# 1NC

### 1NC – DA

#### The US is leading the biopharmaceuticals race – but China is close. Catching up would be a death sentence for US lead.

Gupta 21 [Gaurav; Physician, founder of the biotechnology investment firm Ascendant BioCapital; “As Washington Ties Pharma’s Hands, China Is Leaping Ahead,” Barrons; 6/11/21; <https://www.barrons.com/articles/as-washington-ties-pharmas-hands-china-is-leaping-ahead-51623438808>] Justin

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 innovation.

The remarkable innovation capacity of our biopharmaceutical industry ought to be a source of national pride. Yet while “Made in America” is the global standard for medicines in development today, misguided policy risks ceding our scientific prowess to other countries in the future. This is particularly true in the case of China, where biotechnology has become a strategic pillar for the health of its people and economy.

From 2016 to 2020, the market capitalization of all Chinese biopharma companies increased exponentially from $1 billion to over $200 billion. 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 plan gives away sensitive biotechnology information that facilitates a China lead.

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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.

#### Genomics data uniquely grants them an asymmetrical advantage

Needham ’20 [Kirsty Needham, 8-5-2020, "Special Report: COVID opens new doors for China's gene giant," U.S., <https://www.reuters.com/article/us-health-coronavirus-bgi-specialreport/special-report-covid-opens-new-doors-for-chinas-gene-giant-idUSKCN2511CE> // belle]

BGI Group, described in one 2015 study as “Goliath” in the fast-growing field of genomics research, is using an opening created by the pandemic to expand its footprint globally. In the past six months, it says it has sold 35 million rapid COVID-19 testing kits to 180 countries and built 58 labs in 18 countries. Some of the equipment has been donated by BGI’s philanthropic arm, promoted by China’s embassies in an extension of China’s virus diplomacy.

But as well as test kits, the company is distributing gene-sequencing technology that U.S. security officials say could threaten national security. This is a sensitive area globally. Sequencers are used to analyse genetic material, and can unlock powerful personal information.

In science journals and online, BGI is calling on international health researchers to send in virus data generated on its equipment, as well as patient samples that have tested positive for COVID-19, to be shared publicly via China’s government-funded National GeneBank.

As BGI’s foothold in the gene-sequencing industry grows, a senior U.S. administration official told Reuters on condition of anonymity, so does the risk China could harvest genetic information from populations around the world.

Underpinning BGI’s global expansion are the Shenzhen-based company’s links to the Chinese government, which include its role as operator of China’s national genetic database and its research in government-affiliated key laboratories. BGI, which says in stock market filings it aims to help the ruling Communist Party achieve its goal to “seize the commanding heights of international biotechnology competition,” is coming under increasing scrutiny in an escalating Cold War between Washington and Beijing, Reuters found.

Reuters found no evidence that BGI is violating patient privacy protections where these apply. Responding to questions from the news agency, BGI said it is not owned by the Chinese government.

“Under the current political climate, the fear raised about the use of BGI’s technology is unfounded and misleading,” BGI said in a statement to Reuters. “BGI’s mission is, and has always been, using genomics to benefit people’s health and wellbeing.”

China’s foreign ministry said in a statement the country has been open, transparent and responsible in “sharing information and experience with the international community, providing supplies to relevant countries” including COVID-19 test kits and protective equipment, and helping countries improve epidemic control.

The extent of BGI’s endeavours to dominate an industry with geostrategic value, as well as of its efforts to gather genetic data from around the world, was pieced together by Reuters from public documents and dozens of interviews with scientists, researchers and health officials.

Some U.S. officials warn of a dual risk to national security from BGI: Sensitive genetic information about U.S. citizens may fall into foreign hands, and American companies stand to lose their innovative edge in the field of genomics to Chinese firms.

Earlier this year, the U.S. National Counterintelligence and Security Center (NCSC) published practical tips for health services to avoid “potential threats posed by foreign powers” in connection with COVID-19 tests. Other officials draw parallels between BGI and Huawei Technologies Co., the Chinese telecommunications titan whose 5G technology the United States says could be used to capture personal data that Beijing could exploit. Huawei has said it would refuse to cooperate with spying.

Sharing data is essential for medical research. But in the case of genetic data, officials and scientists say the risks are that it could be weaponized.

Individuals can be identified by a portion of their DNA, and some researchers have found genetic links with behaviours such as depressive disorder. A hostile actor could use such data to target individuals for surveillance, extortion or manipulation, according to a comprehensive report prepared for the U.S. Office of the Director of National Intelligence by science and medical experts in January, which added that such associations are not yet well understood.

Knowledge of the genetic makeup of national decision-makers or the military, and their propensity to act in certain ways, could be used by adversarial intelligence agencies as a mechanism of influence, said the report, “Safeguarding the Bioeconomy,” from the National Academies of Sciences, Engineering and Medicine. Genetic data could reveal a U.S. vulnerability to specific diseases, it added.

As companies race to develop and patent biological drugs for the global market, the ethnic diversity of the U.S. population makes U.S. genomic data more valuable than data from countries with homogeneous populations, the report said. That’s because the more varied the data, the bigger the advantage in identifying genetic disease. The report raised the possibility BGI could amass DNA sequence information from U.S. genetic samples that would give it an “asymmetrical” advantage over U.S. firms.

Genetic information, including family medical history, “is of enormous value and can be exploited by foreign regimes for a range of security and economic purposes,” Bill Evanina, director of the NCSC, told Reuters in response to questions about Chinese genomic companies.

BGI and Huawei have said they work together. In a video that is no longer available on Huawei’s site, a BGI executive said it processes “staggering volumes of data” from its gene sequencers, stored on Huawei’s high-powered systems. In response to questions from Reuters about whether this information could be shared with China’s government, Huawei said only users of its technology can define who to share data with. “Huawei’s Cloud technology and cloud computing services are secure and compliant with international security standards,” it said, adding it complies with all laws.

#### Gains are directly converted to military prowess – destroys US primacy.

Kuo 17 [Mercy A; Executive Vice President at Pamir Consulting; “The Great US-China Biotechnology and Artificial Intelligence Race,” The Diplomat; 8/23/17; <https://thediplomat.com/2017/08/the-great-us-china-biotechnology-and-artificial-intelligence-race/>] TDI // Re-Cut Justin

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.**

#### That causes extinction.

Yulis 17 [Max; Major in PoliSci, Penn Political Review; “In Defense of Liberal Internationalism,” Penn Political Review; 4/8/17; <http://pennpoliticalreview.org/2017/04/in-defense-of-liberal-internationalism/>] // Re-Cut Justin

Over the past decade, international headlines have been bombarded with stories about the unraveling of the post-Cold War world order, the creation of revolutionary smart devices and military technologies, the rise of militant jihadist organizations, and nuclear proliferation. Indeed, times are paradoxically promising and alarming. In relation to treating the world’s ills, fortunately, there is a capable hegemon– one that has the ability to revive the world order and traditionally hallmarked human rights, peace, and democracy. The United States, with all of its shortcomings, had crafted an international agenda that significantly impacted the post-WWII landscape. Countries invested their ambitions into security communities, international institutions, and international law in an effort to mitigate the chances of a nuclear catastrophe or another World War. The horrors and atrocities of the two Great Wars had traumatized the global community, which spurred calls for peace and the creation of a universalist agenda. Today, the world’s fickle and declining hegemon still has the ability, but not the will, to uphold the world order that it had so carefully and eagerly helped construct. Now, the stakes are too high, and there must be a mighty and willing global leader to lead the effort of diffusing democratic ideals and reinforcing stability through both military and diplomatic means. To do this, the United States must abandon its insurgent wave of isolationism and protectionism, and come to grips with the newly transnational nature of problems ranging from climate change to international terrorism.

