### 2NR

Biotech

Biotech indistry strong in squo as we see w vacinees role out and strong phrama- secondary patents k2 strong drigs- one and done kills innovation since compoanie have noi incentive to imporve vac’s along w killing legistation and vac rollout- which stops their future pandemics and bioterror pandemics- which are unique since theyre engirneed to be dagerou which causes exinction

At- read doesn’t cause exinction for pandemics

Bioterror uniique as these are human made pandemics

Infasture bill will pass no per uniqueness- but plan for everugreening skews it up which kills PC because voters of bill have to go back and rethink- that causes the bill ot the pass for lower innovation by no concertration and no funding- China and Russia then can attack us and take over heg which causes exinction since US heg is an impact filter

### 1

#### Biotech industry strong now – new innovation and R&D coming

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

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

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

What about SPACs?

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

Fundamentals continue strong

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

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

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

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

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

More innovation on the horizon

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

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

#### Secondary patents are necessary for innovation of otherwise mediocre drugs—core to cancer and HIV treatments

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection” <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> September 21, 2018)DR 21

The attack on secondary pharmaceutical patents is based in part on the flawed premise that follow-on innovation is of marginal value at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, follow-on innovation can play a critical role in transforming an interesting drug candidate into a safe and effective treatment option for patients. A good example can be seen in the case of AZT (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT began its life as a failed attempt at a cancer drug, and it was **only years later that its potential application in the fight against AIDS was realized**. Follow-on research resulted in **a method-of-use patent** directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate.

Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include Evista (raloxifene, **used in the treatment of** osteoporosis and to reduce the risk of invasive breast cancer), Zyprexa (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime.

Pharmaceutical development is prolonged and unpredictable, and frequently a safe and effective drug occurs only as a result of follow-on innovation occurring long after the initial synthesis and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on **the active ingredient itself.**

#### One and done model kills innovation—chilling effect

**Magiera 2021** (Melissa S., J.D. Candidate, 2021, Indiana UniversityRobert H. McKinney School of Law; B.S. 2017, Indiana University Purdue University Indianapolis – Indianapolis, Indiana. Recipient of the Papke Prize for Best Note in Volume 54, endowed by and named in honor of David R. Papke, former R. Bruce Townsend Professor of Law and faculty advisor to the Indiana Law Review “Leaving the Evergreening Problem to the Patent Experts--The USPTO, the PTAB, and the Federal Circuit” Indiana Law Review, 54(1), 195-220.)DR 21

Additionally, the pharmaceutical industry spends millions of dollars in researching new uses or safer ways to administer known drugs.94 A new use or method of administering or making a known drug should be rewarded with a patent; if not, many pharmaceutical companies will treat the discovered drugs as “one-and-dones.” 95 Patents are meant to be issued for innovations, not for products.96 Just because a patent is granted on a medicine does not mean that the innovation relating to the drug ends; in fact, many pharmaceutical companies continue to research “new ways to make the medicine, new populations who can benefit from its use, better ways to get it to and into patients, and new versions that expand options for patents.” 97 The effect of this legislation, if enacted, likely would be to focus on lowering the price of medicine for patients at the cost of denying rightful patents to pharmaceutical companies that could have made new medical advances for the good of society. 98 Any pharmaceutical company would be scrutinized for any additional innovation of a drug and may be subject to penalties.99 Eventually, this means that the pharmaceutical companies could halt further research on any patented drug, even if there is a better, undiscovered use for that drug. 100 If enacted, the legislation could also “erode[] incentives and threaten[] innovation,” which is what the patent system was created to protect. 101

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror – turns case

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

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

#### COVID incentivizes engineered bioterror- extinction

Walsh, 20 -- Axios Future correspondent [Bryan Walsh, "The coronavirus pandemic reawakens bioweapon fears," Axios, 5-14-2020, https://www.axios.com/coronavirus-pandemic-pathogen-bioweapon-45417c86-52aa-41b1-8a99-44a6e597d3a8.html, accessed 9-7-2020]

The coronavirus pandemic reawakens bioweapon fears

The immense human and economic toll of the COVID-19 pandemic only underscores the threat posed by pathogens that could be deliberately engineered and released.

Why it matters: New technology like gene editing and DNA synthesis has made the creation of more virulent pathogens easier. Yet security and regulation efforts haven't kept pace with the science.

