biotechnology sector also faces other threats, not least growing espionage and intellectual property theft by foreign actors, especially those linked to China. Several high-profile cases brought by the U.S. Department of Justice’s China Initiative have involved biotechnology researchers, and American biotech firms have been top targets for cyber theft and intrusion. Sustained outreach to researchers and research institutions is critical to preventing such theft. But efforts to clamp down on the threats posed by espionage and intellectual property theft can easily go too far and must preserve the researcher mobility and data-sharing that is essential to doing cutting-edge science. Beyond its shores, the United States should work with its partners and allies to enhance export controls on dual-use biotechnology—used for both peaceful and military gain—especially DNA templates. Many forms of genetic material and synthetic biology products are already subject to U.S. export controls, but gaps remain, and screening for genetic sequence orders relies primarily on voluntary regulation by biotech firms. Better coordinating export controls among major economies and U.S. allies can dramatically reduce the risk of sophisticated bioweapons development in the decades to come.

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

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

Since World War II, the United States has had a military second to none. Since the Cold War, America has committed to having overwhelming military primacy. The idea, as George W. Bush declared in 2002, that America must possess “strengths beyond challenge” has featured in every major U.S. strategy document for a quarter century; it has also been reflected in concrete terms.6 From the early 1990s, for example, the United States consistently accounted for around 35 to 45 percent of world defense spending and maintained peerless global power-projection capabilities.7 Perhaps more important, U.S. primacy was also unrivaled in key overseas strategic regions—Europe, East Asia, the Middle East. From thrashing Saddam Hussein’s million-man Iraqi military during Operation Desert Storm, to deploying—with impunity—two carrier strike groups off Taiwan during the China-Taiwan crisis of 1995– 96, Washington has been able to project military power superior to anything a regional rival could employ even on its own geopolitical doorstep. This military dominance has constituted the hard-power backbone of an ambitious global strategy. After the Cold War, U.S. policymakers committed to averting a return to the unstable multipolarity of earlier eras, and to perpetuating the more favorable unipolar order. They committed to building on the successes of the postwar era by further advancing liberal political values and an open international economy, and to suppressing international scourges such as rogue states, nuclear proliferation, and catastrophic terrorism. And because they recognized that military force remained the ultima ratio regum, they understood the centrality of military preponderance. Washington would need the military power necessary to underwrite worldwide alliance commitments. It would have to preserve substantial overmatch versus any potential great-power rival. It must be able to answer the sharpest challenges to the international system, such as Saddam’s invasion of Kuwait in 1990 or jihadist extremism after 9/11. Finally, because prevailing global norms generally reflect hard-power realities, America would need the superiority to assure that its own values remained ascendant. It was impolitic to say that U.S. strategy and the international order required “strengths beyond challenge,

” but it was not at all inaccurate. American primacy, moreover, was eminently affordable. At the height of the Cold War, the United States spent over 12 percent of GDP on defense. Since the mid-1990s, the number has usually been between 3 and 4 percent.8 In a historically favorable international environment, Washington could enjoy primacy—and its geopolitical fruits—on the cheap. Yet U.S. strategy also heeded, at least until recently, the fact that there was a limit to how cheaply that primacy could be had. The American military did shrink significantly during the 1990s, but U.S. officials understood that if Washington cut back too far, its primacy would erode to a point where it ceased to deliver its geopolitical benefits. Alliances would lose credibility; the stability of key regions would be eroded; rivals would be emboldened; international crises would go unaddressed. American primacy was thus like a reasonably priced insurance policy. It required nontrivial expenditures, but protected against far costlier outcomes.9 Washington paid its insurance premiums for two decades after the Cold War. But more recently American primacy and strategic solvency have been imperiled. THE DARKENING HORIZON For most of the post–Cold War era, the international system was— by historical standards—remarkably benign. Dangers existed, and as the terrorist attacks of September 11, 2001, demonstrated, they could manifest with horrific effect. But for two decades after the Soviet collapse, the world was characterized by remarkably low levels of great-power competition, high levels of security in key theaters such as Europe and East Asia, and the comparative weakness of those “rogue” actors—Iran, Iraq, North Korea, al-Qaeda—who most aggressively challenged American power. During the 1990s, some observers even spoke of a “strategic pause,” the idea being that the end of the Cold War had afforded the United States a respite from normal levels of geopolitical danger and competition. Now, however, the strategic horizon is darkening, due to four factors. First, great-power military competition is back. The world’s two leading authoritarian powers—China and Russia—are seeking regional hegemony, contesting global norms such as nonaggression and freedom of navigation, and developing the military punch to underwrite these ambitions. Notwithstanding severe economic and demographic problems, Russia has conducted a major military modernization emphasizing nuclear weapons, high-end conventional capabilities, and rapid-deployment and special operations forces— and utilized many of these capabilities in conflicts in Ukraine and Syria.10 China, meanwhile, has carried out a buildup of historic proportions, with constant-dollar defense outlays rising from US$26 billion in 1995 to US$226 billion in 2016.11 Ominously, these expenditures have funded development of power-projection and antiaccess/area denial (A2/AD) tools necessary to threaten China’s neighbors and complicate U.S. intervention on their behalf. Washington has grown accustomed to having a generational military lead; Russian and Chinese modernization efforts are now creating a far more competitive environment. Second, the international outlaws are no longer so weak. North Korea’s conventional forces have atrophied, but it has amassed a growing nuclear arsenal and is developing an intercontinental delivery capability that will soon allow it to threaten not just America’s regional allies but also the continental United States.12 Iran remains a nuclear threshold state, one that continues to develop ballistic missiles and A2/AD capabilities while employing sectarian and proxy forces across the Middle East. The Islamic State, for its part, is headed for defeat, but has displayed military capabilities unprecedented for any terrorist group, and shown that counterterrorism will continue to place significant operational demands on U.S. forces whether in this context or in others. Rogue actors have long preoccupied American planners, but the rogues are now more capable than at any time in decades. Third, the democratization of technology has allowed more actors to contest American superiority in dangerous ways. The spread of antisatellite and cyberwarfare capabilities; the proliferation of man-portable air defense systems and ballistic missiles; the increasing availability of key elements of the precision-strike complex— these phenomena have had a military leveling effect by giving weaker actors capabilities which were formerly unique to technologically advanced states. As such technologies “proliferate worldwide,” Air Force Chief of Staff General David Goldfein commented in 2016, “the technology and capability gaps between America and our adversaries are closing dangerously fast.”13 Indeed, as these capabilities spread, fourth-generation systems (such as F-15s and F-16s) may provide decreasing utility against even non-great-power competitors, and far more fifth-generation capabilities may be needed to perpetuate American overmatch. Finally, the number of challenges has multiplied. During the 1990s and early 2000s, Washington faced rogue states and jihadist extremism—but not intense great-power rivalry. America faced conflicts in the Middle East—but East Asia and Europe were comparatively secure. Now, the old threats still exist—but the more permissive conditions have vanished. The United States confronts rogue states, lethal jihadist organizations, and great-power competition; there are severe challenges in all three Eurasian theaters. “I don’t recall a time when we have been confronted with a more diverse array of threats, whether it’s the nation state threats posed by Russia and China and particularly their substantial nuclear capabilities, or non-nation states of the likes of ISIL, Al Qaida, etc.,” Director of National Intelligence James Clapper commented in 2016. Trends in the strategic landscape constituted a veritable “litany of doom.”14 The United States thus faces not just more significant, but also more numerous, challenges to its military dominance than it has for at least a quarter century.