First, the increase in intra-state conflict should warrant concern as many countries, namely in Africa and the Middle East, are seeing the total collapse of civil society and government. These power vacuums are being filled with increasingly ideological and dangerous tribal and non-state actors, such as Boko Haram, ISIS, and Al-Shabaab. Other bloody civil wars in Rwanda, Sudan, and the Congo have contributed to the deaths of millions in the past two decades. As the West has seen, however, military intervention has not been all that successful in building and empowering democratic institutions in the Far East. A civil crusade, along with the strengthening of international institutions, may in fact be the answer to undoing tribal, religious, and sectarian divisions, thereby mitigating the prospects of civil conflict. During the Wilsonian era, missionaries did their part to internationalize the concept of higher education, which has contributed to the growth of universities in formerly underdeveloped countries such as China and South Korea.[1] In addition, the teachings of missionaries emphasized the universality of humanity and the oneness of man, which was antithetical to the justifications for imperialism and the rampant sectarianism that plagued much of the Middle East and Africa.[2] Seeing that an increase in the magnitude of human casualty is becoming more of a reality due to advancements in military technology and the increasing outbreaks of civil war, international cooperation and the diffusion of norms that highlight the importance of stable governance, democracy, and human rights is the only recourse to address the rise in sectarian divides and civil conflicts. So long as the trend of the West’s desire to look inward continues, it is likely that nation states mired in conflict will devolve into ethnic or tribal enclaves bent on relying on war to maintain their legitimacy and power. Aside from growing sectarianism and the increasing prevalence of failed states, an even more daunting threat come from weapons that transcend the costs of conventional warfare.

The problem of nuclear proliferation has been around for decades, and on the eve of President Trump’s inauguration, it appeared that Obama’s lofty goal of advocating for nonproliferation would no longer be a priority of American foreign policy.[3] In addition, now that the American president is threatening to undo much of the United States’ extensive network of alliances, formerly non-nuclear states may be forced to rearm themselves. Disarmament is central to liberal internationalism, as was apparent by the Washington Naval Treaty advocated by Wilson, and by the modern CTBT treaty. The reverse is, however, being seen in the modern era, with cries coming from Japan and South Korea to remobilize and begin their own nuclear weapon programs.[4] A world with more nuclear actors is a formula for chaos, especially if nuclear weapons become mass-produced. Non-state actors will increasingly eye these nuclear sites as was the case near a Belgian nuclear power plant just over a year ago.[5] If any government commits a serious misstep, access to nuclear weapons on the behalf of terrorist and insurgent groups will become a reality, especially if a civil war occurs. States with nuclear weapons require domestic stability and strong security, which is why states such as Israel, North Korea, and Pakistan could be in serious trouble in the event of a domestic uprising or military coup. The disarmament of all states is essential for human survival, and if it is not achieved, then a world full of nuclear weapons and an international system guided by realpolitik could give rise to nuclear warfare. In today’s world, nuclear weapons leave all states virtually defenseless. But, for nuclear deproliferation to become a cornerstone of the global agenda, a pacifying and democratic power must rise to the limelight to advocate the virtues of peace, stability, and human rights.

### 1NC – CP

#### CP: Member nations of the World Trade Organization, for CRISPR and genomic medicines, ought to:

#### Fund development and distribution.

#### Provide funding and stipends for university collaboration.

#### Clarify and spread information about licensing and litigation in patent rights.

#### The European Union ought to eliminate their trade restrictions on genome editing.

### 1NC – T

#### Medicines are substances used to prevent, diagnose, or treat harms.

**MRS 20** [(MAINE REVENUE SERVICE SALES, FUEL & SPECIAL TAX DIVISION) “A REFERENCE GUIDE TO THE SALES AND USE TAX LAW” <https://www.maine.gov/revenue/sites/maine.gov.revenue/files/inline-files/Reference%20Guide%202020.pdf> December 2020] SS

[Medicines](https://www.lawinsider.com/dictionary/medicines) means antibiotics, analgesics, antipyretics, stimulants, sedatives, antitoxins, anesthetics, antipruritics, hormones, antihistamines, certain “dermal fillers” (such as BoTox®), injectable contrast agents, vitamins, oxygen, vaccines and other substances that are used in the prevention, diagnosis or treatment of disease or injury and that either (1) require a prescription in order to be purchased or administered to the retail consumer or patient; or (2) are sold in packaging.

#### Medicines solely refer to physical substances.

American Heritage Dictionary of Medicine 18 The American Heritage Dictionary of Medicine 2018 by Houghton Mifflin Harcourt Publishing Company <https://www.yourdictionary.com/medicine> //Elmer

"A **substance**, **especially a drug**, **used to treat** the signs and symptoms of a **disease**, condition, or injury."

#### CRISPR is a platform technology, not a medicine.

Editas Medicine [(a clinical-stage biotechnology company which is developing therapies based on CRISPR–Cas9 gene editing technology)., No Date, CRISPR Gene Editing, <https://www.editasmedicine.com/crispr-gene-editing/>] Justin

CRISPR (pronounced “crisper”) is an acronym for “Clustered, Regularly Interspaced, Short Palindromic Repeats,” and refers to a recently developed gene editing technology that can revise, remove, and replace DNA in a highly targeted manner. CRISPR is a dynamic, versatile tool that allows us to get to and edit nearly any location in the genome, and has the potential to help us develop medicines for people with a wide variety of diseases. We view CRISPR as a “platform” technology because of its ability to target DNA in any cell or tissue.

#### Negate –

#### 1] Limits – their model explodes it to medical devices, any form of strategy for medical research, databases that are used to create medicines and more – only our definition creates a reasonable caselist for medicines while they make prep impossible and wreck engagement

#### 2] Precision – MRS is a legal definition of medicines from codified law and has intent to define which proves we’re right and consistent with topic lit

#### Use competing interps – a) reasonability invites arbitrary judge intervention since we don’t know your bs meter, b) collapses to competing interps – we justify 2 brightlines under an offense defense paradigm just like 2 interps.

