# 1NC

## 1

#### **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, ceding control to China – also can’t solve future diseases

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>, *Erik Paulsen represented Minnesota’s 3rd congressional district in the U.S. House of Representatives from 2009 to 2019. This piece originally ran in the International Business Times.*]//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**,** recentlytold 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 products.” 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.

#### 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.

## 2

#### Interpretation: The affirmative debater must read either a standard or role of the ballot.

#### 1] Strat Skew – I don't know what matters under your framing – our ideas of what exactly matters may vary – means I can't engage substantively. You just have a bunch of random cards which could be reinterpreted in the 1AR depending on the 1NC

#### 2] Resolvability – if there's dispute about whether certain impacts matter at the end of the round, the judge has to intervene because there's no stable standard text to refer to. Resolvability is a voter since the judge needs to come up with a winner.

#### Drop the debater—there’s no argument to drop and the standard affects every part of the debate

#### No rvis—it’s your burden to be fair and educational, same reason you don’t win for answering inherency or putting defense on a disad. Also causes chilling effect where debaters are scared to check abusive positions, proliferating abuse

#### CX Checks don’t solve – a) Pre round prep – I have to wait till cx to determine which offs are most strategic rather than being able to do it pre round or pre-tournament which is when the majority of prep happens, b) **Verifiability – judges don’t** flow cross ex so they might not catch the question or the answer which means that debates become irresolvable.

#### 1AR Spec doesn’t solve –

Competing interps

Fairness

#### Reject 1AR theory –

## 3

#### Counterplan Text: Member states of the WTO should reduce Intellectual property protections for Covid with the exception of the Kington of Saudi Arabia.

## 4

#### The US is concerned about Saudi IPR but trade relations are fine now

US Gov 21 [United States Government, Office of the US Trade Representative “2021 Special 301 Report” Published: 2021] [https://ustr.gov/sites/default/files/files/reports/2021/2021%20Special%20301%20Report%20(final).pdf] || SM

Saudi Arabia remains on the Priority Watch List in 2021.

Ongoing Challenges and Concerns

Saudi Arabia was placed on the Priority Watch List in 2019 for failing to take action against the rampant satellite and online piracy made available by illicit pirate service beoutQ, continued lack of effective protection of intellectual property (IP) for pharmaceutical products, and long-standing concerns regarding enforcement against counterfeit and pirated goods within the country. BeoutQ ceased operations in August 2019. The Saudi Authority for Intellectual Property (SAIP) continued to take steps to improve IP protection, enforcement, and awareness throughout Saudi Arabia in 2020. However, concerns remain over actions by the Saudi Arabia Food and Drug Authority (SFDA), which the Minister of Health oversees, that are contrary to Saudi Arabia’s public statements in paragraph 261 of the Report of the Working Party on the Accession of the Kingdom of Saudi Arabia to the World Trade Organization. Starting in 2016, SFDA has been granting marketing approval to domestic companies for subsequent versions of registered products, without requiring the submission of data that meets the same requirements applied to the initial applicant, despite the period of protection provided to the initial applicant by Saudi regulations. SFDA’s continued actions and the lack of redress for affected companies have intensified concerns. Furthermore, the National Unified Procurement Company for Medical Supplies, also overseen by the Minister of Health, reportedly awarded national tenders to some of these domestic companies for the affected products.

#### The plan stifles Saudi innovation by sending investors away which hurts US Saudi Relations.

Stevens 17 [Stevens, Philip. “Saudi Missteps on Intellectual Property Will Hold Back Its Economy.” *TheHill*, 17 Sept. 2017, thehill.com/opinion/international/351074-saudis-missteps-on-intellectual-property-will-hold-back-its-economy?rl=1., *Philip Stevens is director of Geneva Network, a UK-based research organization focusing on trade and innovation issues.*] //Lex AKu