What's happening: Despite some claims by the White House, overwhelming scientific evidence indicates that the novel coronavirus was not accidentally released from a lab or deliberately engineered, but naturally spilled over from an animal source.

That doesn't mean the threat from bioweapons isn't dire. Along with AI, engineered pandemics are widely considered the biggest existential risk facing humanity.

That's in part because a pathogen could be engineered in a lab for maximum contagiousness and virulence, well beyond what would arise through natural selection.

Case in point: a 2018 pandemic simulation put on by the Johns Hopkins Center for Health Security featured a fictional engineered virus called Clade X that combined the contagiousness of the common cold with the virulence of the real-life Nipah virus, which has a mortality rate of 40-75%. The resulting simulated global outbreak killed 150 million people.

COVID-19 isn't anywhere near that fatal, but the pandemic has shown the vulnerability of the U.S. and the world to biological threats both natural and manmade.

"Potential adversaries are of course seeing the same things we’re seeing," says Richard Pilch of the Middlebury Institute of International Studies. "Anyone looking for a radical leveling approach — whether a state actor like North Korea or a motivated terrorist organization — may be influenced by COVID-19 to consider pursuing a biological weapons capability."

Background: Bioweapons were officially banned by the Biological Weapons Convention in 1975, though North Korea is suspected of maintaining an offensive bioweapons program.

A particular concern about biowarfare and bioterror, though, is that many of the tools and methods that could be used to create a weaponized virus are largely indistinguishable from those used in the course of legitimate scientific research. This makes biotechnology "dual-use" — and that much more difficult to safely regulate without cutting off research that could be vitally important.

While earlier bioweapons fears focused on the possibility that a state or terror group could try to weaponize a known dangerous agent like smallpox — which would require somehow obtaining restricted pathogens — new technology means that someone could obtain the genetic sequence of a germ online and synthesize it in the lab.

"If you've been trained in a relevant technical discipline, that means you can make almost any potentially harmful agent that you're aware of," says Kevin Esvelt, a biologist at the MIT Media Lab and a member of the CDC's Biological Agent Containment Working Group. That would include the novel coronavirus that causes COVID-19, which was recently synthesized from its genetic sequence in a study published in Nature.

How it works: Currently, synthetic DNA is ordered through commercial suppliers. But while most suppliers screen DNA orders for the sequences of dangerous pathogens, they're not required to — and not all do, which means safety efforts are "incomplete, inaccurate, and insecure," says Esvelt.

Screening efforts that look for the genetic sequences of known pathogens also wouldn't necessarily be able to detect when synthetic DNA was being used to make something entirely novel and dangerous.

In the near future, desktop DNA synthesizers may be able to generate synthetic DNA in the lab, cutting out the need for commercial suppliers — and potential security screenings.

The democratization of biotechnology could unleash a wave of creativity and innovation, just as the democratization of personal computing did. But it also increases the number of people who could potentially make a dangerous engineered virus, whether deliberately or by accident.

### 2

#### Bipartisan antitrust bills passing now but continued PC needed to pacify republicans.

Perlman 9/3 [Matthew; 9/3/21; “*Interest Groups Back Big Tech Antitrust Bills In House,*” LAW360, <https://www.law360.com/competition/articles/1418789/interest-groups-back-big-tech-antitrust-bills-in-house>] Justin