### 1NC – DA

#### Infrastructure passes now due to Biden and Pelosi involvement – Biden PC and tight timetables makes the margin for error literally ZERO

Elliott 9-16 (Philip Elliott is a Washington Correspondent for TIME. Before joining TIME in early 2015, he spent almost a decade at The Associated Press, where he covered politics, campaign finance, education and the White House. He is a graduate of the E.W. Scripps School of Journalism at Ohio University, September 16, 2021, accessed on 9-17-2021, Time, "Democrats Face a Grueling Two Weeks as Infighting Erupts Over Infrastructure", https://time.com/6098810/house-democrats-reconciliation/)//babcii

House Democrats yesterday finished penning a 2,600-page bill that **finally outlines the specifics** of their ambitious “soft” infrastructure plan that won’t attract a single Republican vote. But no one was really rushing to Schneider’s for bottles of bubbly. For a party ready to spend $3.5 trillion to fund its social policy agenda, there were plenty of glum faces on Capitol Hill. In fact, one key piece of the legislation—a deal that would finally let Medicare negotiate lower prices with drug companies—fell apart in the Energy and Commerce Committee when three Democrats voted against it. It found resurrection a short time later when Leadership aides literally plucked it from the Energy and Commerce team and delivered it to the Ways and Means Committee for its approval instead. Even there, though, one Democrat voted against it, saying the threat it posed to pharmaceutical companies’ profits would doom it in the Senate. “Every moment we spend debating provisions that will never become law is a moment wasted and will delay much-needed assistance to the American people,” Rep. Stephanie Murphy of Florida later argued. Put another way? Brace **for some nasty politics** over the next two weeks as House Speaker Nancy Pelosi tries to get this bill to a vote before the budget year ends on Sept. 30. And those 2,600 pages had better be recyclable. Democrats can **only afford three defectors** if they want to usher this bill into law, **and they’re perilously close to failure**. So far, five centrist Democrats in the House have said they prefer a scaled-back version of the Medicare component. But if Pelosi gives the five centrists that win, she risks losing the support of progressives who are already sour that things like a punitive wealth tax and the end to tax loopholes aren’t present in the current version of the bill. As it stands now, letting Medicare negotiate drug prices would save the government about $500 billion over the next decade. The scaled-back version doesn’t have an official cost, but a very similar version got its score in the Senate last year: roughly $100 billion in savings. Because Democrats are using a budgeting loophole to help them avoid a filibuster and pass this with bare majorities, that $400 billion gap matters a lot more than on most bills. Scaling back the Medicare savings means they would also have to scale back their overall spending on the bill—a big line in the sand for progressives who say they’ve already compromised too much. All of this, of course, comes as President Joe Biden and his top aides in the White House have been trying to get Senate **centrists onboard**. Just yesterday, he **met separately with Sens. Kyrsten Sinema and Joe Manchin**, fellow Democrats who have expressed worries about the $3.5 trillion price tag but have been vague about what exactly they want to cut back on. With the Senate evenly divided at 50-50, and Vice President Kamala Harris in position to break the ties to Democrats’ victories, any shenanigans from those two independent thinkers scrambles the whole package. Oh, and that other bipartisan infrastructure plan that carries $550 billion in new spending? It’s still sitting on the shelf in the House. Pelosi said she’d bring it to the floor only when the bigger—and entirely partisan—bill was ready. And there’s plenty of grumbling about that package, too. If this is all beginning to sound like a scratched record that keeps repeating, it’s because this has become something of a pattern here in Washington. Things look pretty grim for legislation in town these days, despite Democrats controlling the House, the Senate and the White House. Their margin for error **is literally zero**, and so hiccups from a half-dozen centrists can forewarn a doomed agenda. So far, Pelosi has been a master of holding the line on crucial votes and has managed to maneuver her team to victories, including on an earlier pandemic relief package that passed with only Democratic votes. Now she’s trying again, but the clock is ticking, and $3.5 trillion is an eye-popping sum of money that rivals the spending the United States unleashed to close out World War II.

#### Attacks on pharmaceutical profits triggers Mod Dem Backlash – it disrupts unity.

Cohen 9-6 Joshua Cohen 9-6-2021 "Democrats’ Plans To Introduce Prescription Drug Pricing Reform Face Formidable Obstacles" <https://www.forbes.com/sites/joshuacohen/2021/09/06/democrats-plans-to-introduce-prescription-drug-pricing-reform-face-obstacles/?sh=37a269917395> (independent healthcare analyst with over 22 years of experience analyzing healthcare and pharmaceuticals.)//Elmer

There’s considerable uncertainty regarding passage with a simple majority of the 2021 massive budget reconciliation bill. Last week, Senator Joe Manchin called on Democrats to pause pushing forward the budget reconciliation bill. If Manchin winds up saying no to the bill, this would scuttle it as the Democrats can’t afford to lose a single Senator. And, there’s speculation that provisions to reduce prescription drug prices may be watered down and not incorporate international price referencing. Additionally, reduced prices derived through Medicare negotiation may not be able to be applied to those with employer-based coverage. While the progressive wing of the Democratic Party supports drug pricing reform, **several key centrist Democrats** in both the House and Senate appear to be **uncomfortable** **with** particular aspects of the budget reconciliation bill, including a potential deal-breaker, namely the potential **negative impact of drug price controls on the domestic pharmaceutical industry**, as well as long-term patient access to new drugs. A paper released in 2019 by the nonpartisan Congressional Budget Office found that the proposed legislation, H.R. 3, would reduce global revenue for new drugs by 19%, leading to 8 fewer drugs approved in the U.S. between 2020 and 2029, and 30 fewer drugs over the next decade. And, a new report from the CBO reinforces the message that drug pricing legislation under consideration in Congress could lead to fewer new drugs being developed and launched. **Intense lobbying efforts from biopharmaceutical industry groups** **are underway**, **warning of** what they deem are **harms from price controls in** the form of diminished patient **access to new innovations**. The argument, based in part on assumptions and modeling included in the CBO reports, asserts that price controls would dampen investment critical to the biopharmaceutical industry’s pipeline of drugs and biologics. **This** won’t sway most Democrats, but has been a traditional talking point in the Republican Party for decades, and **may convince some centrist Democrats to withdraw backing** of provisions **that** in their eyes **stymie pharmaceutical innovation.** If the budget reconciliation bill would fail to garner a majority, a pared down version of H.R. 3, or perhaps a new bill altogether, with Senator Wyden spearheading the effort, could eventually land in the Senate. But, a similar set of provisos would apply, as majority support in both chambers would be far from a sure thing. In brief, Democrats’ plans at both the executive and legislative branch levels to introduce prescription **drug pricing reform** **encounter challenges** which may prevent impactful modifications from taking place.