Saudi Arabian policymakers know that increasing knowledge-based sectors is the key to sustainable growth as their economy transitions away from oil. “You cannot be depending on oil in a world where the knowledge economy is the driver of economic development — manufacturing is 20th century,” Fahd Al-Rasheed, CEO of King Abdullah Economic City, said in June. Vision 2030, the plan to diversify the Saudi economy, also sees a big role for knowledge-based industries. This makes sense. In the U.S., knowledge-intensive goods and services from sectors including biotech, chemicals, entertainment and information technology now make up over half of all U.S. exports, reversing the situation of only 40 years ago when manufacturing dominated. Advanced Asian economies — Japan, the Republic of Korea, Advanced Asian economies — Japan, the Republic of Korea, Singapore and Taiwan — have also taken this path, moving over recent decades from agriculture to manufacturing to knowledge-based economies. Few countries have developed thriving knowledge-based industries purely from domestic resources. Scientific knowledge, technological know-how and the required research and development capital are dispersed globally. Gone are the days when one R&D company, for example, the industrial behemoth General Electric or the biopharmaceutical major Merck, created products in-house from start to finish. Today, innovation is a result of collaboration between multinational companies, small companies, start-ups, academia and the public sector at all stages of the R&D cycle, often across borders. Saudi Arabia’s challenge is to become a meaningful participant in this new world of networked innovation. It must attract innovative companies to its shores, bringing with them the capital, skills and technological know-how the Kingdom may be missing. The potential prize is enormous: China now captures more Foreign Direct Investment in R&D than the U.S. thepharmaceuticals sector leads the way with investments, totaling $1.6bn between 2010 and 2015, according to FDI Markets. The Kingdom has some advantages that could direct it down the R&D path. It has a young population, a growing base of science graduates and relatively high investment in health care, internet and other forms of infrastructure. Tax incentives, and investment in education and information technology will only go so far, though. Above all, foreign investors need certainty over their intellectual property rights, including clearly defined and easily enforceable patent rights. If this protection is strong, companies will be more likely to invest in local R&D facilities, or enter into partnerships with local companies. New products will be launched early into Saudi Arabia, as innovators will have no fear of their valuable IP rights being compromised. Saudi Arabia has the intellectual property basics in place, in line with its World Trade Organization commitments. In fact, the U.S. Chamber of Commerce’s 2017 International IP index noted Saudi Arabia has a “strong patenting environment.” Yet, recent developments risk derailing this progress. Just months after granting a patent for a new medicine to a company based in the United States, the Saudi Food and Drug Administration (SFDA) reneged on the deal.The Saudi patent for Hepatitis drug Daclatasvir was granted by the Patent Office of the Gulf Cooperation council (which encompasses Saudi Arabia) to BMS in Dec 2016. Nevertheless, the SFDA granted marketing approval to a generic version manufactured Saudi company in May 2017, despite the BMS patent still being in force. Granting marketing approval to generic copies of the product in this way is arguably a breach of patent rights. Likewise, the SDFA has also recently allowed local companies to manufacture generic versions of another medicine developed by another U.S. biotech company — potentially contrary to World Trade Organization rules surrounding the protection of clinical test data, itself an important intellectual property right. Saudi IP law allows for 5-year period in which generic companies may not use the clinical trial data submitted to regulatory authorities by originator drug manufacturers to gain marketing approval ("data exclusivity"). Gilead Sciences was granted marketing approval by the SFDA in 2014 for its product Sofosbuvir. The SFDA has subsequently granted marketing approval for generic versions of this product made by a Saudi and Egyptian company — within the 5-year data exclusivity window. This could be a breach of Saudi data exclusivity regulations. Taken together, such actions send a hostile message to foreign investors that their valuable IP rights are not safe in Saudi Arabia. Such hostility will undermine Saudi’s economic ambition by scaring off valuable investment and skills. They also act as an irritant to U.S.-Saudi relations, with the Trump administration indicating a higher prioritization of IP enforcement amongst its trading partners. Meanwhile, regional neighbors such as the UAE and Asian competitors such as Singapore are seizing the opportunities presented by the globalization of innovation, which drive increasing proportions of their economic growth. Saudi Arabia could emerge as a global competitor in knowledge-based industries. It’s an achievable vision, but it requires the policy details to be right, not just the rhetoric.