Law360 (September 3, 2021, 7:25 PM EDT) -- A contingent of public interest groups are urging leaders of the U.S. House of Representatives to advance a package of legislation aimed at reining in Big Tech companies through updates and changes to antitrust law, though free market advocates have been jeering many of the bills. A total of 58 public interest and consumer advocacy groups signed on to a letter Thursday asking House leaders to swiftly pass the package of six antitrust bills that the Judiciary Committee approved in late June after a marathon markup session. The proposals include legislation prohibiting large platform companies from acquiring competitive threats, preferencing their own services and using their control of multiple business lines to disadvantage competitors in other ways. The proposals would also impose interoperability and data portability requirements on large tech platforms, increase merger filing fees and boost enforcement by state attorneys general. Charlotte Slaiman, competition policy director for Public Knowledge, which signed on to the letter, said in a statement Thursday that the package charts a path toward putting "people back in control of the digital economy." "The broad range of groups supporting this package shows just how widespread the problem of Big Tech dominance is, and that these bills deserve a full vote in the House imminently," Slaiman said. The letter contends that America has a monopoly problem that is resulting in lower wages, reduced innovation and increased inequality, while also undermining the free press and perpetuating "racial, gender and class dominance." "Big Tech monopolies are at the center of many of these problems," the letter said. "Reining in these companies is an essential first step to reverse the damage of concentrated corporate power throughout our economy." The proposals followed a 16-month investigation by the House antitrust subcommittee into Amazon, Apple, Facebook and Google that resulted in a sprawling report from Democratic members calling for a range of reform measures to rein in the dominance of the companies. While consumer advocacy groups have largely supported the measures, the tech companies themselves and other interest groups have been highly critical, including a coalition of more than 25 right-leaning groups that sent a letter to Congress ahead of the markup hearing. The letter called the bills a "Trojan horse package" aimed at cynically using conservative anger over Big Tech, particularly at perceived censorship by social media platforms, to seek bipartisan support for "European-style over-regulation." For its part, Facebook has called the proposals a "poison pill for America's tech industry at a time our economy can least afford it" and said the bills underestimate the fierce competition the U.S. companies face from abroad. Apple and Google also raised concerns about the impact the bills would have on innovation, as well as on privacy and security. And Amazon has warned about the potential consequences of the proposals for both small businesses that sell on its platform and the consumers who use it to shop. Ending Platform Monopolies Act Thursday's letter said that the Ending Platform Monopolies Act would address "the most problematic aspects of the Big Tech companies" by allowing enforcers to break-up or separate pieces of the businesses when they create conflicts of interest that give the platforms an advantage over potential competitors and business users. A fact sheet from Public Knowledge accompanying the letter said that the bill is an important tool to help the antitrust agencies "protect consumers from mammoth platforms and to ensure compliance with other parts of the package." But during the markup hearing, ranking Republican committee member Rep. Jim Jordan of Ohio blasted the bill as a regulatory overreach, calling it "quite literally central planning" and arguing that it has significant ambiguities, which is bad for business. The Competitive Enterprise Institute argued in a June statement that the bill "kills the goose that lays the golden egg," and would actually result in small businesses being unable to access the large platforms, which in turn would focus on their own offerings instead. The Chamber of Progress has warned that the proposal could bar Amazon from offering its Prime services and its Amazon Basics private label products, since they would compete against other sellers on the platform. Other groups have also warned it could also force tech companies to divest popular apps, including Google's Maps and YouTube, Facebook's WhatsApp and Instagram and Apple's iMessage and FaceTime. American Innovation and Choice Online Act The American Innovation and Choice Online Act is aimed at barring the platform companies from preferencing their own products and services over those of rival businesses and from excluding or discriminating against rivals. Thursday's letter said this proposal would "promote innovation and competition" by preventing the platforms from protecting their monopolies. The right-leaning think tank American Enterprise Institute and others have argued that the bill could prevent Apple from pre-installing certain apps on its mobile phones, since that would advantage it over competing app developers. It could also prevent Google from integrating maps or customer reviews into search results, among other things. "At a minimum, the act would significantly disrupt these platforms' business models in ways that undermine consumer value," Daniel Lyons, a senior fellow for the group wrote in a blog post in June. Platform Competition and Opportunity Act The Platform Competition and Opportunity Act is aimed at preventing platform companies from acquiring potential or nascent competitors and its supporters argued in Thursday's letter that it would prevent the tech giants from enhancing or maintaining their market power. The bill would presumably have blocked Facebook's purchases of WhatsApp, Instagram and other services it has acquired, as well as a slew of deals by Google over the past two decades. Detractors have contended that this bill would limit investments in startups because it restricts their ability to be acquired by the larger technology firms, which they say is a key way for founders to benefit from their success. An American Enterprise Institute blog post from June argues that "opportunities for acquisition have been important drivers of innovation in tech" and also said the bill would prevent the tech companies from entering new areas of business to compete with each other. ACCESS Act The Augmenting Compatibility and Competition by Enabling Service Switching, or ACCESS Act, imposes requirements for the tech companies to make user data portable and able to be used by competing services. The bill's supporters argued in Thursday's letter that this prevents the tech giants from locking users into their services, since users can take their data with them and use it on other networks. Privacy and security implications have been flagged as potential problems for the proposal, with the Competitive Enterprise Institute saying in a statement in June that it's an "anti-privacy bill" that forces companies to turn over private user information to others. The group also said the bill would try to micromanage "complex, dynamic, and highly competitive markets" that are beyond understanding for most politicians and regulators. The American Enterprise Institute has also contended that the requirements would actually make rivals even more dependent on the incumbent platforms. Filing fees and state enforcement Of the antitrust bills approved by the House Judiciary Committee, the ones with the most bipartisan support appear to be the Merger Filing Fee Modernization Act and the State Antitrust Enforcement Venue Act, though it took a day of debate before the committee passed them. A Senate version of the filing fee bill passed that chamber in June as part of the U.S. Innovation and Competition Act. It would raise the fees merging parties pay when reporting large transactions, while lowering fees for smaller deals, in order to raise more resources for the antitrust agencies. Information Technology & Innovation Foundation argued in an August blog post that the legislation does not give Congress enough oversight over how the agencies will use the funds that it raises and called for the bill to include provisions requiring the money be used to hire more staff dedicated to antitrust enforcement. The Competitive Enterprise Institute also raised concerns about congressional oversight and contended that the bill would increase the cost of doing business at a time when the economy is sputtering. "U.S. consumers need innovative services and affordable products, not higher prices passed onto them by businesses avoiding new, unnecessary regulatory compliance costs," the group said in a June blog post. The state enforcement bill would prevent antitrust cases brought by state attorneys general from being transferred to a different venue by the Judicial Panel on Multidistrict Litigation, similar to protections afforded to federal enforcers. The bill is intended to prevent companies targeted by state-led enforcement actions from trying to move the cases to more favorable venues, and it also has an analog in the Senate. Information Technology & Innovation Foundation acknowledged in their August post that having cases included in multidistrict litigation can handicap state enforcers, but contended the changes should only apply to criminal matters and that the current version is wrong to block transfers of civil cases too. Thursday's letter from supporters of the bills said the proposals were carefully crafted to address the abusive practices of Big Tech, informed by the House antitrust subcommitee's sprawling investigation and "historic" 450-page report. "We believe that these bills will bring urgently needed change and accountability to these companies and an industry that most Americans agree is already doing great harm to our democracy," the letter said.