#### Infrastructure reform solves Existential Climate Change – it results in spill-over.

USA Today 7-20 7-20-2021 "Climate change is at 'code red' status for the planet, and inaction is no longer an option" <https://www.usatoday.com/story/opinion/todaysdebate/2021/07/20/climate-change-biden-infrastructure-bill-good-start/7877118002/> //Elmer

**Not long ago**, **climate change** for many Americans **was** like **a distant bell**. News of starving polar bears or melting glaciers was tragic and disturbing, but other worldly. Not any more. **Top climate scientists** from around the world **warned of a "code red for humanity**" in a report issued Monday that says severe, human-caused global warming is become unassailable. Proof of the findings by the United Nations' Intergovernmental Panel on Climate Change is a now a factor of daily life. Due to **intense heat waves and drought**, 107 wildfires – including the largest ever in California – are now raging across the West, consuming 2.3 million acres. Earlier this summer, hundreds of people died in unprecedented triple-digit heat in Oregon, Washington and western Canada, when a "heat dome" of enormous proportions settled over the region for days. Some victims brought by stretcher into crowded hospital wards had body temperatures so high, their nervous systems had shut down. People collapsed trying to make their way to cooling shelters. Heat-trapping greenhouse gases Scientists say the event was almost **certainly made worse and more intransigent by human-caused climate change**. They attribute it to a combination of warming Arctic temperatures and a growing accumulation of heat-trapping greenhouse gases caused by the burning of fossil fuels. The **consequences of** what mankind has done to the atmo**sphere are now inescapable**. Periods of **extreme heat** are projected to **double** in the lower 48 states by 2100. **Heat deaths** are far **outpacing every other form of weather killer** in a 30-year average. A **persistent megadrought** in America's West continues to create tinder-dry conditions that augur another devastating wildfire season. And scientists say **warming oceans** are **fueling** ever **more powerful storms**, evidenced by Elsa and the early arrival of hurricane season this year. Increasingly severe weather is causing an estimated $100 billion in damage to the United States every year. "It is honestly surreal to see your projections manifesting themselves in real time, with all the suffering that accompanies them. It is heartbreaking," said climate scientist Katharine Hayhoe. **Rising seas** from global warming Investigators are still trying to determine what led to the collapse of a Miami-area condominium that left more than 100 dead or missing. But one concerning factor is the corrosive effect on reinforced steel structures of encroaching saltwater, made worse in Florida by a foot of rising seas from global warming since the 1900s. The clock is ticking for planet Earth. While the U.N. report concludes some level of severe climate change is now unavoidable, there is still a window of time when far more catastrophic events can be mitigated. But mankind must act soon to curb the release of heat-trapping gases. Global **temperature** has **risen** nearly **2 degrees** Fahrenheit since the pre-industrial era of the late 19th century. Scientists warn that in a decade, it could surpass a **2.7**-degree increase. That's **enough** warming **to cause catastrophic climate changes**. After a brief decline in global greenhouse gas emissions during the pandemic, pollution is on the rise. Years that could have been devoted to addressing the crisis were wasted during a feckless period of inaction by the Trump administration. Congress must act Joe Biden won the presidency promising broad new policies to cut America's greenhouse gas emissions. But Congress needs to act on those ideas this year. Democrats cannot risk losing narrow control of one or both chambers of Congress in the 2022 elections to a Republican Party too long resistant to meaningful action on the climate. So what's at issue? A trillion dollar **infrastructure bill** negotiated between Biden and a group of centrist senators (including 10 Republicans) is a start. In addition to repairing bridges, roads and rails, it would **improve access** by the nation's power infrastructure **to renewable energy sources,** **cap millions of abandoned oil and gas wells spewing greenhouse gases**, **and harden structures against climate change**. It also **offers tax credits for** the **purchase of electric vehicles** and funds the construction of charging stations. (**The nation's largest source of climate pollution are gas-powered vehicles**.) Senate approval could come very soon. Much **more is needed** if the nation is going to reach Biden's necessary goal of cutting U.S. climate pollution in half from 2005 levels by 2030. His ideas worth considering include a federal clean electricity standard for utilities, federal investments and tax credits to promote renewable energy, and tens of billions of dollars in clean energy research and development, including into ways of extracting greenhouse gases from the skies. Another idea worth considering is a fully refundable carbon tax. **The vehicle** for these additional proposals **would be a second infrastructure bill**. And if Republicans balk at the cost of such vital investment, Biden is rightly proposing to pass this package through a process known as budget reconciliation, which allows bills to clear the Senate with a simple majority vote. These are drastic legislative steps. But drastic times call for them. And when Biden attends a U.N. climate conference in November, he can use American progress on climate change as a mean of persuading others to follow our lead. Further delay is not an option.

#### Warming guarantees extinction – multiple scenarios

Specktor 19 [Brandon Specktor] “Human Civilization Will Crumble by 2050 If We Don't Stop Climate Change Now, New Paper Claims.” Live Science. June 4, 2019. <https://www.livescience.com/65633-climate-change-dooms-humans-by-2050.html> TG

It seems every week there's a scary new report about how man-made climate change is going to cause the collapse of the world's ice sheets, result in the extinction of up to 1 million animal species and — if that wasn't bad enough — make our [beer very, very expensive](https://www.livescience.com/63832-climate-change-will-ruin-beer.html). This week, a new policy paper from an Australian think tank claims that those other reports are slightly off; the risks of climate change are actually much, much worse than anyone can imagine.

[According to the paper](https://docs.wixstatic.com/ugd/148cb0_b2c0c79dc4344b279bcf2365336ff23b.pdf), climate change poses a "near- to mid-term existential threat to human civilization," and there's a good chance society could collapse as soon as 2050 if serious mitigation actions aren't taken in the next decade.

Published by the Breakthrough National Centre for Climate Restoration in Melbourne (an independent think tank focused on climate policy) and authored by a climate researcher and a former fossil fuel executive, the paper's central thesis is that climate scientists are too restrained in their predictions of how climate change will affect the planet in the near future. [[Top 9 Ways the World Could End](https://www.livescience.com/36999-top-scientists-world-enders.html)]

The current climate crisis, they say, is larger and more complex than any humans have ever dealt with before. General climate models — like the one that the [United Nations' Panel on Climate Change](https://www.ipcc.ch/sr15/) (IPCC) used in 2018 to predict that a global temperature increase of 3.6 degrees Fahrenheit (2 degrees Celsius) could put hundreds of millions of people at risk — fail to account for the sheer complexity of Earth's many interlinked geological processes; as such, they fail to adequately predict the scale of the potential consequences. The truth, the authors wrote, is probably far worse than any models can fathom.

How the world ends

What might an accurate worst-case picture of the planet's climate-addled future actually look like, then? The authors provide one particularly grim scenario that begins with world governments "politely ignoring" the advice of scientists and the will of the public to decarbonize the economy (finding alternative energy sources), resulting in a global temperature increase 5.4 F (3 C) by the year 2050. At this point, the world's ice sheets vanish; brutal droughts kill many of the trees in the [Amazon rainforest](https://www.livescience.com/57266-amazon-river.html) (removing one of the world's largest carbon offsets); and the planet plunges into a feedback loop of ever-hotter, ever-deadlier conditions.

"Thirty-five percent of the global land area, and 55 percent of the global population, are subject to more than 20 days a year of lethal heat conditions, beyond the threshold of human survivability," the authors hypothesized.

Meanwhile, droughts, floods and wildfires regularly ravage the land. Nearly one-third of the world's land surface turns to desert. Entire ecosystems collapse, beginning with the planet's coral reefs, the rainforest and the Arctic ice sheets. The world's tropics are hit hardest by these new climate extremes, destroying the region's agriculture and turning more than 1 billion people into refugees.