#### US Saudi Coop key to prevent nuclear proliferation

Emily B. Landau and Shimon Stein 18 [Landau is senior research associate at the Institute for National Security Studies, where she is also director of the Arms Control and Regional Security Project. Stein was Israel's ambassador to Germany from 2001 to 2007. Previously, he participated in the Arms Control and Regional Security working group, as well as negotiations of the Comprehensive Nuclear Test Ban Treaty, and served as head of the Regional Security, Arms Control, and Nonproliferation Department at the Israel Ministry of Foreign Affairs.], 12-4-2018, "Can the United States Prevent Saudi Arabia from Getting Nuclear Weapons?," National Interest, <https://nationalinterest.org/feature/can-united-states-prevent-saudi-arabia-getting-nuclear-weapons-37812> {OS}

The United States has always been very concerned about the proliferation risks involved in nuclear cooperation, and in 2008 it was able to achieve a memorandum of understanding with Saudi Arabia on nuclear energy cooperation whereby the latter pledged to acquire nuclear fuel from international markets, rather than producing it indigenously. But ten years later, it seems that Saudi Arabia no longer views itself as bound by that understanding. The current challenge for the United States is how to insist on what is known as a 123 agreement with Saudi Arabia, meaning that the agreement explicitly denies Saudi Arabia the right to work on sensitive nuclear technologies (enrichment capabilities and plutonium reprocessing), without driving it into the hands of other nuclear suppliers, such as Russia, China and South Korea, that may be less worried about ensuring these restrictions.¶ There are concerns that the Trump administration might be willing to concede to Saudi Arabia sensitive capabilities, and the fact that it is not willing to divulge information regarding the status of the negotiations does not bode well in this regard. The administration is keenly aware of the link to Iran’s nuclear posture, and that the Joint Comprehensive Plan of Action (JCPOA) set a very negative precedent for nuclear cooperation with other states when it legitimized Iran’s enrichment capabilities. While Iran must cap its stockpile of enriched uranium for the duration of the deal, it is allowed—under the explicit terms of the deal—to work on R&D into an entire range of advanced centrifuges. Iran has plans to install and operate these centrifuges eleven years into the deal. There is a real question of how these capabilities can be denied to states like Saudi Arabia who are in good standing with the NPT, whereas Iran—who blatantly violated the nonproliferation treaty—was granted the right to continue with these dangerous enrichment-related activities.

#### Saudi prolif draws in India and Pakistan – goes nuclear

Edelman 11—Fellow at the Center for Strategic and Budgetary Assessments. Former Undersecretary for Defense—AND—Andrew Krepinevich—President of the Center for Strategic and Budgetary Assessments—AND—Evan Montgomery—Research Fellow at the Center for Strategic and Budgetary Assessments (Eric, The dangers of a nuclear Iran, FA 90;1, http://www.csbaonline.org/wp-content/uploads/2010/12/2010.12.27-The-Dangers-of-a-Nuclear-Iran.pdf)