#### Aff requires negotiations that saps PC.

Pooley 21 [James; Former deputy director general of the United Nations’ World Intellectual Property Organization and a member of the Center for Intellectual Property Understanding; “Drawn-Out Negotiations Over Covid IP Will Blow Back on Biden,” Barron’s; 5/26/21; <https://www.barrons.com/articles/drawn-out-negotiations-over-covid-ip-will-blow-back-on-biden-51621973675>] Justin

The Biden administration recently announced its support for a proposal before the World Trade Organization that would suspend the intellectual property protections on Covid-19 vaccines as guaranteed by the landmark TRIPS Agreement, a global trade pact that took effect in 1995.

The decision has sparked furious debate, with supporters arguing that the decision will speed the vaccine rollout in developing countries. The reality, however, is that even if enacted, the IP waiver will have zero short-term impact—but could inflict serious, long-term harm on global economic growth. The myopic nature of the Biden administration’s announcement cannot be overstated.

Even if WTO officials decide to waive IP protections at their June meeting, it’ll simply kickstart months of legal negotiations over precisely which drug formulas and technical know-how are undeserving of IP protections. And it’s unthinkable that the Biden administration, or Congress for that matter, would actually force American companies to hand over their most cutting-edge—and closely guarded—secrets.

As a result, the inevitable foot-dragging will cause enormous resentment in developing countries. And that’s the real threat of the waiver—precisely because it won’t accomplish either of its short-term goals of improving vaccine access and facilitating tech transfers from rich countries to developing ones. It’ll strengthen calls for more extreme, anti-IP measures down the road.

Experts overwhelmingly agree that waiving IP protections alone won’t increase vaccine production. That’s because making a shot is far more complicated than just following a recipe, and two of the most effective vaccines are based on cutting-edge discoveries using messenger RNA.

As Moderna Chief Executive Stephane Bancel said on a recent earnings call, “This is a new technology. You cannot go hire people who know how to make the mRNA. Those people don’t exist. And then even if all those things were available, whoever wants to do mRNA vaccines will have to, you know, buy the machine, invent the manufacturing process, invent creation processes and ethical processes, and then they will have to go run a clinical trial, get the data, get the product approved and scale manufacturing. This doesn’t happen in six or 12 or 18 months.”

Anthony Fauci, the president’s chief medical adviser, has echoed that sentiment and emphasized the need for immediate solutions. “Going back and forth, consuming time and lawyers in a legal argument about waivers—that is not the endgame,” he said. “People are dying around the world and we have to get vaccines into their arms in the fastest and most efficient way possible.”