This mass movement of refugees — coupled with [shrinking coastlines](https://www.livescience.com/51990-sea-level-rise-unknowns.html) and severe drops in food and water availability — begin to stress the fabric of the world's largest nations, including the United States. Armed conflicts over resources, perhaps culminating in nuclear war, are likely.

The result, according to the new paper, is "outright chaos" and perhaps "the end of human global civilization as we know it."

### 1NC – CP

#### CP: The member nations of the World Trade Organization except for the United States ought to [plan].

#### The United States ought to [plan] through a Supreme Court decision by petitioning the PTAB and getting a formal ruling from APJs.

#### APJs have the authority to rule on intellectual property---the CP solves case.

Mosier 21 [Kevin; 8/9/21; “*Supreme Court Finds Constitutional Violation in Patent Challenges, But Provides Quick Fix*,” JDSupra, <https://www.jdsupra.com/legalnews/supreme-court-finds-constitutional-4702991/>] Justin

For those familiar with inter partes review—or IPR, as it is known—the recent Supreme Court decision in U.S. v. Arthrex was much anticipated because it carried with it the potential to upend the entire IPR system. IPR has been popular with patent challengers and trial court defendants since 2012, when the America Invents Act (“AIA”) took effect. Any person or entity may challenge the validity of a patent by petitioning the Patent Trial and Appeals Board (“the PTAB”). Although IPR petitioners are limited as to the grounds for invalidity they may present, IPR remains an efficient alternative to district court litigation on issues that can overlap with an IPR petition. If the PTAB determines there is a reasonable likelihood that the petitioner would prevail on least one of the patent claims challenged in the petition, the PTAB will institute the petition and hold a trial-like proceeding to determine whether the challenged claims are invalid. Active litigations concerning the same patent are often stayed, that is, put on ice, pending results of the IPR. IPRs are conducted by a panel of administrative patent judges (“APJs”) who are appointed by the Secretary of Commerce. Arthrex, a maker of surgical equipment, argued that APJs are “principal officers” under the Constitution because they wield significant authority and lack meaningful oversight. If APJs are principal officers, they must be appointed by the President and confirmed by the Senate. A Supreme Court holding that APJs are principal officers could have theoretically invalidated all IPR decisions and dramatically altered the IPR system. The lower appellate court—the Federal Circuit—had already determined that APJs are principal officers, but sought to remedy the constitutional concerns in a way that preserved the IPR system. As we wrote at the time, the Federal Circuit reinterpreted statutory limitations on at-will removal of APJs, rendering APJs “inferior officers” who do not need to be appointed by the President and confirmed by the Senate. Although the Supreme Court agreed with the Federal Circuit that the AIA as written caused the APJs to be principal officers, it reversed the Federal Circuit’s decision. The majority opinion held that the root of the constitutional violation was the lack of review authority by a superior officer. The court fixed this problem by bestowing upon the Director of the United States Patent and Trademark Office the unilateral authority to review all IPR decisions so that APJs are properly classified as inferior officers. U.S. v. Arthrex is highly significant for patent owners and IPR petitioners. First and foremost, patent owners who hoped that the IPR system would be scrapped or at least significantly altered did not get their wish. IPR has survived the day and will likely remain as popular as ever with patent challengers and parties accused as infringers. IPR litigants who were hoping for a new hearing before a new panel of APJs did not get their wish either: the Supreme Court made clear that this decision does not entitle prior litigants to new hearings. This decision does, however, present litigants with a vehicle to request that the Director review an IPR determination. All IPR determinations are subject to review and possibly modification or reversal by the Director. Previously, a final written decision by the PTAB was subject to a request for rehearing and then potentially an appeal to the Federal Circuit. Now, as explained in a PTAB Q&A, a party may request either a Director review or panel rehearing, but not both. The Director may also choose to review a final written decision on his or her own initiative. Like a panel rehearing, the Director’s review is appealable to the Federal Circuit. So what next? For now, not much will change aside from potentially greater influence being wielded by the Director. The Supreme Court did not issue guidelines for this additional avenue of review. The decision in Arthrex is notable for providing a simple, direct fix to a constitutional infirmity and not the sea change that those sympathetic to Arthrex’s cause were hoping for.

#### Congress is normal means

Cornell Law [no date, https://www.law.cornell.edu/wex/intellectual\_property\_clause](no%20date,%20https://www.law.cornell.edu/wex/intellectual_property_clause) SM

Article I, Section 8, Clause 8, of the United States Constitution grants Congress the enumerated power "To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

Because this clause is also the source of Congress' power to enact legislation governing copyrights and patents, it is often also referred to as the "Patent and Copyright Clause."

### 1NC – Innovation

#### 1] They don't solve their advantage

#### A] CRISPR tech is so much more than medicine – it can also be used for cosmetic gene editing or warfare. Only reducing patents on genomic medicine can't stop fights over other uses of genomics or threats of lawsuits that trigger all their internal links – read their ev – it doesn’t even reference genomic medicine specifically, which means non-medicinal genomics are a huge alt cause they can’t solve.

#### B] CRISPR is a platform technology, not a medicine.

Editas Medicine [(a clinical-stage biotechnology company which is developing therapies based on CRISPR–Cas9 gene editing technology)., No Date, CRISPR Gene Editing, <https://www.editasmedicine.com/crispr-gene-editing/>] Justin

CRISPR (pronounced “crisper”) is an acronym for “Clustered, Regularly Interspaced, Short Palindromic Repeats,” and refers to a recently developed gene editing technology that can revise, remove, and replace DNA in a highly targeted manner. CRISPR is a dynamic, versatile tool that allows us to get to and edit nearly any location in the genome, and has the potential to help us develop medicines for people with a wide variety of diseases. We view CRISPR as a “platform” technology because of its ability to target DNA in any cell or tissue.

#### 2] Patents are good.

**Sherkow 17** [(Jacob, Professor of Law at the College of Law and Affiliate of the Carl R. Woese Institute for Genomic Biology at the University of Illinois, where his research focuses on the legal and ethical implications of advanced biotechnologies, especially as related to intellectual property. He is a leading expert on IP protection for genome-editing technologies, including CRISPR. He is the author of over 60 articles published in both scientific journals and traditional law reviews, including Science, Nature, the Yale Law Journal, and the Stanford Law Review. Since 2018, Sherkow has also been a Permanent Visiting Professor at the Center for Advanced Studies in Biomedical Innovation Law (“CeBIL”) at the University of Copenhagen Faculty of Law) “Patent protection for CRISPR: an ELSI review” Journal of Law and the Biosciences 12/7/2017 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5965580/>] // Re-Cut Justin

Most of the commentary on the CRISPR patents has been negative—and, in particular, the negative side of patenting the products of academic research.[59](javascript:;) But—aside from money—there are some significant social positives as well. At their core, patents are rights to exclude others from practicing the claimed invention.[60](javascript:;) The corollary to this axiom is that patents therefore allow their owners to dictate to the rest of the world *how* to use the inventors’ technology.[61](javascript:;) This power to direct others’ research can be harnessed for societal good.[62](javascript:;) Where the claimed technology raises ethical or social concerns, patent holders have the right to tell their technologies’ users to behave ethically and to provide access to downstream inventions.[63](javascript:;) In this sense, patents—when used well—can function as a powerful form of private governance.[64](javascript:;)

This is certainly the case with CRISPR, the ethical and social issues of which have been explored at length.[65](javascript:;) One potentially problematic use of CRISPR is its use in ‘gene drives’, a daisy chain of genetic editing that essentially forces future generations to inherit and subsequently pass on only a single variant of a particular gene.[66](javascript:;) The concern, as detailed by Kevin Esvelt, is that gene drives, because they are forcibly heritable, become difficult to control once put in place.[67](javascript:;) Should later research find negative, unintended effects of the particular genetic variant driven through the population, it may simply be too late.[68](javascript:;) To that end, Esvelt and others have proposed patenting the use of CRISPR-based gene drives to, essentially, prevent others from using the technology without rigorous scientific and ethical controls.[69](javascript:;) The legal mechanics of enforcing patent protection in this manner leave some gaps that likely need to be addressed. But Esvelt's proposal suggests, at a minimum, that patenting controversial technologies is one possible tool to further their ethical use.