There is, however, at least one state that could receive significant outside support: Saudi Arabia. And if it did, proliferation could accelerate throughout the region. Iran and Saudi Arabia have long been geopolitical and ideological rivals. Riyadh would face tremendous pressure to respond in some form to a nuclear-armed Iran, not only to deter Iranian coercion and subversion but also to preserve its sense that Saudi Arabia is the leading nation in the Muslim world. The Saudi government is already pursuing a nuclear power capability, which could be the first step along a slow road to nuclear weapons development. And concerns persist that it might be able to accelerate its progress by exploiting its close ties to Pakistan. During the 1980s, in response to the use of missiles during the Iran-Iraq War and their growing proliferation throughout the region, Saudi Arabia acquired several dozen css-2 intermediate-range ballistic missiles from China. The Pakistani government reportedly brokered the deal, and it may have also oªered to sell Saudi Arabia nuclear warheads for the css-2s, which are not accurate enough to deliver conventional warheads eªectively. There are still rumors that Riyadh and Islamabad have had discussions involving nuclear weapons, nuclear technology, or security guarantees. This “Islamabad option” could develop in one of several different ways. Pakistan could sell operational nuclear weapons and delivery systems to Saudi Arabia, or it could provide the Saudis with the infrastructure, material, and technical support they need to produce nuclear weapons themselves within a matter of years, as opposed to a decade or longer. Not only has Pakistan provided such support in the past, but it is currently building two more heavy-water reactors for plutonium production and a second chemical reprocessing facility to extract plutonium from spent nuclear fuel. In other words, it might accumulate more fissile material than it needs to maintain even a substantially expanded arsenal of its own. Alternatively, Pakistan might oªer an extended deterrent guarantee to Saudi Arabia and deploy nuclear weapons, delivery systems, and troops on Saudi territory, a practice that the United States has employed for decades with its allies. This arrangement could be particularly appealing to both Saudi Arabia and Pakistan. It would allow the Saudis to argue that they are not violating the npt since they would not be acquiring their own nuclear weapons. And an extended deterrent from Pakistan might be preferable to one from the United States because stationing foreign Muslim forces on Saudi territory would not trigger the kind of popular opposition that would accompany the deployment of U.S. troops. Pakistan, for its part, would gain financial benefits and international clout by deploying nuclear weapons in Saudi Arabia, as well as strategic depth against its chief rival, India. The Islamabad option raises a host of difficult issues, perhaps the most worrisome being **how India would respond**. Would it **target Pakistan**’s weapons in Saudi Arabia with its own conventional or nuclear weapons? How would this expanded nuclear competition influence **stability** during a crisis in either the Middle East or South Asia? Regardless of India’s reaction, any decision by the Saudi government to seek out nuclear weapons, by whatever means, would be **highly destabilizing**. It would increase the incentives of other nations in the Middle East to pursue nuclear weapons of their own. And it could increase their ability to do so by eroding the remaining barriers to nuclear proliferation: each additional state that acquires nuclear weapons **weakens the nonprolif**eration **regime**, even if its particular method of acquisition only circumvents, rather than violates, the npt. Were Saudi Arabia to acquire nuclear weapons, the Middle East would count three nuclear-armed states, and perhaps more before long. It is unclear how such an n-player competition would unfold because most analyses of nuclear deterrence are based on the U.S.- Soviet rivalry during the Cold War. It seems likely, however, that the interaction among three or more nuclear-armed powers would be more prone to **miscalc**ulation and **escalation** than a bipolar competition. During the Cold War, the United States and the Soviet Union only needed to concern themselves with an attack from the other.Multipolar systems are generally considered to be less stable than bipolar systems because coalitions can shift quickly, upsetting the balance of power and creating incentives for an attack. More important, emerging nuclear powers in the Middle East might not take the costly steps necessary to preserve regional stability and avoid a nuclear exchange. For nuclear-armed states, **the bedrock of deterrence** is the knowledge that each side has a secure second-strike capability, so that no state can launch an attack with the expectation that it can wipe out its opponents’ forces and avoid a devastating retaliation. However, **emerging nuclear powers might not invest in** expensive but **survivable capabilities** such as hardened missile silos or submarinebased nuclear forces. Given this likely vulnerability, the close proximity of states in the Middle East, and the very short flight times of ballistic missiles in the region, any new nuclear powers might be compelled to “launch on warning” of an attack or even, during a crisis, to use their nuclear forces preemptively. Their governments might also delegate launch authority to lower-level commanders, heightening the possibility of miscalculation and escalation. Moreover, if early warning systems were not integrated into robust command-and-control systems, the risk of an unauthorized or accidental launch would increase further still. And without sophisticated early warning systems, a nuclear attack might be unattributable or attributed incorrectly. That is, assuming that the leadership of a targeted state survived a first strike, it might not be able to accurately determine which nation was responsible. And this uncertainty, when combined with the pressure to respond quickly, would create a significant risk that it would retaliate against the wrong party, potentially triggering **a regional nuclear war.** Most existing nuclear powers have taken steps to protect their nuclear weapons from unauthorized use: from closely screening key personnel to developing technical safety measures, such as permissive action links, which require special codes before the weapons can be armed. Yet there is no guarantee that emerging nuclear powers would be willing or able to implement these measures, creating a significant risk that their governments might lose control over the weapons or nuclear material and that nonstate actors could gain access to these items. Some states might seek to mitigate threats to their nuclear arsenals; for instance, they might hide their weapons. In that case, however, a single intelligence compromise could leave their weapons vulnerable to attack or theft.