Those claiming the waiver poses an immediate, rather than long-term, threat to IP rights also misunderstand what the waiver will—and won’t—do.

The waiver petition itself is more akin to a statement of principle than an actual legal document. In fact, it’s only a few pages long.

As the Office of the United States Trade Representative has said, “Text-based negotiations at the WTO will take time given the consensus-based nature of the institution and the complexity of the issues involved.” The WTO director-general predicts negotiations will last until early December.

That’s a lot of wasted time and effort. The U.S. Trade Representative would be far better off spending the next six months breaking down real trade barriers and helping export our surplus vaccine doses and vaccine ingredients to countries in need.

#### Antitrust is key to the DIB – brink is now.

Sitaraman 20 [Ganesh; Vanderbilt University Law School; “The National Security Case for Breaking Up Big Tech,” Knight First Amendment Institute at Columbia; 3/12/20; <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3537870>] brett // Re-Cut Justin

Concentration in the tech sector also threatens the defense industrial base due to higher costs, lower quality, less innovation, and even corruption and fraud.71 Each of these dynamics has already been a problem for America’s over-consolidated defense industrial base. As technology becomes more and more central to defense and national security, it is likely that these same dynamics will replicate themselves with big tech companies. This will become a national security threat, both directly, in terms of the quality and speed of procurement, and indirectly, by reducing innovation and functionally redirecting defense budgets from research spending to higher monopoly profits.72 Conventional economic theory suggests that monopolists have the ability to increase prices and reduce quality because consumers are captive.73 When it comes to defense spending, the Government Accountability Office commented in 2019 that “competition is the cornerstone of a sound acquisition process and a critical tool for achieving the best return on investment for taxpayers.”74 At the same time, the GAO observed that “portfolio-wide cost growth has occurred in an environment where awards are often made without full and open competition.”75 Indeed, it found that 67 percent of 183 major weapons systems contracts had no competition and almost half of contracts went to a handful of firms. Of course, consolidation also means that the Defense Department is in a symbiotic relationship with these big contractors. Some startup executives wanting to sell to the government thus see the Pentagon as “a bad customer, one that is heavily skewed in favor of larger, traditional players,” and they don’t feel like they can break into the sector.76 Standard stories about political economy and capture also suggest that these firms will have outsized power over government.77 As Frank Kendall, the former head of acquisitions at the Pentagon, has said, “With size comes power, and the department’s experience with large defense contractors is that they are not hesitant to use this power for corporate advantage.”78 In the defense context, that means monopolists retain power (and profits), even if they overcharge taxpayers and risk the safety of military personnel in the field. In an important article in The American Conservative on concentration in the defense sector, researchers Matt Stoller and Lucas Kunce argue that contractors with de facto monopoly at the heart of their business models threaten national security. They write that one such contractor, TransDigm, buys up companies that supply the government with rare but essential airline parts and then hike up the prices, effectively holding the government “hostage.”79 They also point to L3, a defense contractor that had ambitions to be a “Home Depot” for the Pentagon, as its former CEO put it. L3’s de facto monopoly over certain products, according to Stoller and Kunce, means that it continues to receive lucrative government contracts, even after admitting in 2015 that it knowingly supplied defective weapons sights to U.S. forces.80 Consolidation also threatens U.S. defense capacity. The decline of competition, according to a 2019 Pentagon report, leaves the military vulnerable to “sole source suppliers, capacity shortfalls, a lack of competition, a lack of workforce skills, and unstable demand.”81 With a limited number of producers, there is less talent and knowhow available in the country if there is a need to build capacity rapidly.82 In 2018, the Defense Department released a report on vulnerable items in the military supply chain, including numerous items in which only one or two domestic companies (and, in some cases, zero domestic companies) produced the essential goods.83 How did the United States lose so much of its industrial base? The combination of consolidation and global integration is part of the story. As Stoller and Kunce argue, companies consolidated in the 1980s and 1990s while shifting emphasis from production and R&D to Wall Street-demanded profits. Globalization then allowed them to shift production overseas at a lower cost. The result was to gut America’s domestic industrial base—and, in many cases, to shift it to China, which engaged in a decades-long strategic plan to develop its own industrial base. The result, in the words of the 2018 Defense Department report, is that “China is the single or sole supplier for a number of specialty chemicals used in munitions and missiles.” In other areas too, the risks of losing access to critical resources are real. Describing the problem of limited carbon fiber sources, the same Pentagon report notes, “[a] sudden and catastrophic loss of supply would disrupt DoD missile, satellite, space launch, and other defense manufacturing programs. In many cases, there are no substitutes readily available.”84 As technology becomes more integral to the future of national security, it is hard to see how big tech will not simply go the way of the big defense contractors. Corporate mottos not to “be evil” are long gone,85 and big tech companies spend millions on conventional Washington, D.C., lobbying efforts.86 Over time, as contracts move to tech behemoths, there will no longer be competitive alternatives, and the Pentagon will likely be locked into relationships with big tech companies—just as they currently are with big defense contractors.87 Some commentators suggest that robust antitrust policies are a problem because only a small number of tech companies can contract for defense projects.88 But there is another way to look at it: The goal should be to encourage competition in the tech sector so that there are multiple contractors available. As former secretary of homeland security Michael Chertoff has said, defending the antitrust case against Qualcomm, “a single-source national champion creates an unacceptable risk to American security—artificially concentrating vulnerability in a single point. ... We need competition and multiple providers, not a potentially vulnerable technological monoculture.”89 The consequence of consolidation in tech is that taxpayers will likely see higher bills even as innovation slows due to reduced competition. Worse still, every taxpayer dollar that goes to monopoly profits—whether in the form of higher prices or fraud and corruption—is a dollar that is not going toward innovation for the future. A concentrated defense sector means not only less innovation due to the lack of competition in the sector; it means that funding that could have been available for innovation instead gets redirected via monopoly profits to the pockets of big tech executives and shareholders.