In other cases, rather than using patents to ethically *restrict* access to controversial technologies, patents can be used to ethically promote access to the same. That is, patent holders can demand licensees promise that they make their technology available to broad segments of society, and on fair terms.[70](javascript:;) This is largely the case with Monsanto's license from the Broad Institute covering the use of CRISPR-Cas9 for a variety of agricultural purposes. That license essentially requires Monsanto to allow its farmer customers to save and resew seed from one season to the next, in contrast to some of Monsanto's past practices.[71](javascript:;) Requiring this of Monsanto provides greater access to the fruits of CRISPR technology to farmers, who would otherwise be required to purchase expensive new seed each year from Monsanto.[72](javascript:;) In the therapeutics context, similar license restrictions could be used, in theory, to require price controls, access plans, or that research and development funds be used, in part, to develop treatments for neglected diseases.[73](javascript:;)

And, perhaps counterintuitively, patents could also be used to ensure research access to a variety of technologies. Patent holders can publicly commit to refuse to enforce their patents against researchers or academic institutions. In the USA, these frequently take the form of ‘patent pledges’—‘commitments made voluntarily by patent holders to limit the enforcement or other exploitation of their patents’.[74](javascript:;) Doing so both prevents others from patenting—and suing others—on the same technology, and dissuades less ethically minded competitors from entering the field.[75](javascript:;) Patent holders can also use open licensing systems to researchers interesting in developing and sharing the technology for the public good. In the CRISPR context, this non-commercial use is mediated through a non-profit organization, AddGene, a company that provides access to CRISPR constructs and plasmids through a standardized Biological Materials Transfer Agreement (BMTA). AddGene's BMTA’s contains patent licenses for academic use of the underlying technology.[76](javascript:;)

#### 3] CRISPR fails.

CUMC 17, Columbia University Medical Center, 5-30-2017, "CRISPR Gene Editing Can Cause Hundreds of Unintended Mutations," http://newsroom.cumc.columbia.edu/blog/2017/05/30/crispr-gene-editing-can-cause-hundreds-of-unintended-mutations/

As CRISPR-Cas9 starts to move into clinical trials, a new study published in Nature Methods has found that the gene-editing technology can introduce hundreds of unintended mutations into the genome. “We feel it’s critical that the scientific community consider the potential hazards of all off-target mutations caused by CRISPR, including single nucleotide mutations and mutations in non-coding regions of the genome,” says co-author Stephen Tsang, MD, PhD, the Laszlo T. Bito Associate Professor of Ophthalmology and associate professor of pathology & cell biology in the Institute of Genomic Medicine and the Institute of Human Nutrition at Columbia University Medical Center. CRISPR-Cas9 editing technology—by virtue of its speed and unprecedented precision—has been a boon for scientists trying to understand the role of genes in disease. The technique also has raised hope for more powerful gene therapies that can delete or repair flawed genes, not just add new genes. The first clinical trial to deploy CRISPR is now underway in China, and a U.S. trial is slated to start next year. But even though CRISPR can precisely target specific stretches of DNA, it sometimes hits other parts of the genome. Most studies that search for these off-target mutations use computer algorithms to identify areas most likely to be affected and then examine those areas for deletions and insertions. “These predictive algorithms seem to do a good job when CRISPR is performed in cells or tissues in a dish, but whole genome sequencing has not been employed to look for all off-target effects in living animals,” says co-author Alexander Bassuk, MD, PhD, professor of pediatrics at the University of Iowa. In the new study, the researchers sequenced the entire genome of mice that had undergone CRISPR gene editing in the team’s previous study and looked for all mutations, including those that only altered a single nucleotide. The researchers determined that CRISPR had successfully corrected a gene that causes blindness, but Kellie Schaefer, a PhD student in the lab of Vinit Mahajan, MD, PhD, associate professor of ophthalmology at Stanford University, and co-author of the study, found that the genomes of two independent gene therapy recipients had sustained more than 1,500 single-nucleotide mutations and more than 100 larger deletions and insertions. None of these DNA mutations were predicted by computer algorithms that are widely used by researchers to look for off-target effects. “Researchers who aren’t using whole genome sequencing to find off-target effects may be missing potentially important mutations,” Dr. Tsang says. “Even a single nucleotide change can have a huge impact.”

#### 4] CRISPR’s useless OR mutations are inev regardless

Fu et al 13 [Yanfang Fu, Molecular Pathology Unit at Mass General Hospital, Department of Pathology, Harvard Medical School.] “High-frequency off-target mutagenesis induced by CRISPR-Cas nucleases in human cells” Nature Biotechnology volume 31, pages 822–826 (2013) (https://www.nature.com/articles/nbt.2623) – MZhu

Clustered, regularly interspaced, short palindromic repeat (CRISPR) RNA-guided nucleases (RGNs) have rapidly emerged as a facile and efficient platform for genome editing. Here, we use a human cell–based reporter assay to characterize off-target cleavage of CRISPR-associated (Cas)9-based RGNs. We find that single and double mismatches are tolerated to varying degrees depending on their position along the guide RNA (gRNA)-DNA interface. We also readily detected off-target alterations induced by four out of six RGNs targeted to endogenous loci in human cells by examination of partially mismatched sites. The off-target sites we identified harbored up to five mismatches and many were mutagenized with frequencies comparable to (or higher than) those observed at the intended on-target site. Our work demonstrates that RGNs can be highly active even with imperfectly matched RNA-DNA interfaces in human cells, a finding that might confound their use in research and therapeutic applications.

#### 5] CRISPR induces secondary mutations that ensures it will fail clinical trials, and any legitimate applications.

Schaefer 17 [Kellie Schaefer, Omnics Laboratory at Stanford University.] “Unexpected mutations after CRISPR–Cas9 editing in vivo” Nature Methods 14, 547–548 (2017) (<https://www.nature.com/nmeth/journal/v14/n6/full/nmeth.4293.html>) – MZhu

CRISPR–Cas9 editing shows promise for correcting disease-causing mutations. For example, in a recent study we used CRISPR-Cas9 for sight restoration in blind rd1 mice by correcting a mutation in the Pde6b gene1. However, concerns persist regarding secondary mutations in regions not targeted by the single guide RNA (sgRNA)2. Algorithms generate likely off-target sites for a given gRNA, but these algorithms may miss mutations. Whole-genome sequencing (WGS) has been used to assess the presence of small insertions and deletions (indels)3 but not to probe for single-nucleotide variants (SNVs) in a whole organism. We performed WGS on a CRISPR–Cas9-edited mouse to identify all off-target mutations and found an unexpectedly high number of SNVs compared with the widely accepted assumption that CRISPR causes mostly indels at regions homologous to the sgRNA. We tested four sgRNAs in cells then chose the sgRNA with the highest activity for in vivo targeting. DNA was isolated from two CRISPR-repaired mice (F03 and F05) and one uncorrected control1. CRISPR–Cas9-treated mice were sequenced at an average depth of 50×, and the control was sequenced at 30×. Variant calls were confirmed by at least 23× sequencing coverage (Supplementary Tables 1 and 2). Multiple variant-calling software pipelines identified indels and SNVs (Fig. 1 and Supplementary Methods). In the CRISPR-treated mice, targeted alleles were repaired1. Off-target mutations were identified as those present in the CRISPR-treated animals but absent in the uncorrected control. All pipelines showed that F03 harbored 164 indels and 1,736 SNVs (63 and 885 of these, respectively, associated with known genes). F05 harbored 128 indels and 1,696 SNVs (51 and 865 of these, respectively, associated with known genes) (Fig. 1). The same 117 indels and 1,397 SNVs were detected in both of the CRISPR-treated mice, which indicated nonrandom targeting. SNVs appeared to slightly favor transitions over transversions (Supplementary Fig. 1). The mutation rate detected in CRISPR-treated mice was substantially higher than that generated by spontaneous germline mutations (3 to 4 indels and 90 to 100 SNVs, de novo, per generation)4, 5. As additional controls, each of the variants was compared with the FVB/NJ genome in the mouse dbSNP database (v138), and each of the SNVs was also compared with all 36 strains in the Mouse Genome Project (v3). None of the CRISPR-generated off-target mutations were found in any of these strains, which further confirmed that these WGS-identified SNVs were the result of CRISPR–Cas9 off targeting. All pipelines identified 6 and 3 indels and 60 and 51 SNVs in F03 and F05 mice, respectively, in exonic regions only (Fig. 1); 5 indels and 24 SNVs caused nonsynonymous mutations in protein-coding sequences (Supplementary Tables 3 and 4). Of these, all five indels and one SNV (introducing a premature stop codon) were expected to be deleterious. Several mutated protein-coding genes were associated with a human and/or mouse phenotype (Supplementary Tables 3 and 4). Of the 29 coding-sequence variants, 7 variants were mutated identically in both mice. 24 CRISPR-associated variants were selected, and all were confirmed by Sanger sequencing (Supplementary Fig. 2 and Supplementary Methods). Among the top-fifty sequences predicted for off targeting, none were mutated. Additionally, there was poor sequence homology between the sgRNA and sequences near the actual off-target coding and noncoding variants (Supplementary Fig. 3). Our results suggest current in silico modeling cannot predict bona fide off-target sites. Together, these results indicate that at least certain sgRNAs may target loci independently of their target in vivo. The unpredictable generation of these variants is of concern. The impact of the numerous mutations occurring in noncoding RNAs or other regulatory intragenic regions could be detrimental to key cellular processes (Supplementary Fig. 4 and Supplementary Table 5)6. Although our CRISPR-treated mice did not display obvious extraocular phenotypes, it is possible the mice may reveal phenotypes in time, when they are challenged or bred to homozygosity. The present study demonstrates WGS analysis of both indels and SNVs as the most thorough method for identifying off-target mutations and shows a significantly higher number of potentially deleterious CRISPR–Cas9-induced mutations than have been previously reported3. It is not clear whether improved sgRNA design or use of high-fidelity Cas9 may reduce off-target mutations, or whether in vivo off targets are a general problem of any sgRNA. Our study places the onus on researchers to carefully assay their specific gRNA and Cas9 for off-target mutations. More work may be needed to increase the fidelity of CRISPR–Cas9 with regard to off-target mutation generation before the CRISPR platform can be used without risk, especially in the clinical setting. Future studies employing new CRISPR methods and reagents should consider using WGS to determine the presence of off-target mutations in vivo.

### 1NC – WTO

#### No war from econ decline

Clary 15 – Christopher Clary, former International Affairs Fellow in India at the Council on Foreign Relations, Postdoctoral Fellow at the Watson Institute at Brown University, Adjunct Staff Member @ RAND Corporation, Security Studies Program @ MIT, country director for South Asian affairs in the Office of the Secretary of Defense, former Research Fellow @ the Harvard Kennedy School's Belfer Center for Science and International Affairs, former research associate in the Department of National Security Affairs at the Naval Postgraduate School, BA from Wichita State University and an MA from the U.S. Naval Postgraduate School, 2015 (“Economic Stress and International Cooperation: Evidence from International Rivalries,” Massachusetts Institute of Technology Political Science Department Research Paper No. 2015-­‐8, “Economic Stress and International Cooperation: Evidence from International Rivalries,” <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2597712>)

Do economic downturns generate pressure for diversionary conflict? Or might downturns encourage austerity and economizing behavior in foreign policy? This paper provides new evidence that economic stress is associated with conciliatory policies between strategic rivals. For states that view each other as military threats, the biggest step possible toward bilateral cooperation is to terminate the rivalry by taking political steps to manage the competition. Drawing on data from 109 distinct rival dyads since 1950, 67 of which terminated, the evidence suggests rivalries were approximately twice as likely to terminate during economic downturns than they were during periods of economic normalcy. This is true controlling for all of the main alternative explanations for peaceful relations between foes (democratic status, nuclear weapons possession, capability imbalance, common enemies, and international systemic changes), as well as many other possible confounding variables. This research questions existing theories claiming that economic downturns are associated with diversionary war, and instead argues that in certain circumstances peace may result from economic troubles. Defining and Measuring Rivalry and Rivalry Termination I define a rivalry as the perception by national elites of two states that the other state possesses conflicting interests and presents a military threat of sufficient severity that future military conflict is likely. Rivalry termination is the transition from a state of rivalry to one where conflicts of interest are not viewed as being so severe as to provoke interstate conflict and/or where a mutual recognition of the imbalance in military capabilities makes conflict-causing bargaining failures unlikely. In other words, rivalries terminate when the elites assess that the risks of military conflict between rivals has been reduced dramatically. This definition draws on a growing quantitative literature most closely associated with the research programs of William Thompson, J. Joseph Hewitt, and James P. Klein, Gary Goertz, and Paul F. Diehl.1 My definition conforms to that of William Thompson. In work with Karen Rasler, they define rivalries as situations in which “[b]oth actors view each other as a significant politicalmilitary threat and, therefore, an enemy.”2 In other work, Thompson writing with Michael Colaresi, explains further: The presumption is that decisionmakers explicitly identify who they think are their foreign enemies. They orient their military preparations and foreign policies toward meeting their threats. They assure their constituents that they will not let their adversaries take advantage. Usually, these activities are done in public. Hence, we should be able to follow the explicit cues in decisionmaker utterances and writings, as well as in the descriptive political histories written about the foreign policies of specific countries.3 Drawing from available records and histories, Thompson and David Dreyer have generated a universe of strategic rivalries from 1494 to 2010 that serves as the basis for this project’s empirical analysis.4 This project measures rivalry termination as occurring on the last year that Thompson and Dreyer record the existence of a rivalry.5 Why Might Economic Crisis Cause Rivalry Termination? Economic crises lead to conciliatory behavior through five primary channels. (1) Economic crises lead to austerity pressures, which in turn incent leaders to search for ways to cut defense expenditures. (2) Economic crises also encourage strategic reassessment, so that leaders can argue to their peers and their publics that defense spending can be arrested without endangering the state. This can lead to threat deflation, where elites attempt to downplay the seriousness of the threat posed by a former rival. (3) If a state faces multiple threats, economic crises provoke elites to consider threat prioritization, a process that is postponed during periods of economic normalcy. (4) Economic crises increase the political and economic benefit from international economic cooperation. Leaders seek foreign aid, enhanced trade, and increased investment from abroad during periods of economic trouble. This search is made easier if tensions are reduced with historic rivals. (5) Finally, during crises, elites are more prone to select leaders who are perceived as capable of resolving economic difficulties, permitting the emergence of leaders who hold heterodox foreign policy views. Collectively, these mechanisms make it much more likely that a leader will prefer conciliatory policies compared to during periods of economic normalcy. This section reviews this causal logic in greater detail, while also providing historical examples that these mechanisms recur in practice.

#### Lake doesn’t say anything—it cites no statistics or examples and just says it might trigger conflict between two great powers, not that that conflict will break out into war—there can be militarized conflicts that aren’t war, i.e Noko US relations happening now.

#### The aff causes the WTO to attract jurisdiction which trades off with the efficacy and legitimacy of regional trade agreements.

Kwak and Marceau 16 “Overlaps and Conflicts of Jurisdiction between the World Trade Organization and Regional Trade Agreements,” Kyung Kwak [Kyung Kwak is an associate of a law firm, Ashurst, in Brussel] and Gabrielle Marceau [Gabrielle Marceau, Ph.D., is counsellor in the Légal Affairs Division of the Secretariat to the World Trade Organization] Published online by Cambridge University Press: 09 March 2016 <https://www.cambridge.org/core/journals/canadian-yearbook-of-international-law-annuaire-canadien-de-droit-international/article/abs/overlaps-and-conflicts-of-jurisdiction-between-the-world-trade-organization-and-regional-trade-agreements/6C0C9CA77BED3390A38226F9E01EB44D> SM

The relationship between the dispute settlement mechanism of the World Trade Organization (WTO) and that of regional trade agreements (RTAs) demonstrates the difficulties surrounding the issues of overlaps/conflicts of Jurisdiction and of hierarchy of norms in international law.1 Jurisdiction is often defined in terms of either legislative or judicial Jurisdiction — that is, the authority to legislate or to adjudicate on a matter. Jurisdiction may be analyzed from horizontal points of view (the allocation of Jurisdiction among states or among international organizations) and from a vertical point of view (the allocation of jurisdiction between states and international organizations) . 2

This article addresses the issue of horizontal allocation of judicial jurisdiction between RTAs and the WTO, as expressed in the dispute settlement provisions of each treaty. The choice of a dispute settlement forum is often an expression of the importance that states give to the System of norms that may be enforced by the related dispute settlement mechanism. For instance, if the same states — which are parties to two treaties A and B that contain similar obligations — provide that priority or exclusivity is given to the dispute settlement mechanism of A over that of B, it may be that the states are expressing their choice to favour the enforcement of treaty A over treaty B.

In the case of RTAs, the situation is further complicated because the General Agreement on Tariffs and Trade (GATT)3 authorizes WTO members to form regional trade agreements. The WTO jurisprudence has made it clear that members have a "right" to form preferential trade agreements. This right is however conditional. In the context of an RTA, Article XXIV may justify a measure that is inconsistent with certain other GATT provisions. However, in a case involving the formation of a customs union, this RTA "defence" is available only when two conditions are fulfilled. First, the party claiming the benefit of this defence must demonstrate that the measure at issue is introduced upon the formation of a customs union that fully meets the requirements of sub-paragraphs 8 (a) and 5 (a) of Article XXIV. Second, this party must demonstrate that the formation of the customs union would be prevented if it were not allowed to introduce the measure at issue. Again, both of these conditions must be met to have the benefit of the defence under Article XXIV of GATT.4

Many RTAs include (substantive) rights and obligations that are parallel to those of the Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement).5 Generally, these RTAs may provide for their own dispute settlement mechanism, which makes it possible for the states to resort to different but parallel dispute settlement mechanisms for parallel or even similar obligations. This situation is not unique as states are often bound by multiple treaties, and the dispute settlement Systems of these treaties operate in a parallel manner.6 At the same time, the WTO dispute settlement System claims to be compulsory and exclusive. Article 23 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU)7 mandates exclusive jurisdiction in favour of the DSU for WTO violations. By simply alleging that a measure affects or impairs its trade benefits, a WTO member is entitled to trigger the quasi-automatic, rapid, and powerful WTO dispute settlement mechanism, excluding thereby the competence of any other mechanism to examine WTO law violations. The challenging member does not need to prove any specific economic or legal interest nor provide any evidence of the trade impact of the challenged measure in order to initiale the DSU mechanism.8 The WTO will thus often "attract" jurisdiction over disputes with (potential) trade effects even if such disputes could also be handled in fora other than that of the WTO.

OVERLAPS OF JURISDICTION BETWEEN RTAs AND THE WTO

Overlaps of jurisdiction in dispute settlement can be defined as situations where the same dispute or related aspects of the same dispute could be brought to two distinct institutions or two different dispute settlement Systems. Under certain circumstances, this occurrence may lead to difficulties relating to "forum-shopping," whereby disputing entities would have a choice between two adjudicating bodies or between two different jurisdictions for the same facts. When the dispute settlement mechanisms of two agreements are triggered in parallel or in sequence, there are problems on two levels: first, the two tribunals may claim final jurisdiction (supremacy) over the matter and, second, they may reach different, or even opposite, results.9

Various types of overlaps of jurisdiction may occur. For the purpose of the present discussion, an overlap of jurisdiction occurs: ( i ) when two fora claim to have exclusive jurisdiction over the matter; (2) when one forum claims to have exclusive jurisdiction and the other one offers jurisdiction, on a permissive basis, for dealing with the same matter or a related one; or (3) when the dispute settlement mechanisms of two different fora are available (on a non-mandatory basis) to examine the same or similar matters. Conflicts are possible in any of these three situations. All of the RTAs examined in Table i at the end of this article have dispute settlement mechanisms with jurisdiction that may potentially overlap with that of the WTO Agreement.