#### That solves extinction through great power war.

Marks 19 [Michael; Former Senior Policy Advisor to the Under Secretary for Security Assistance, Science and Technology at the U.S. Department of State; "Strengthen US Industry To Counter National Security Challenges," American Military News; 10/10/19; <https://americanmilitarynews.com/2019/10/strengthen-us-industry-to-counter-national-security-challenges/>] Justin

While U.S. defense budgets have recently been on the rise, it is likely that we will see a spending decline in the coming years as competition for non-defense federal budget dollars increases and deficits grow. The United States, therefore, must take action to ensure that we maintain our technological edge against our adversaries by empowering the private sector to provide cost-effective innovation for America’s defense. Since the end of the Second World War the U.S. has relied on qualitative superiority over its potential adversaries, especially those like the Soviet Union/Russia and China, who enjoyed comparative quantitative advantages. These qualitative advantages were vital to maintaining global stability and helped enable our nation to become the preeminent global economy, but they have been eroded over the last few decades. In 1960, the U.S. share of global research and development (R&D) spending stood at 69%. U.S. defense-related R&D alone accounted for 36% of total global expenditures. Soon thereafter other nations recognized the need to increase their R&D expenditures and build their own defense industrial bases to compete with the United States. From 2000-2016, China’s share of global R&D rose from 4.9% to 25.1% while the U.S. share of global R&D dropped to 28%. U.S. defense-related R&D meanwhile now makes up a mere 4% of global R&D spending. There can be no doubt that Russia and China are determined to challenge America’s qualitative advantage. From the rebirth of Russian military power under Vladimir Putin to the ever-growing Chinese military prowess across the board, their efforts show no sign of slowing down. Russia has been and continues to undergo a major modernization of its armed forces. For example, they are in the midst of a ten-year program to build hundreds of new nuclear missiles and have set a goal of modernizing 70% of the Russian Ground Force’s equipment by 2020. One of the most frightening examples of Russia’s resurgence is its development of a hypersonic missile that could be ready for combat as early as 2020. Worryingly, the US is currently unable to defend against this type of missile. To accompany these developments came the emergence in 2017 of Russia as the world’s second-largest arms producer, ready and able to support nations hostile to US interests. China, on the other hand, used to be a country that only manufactured cheap products and knockoffs, but that is no longer true. Technology development and innovation figure prominently in all of China’s national planning goals, with plans to make the country the global leader in science and innovation and the preeminent technological and manufacturing power by 2049, the 100th anniversary of the Chinese communist revolution. This, of course, has huge implications for China’s military capability. The country now has the second-largest national defense budget behind the U.S. and wants to be Asia’s preeminent military power. Beijing is developing next-generation fighter jets, ICBMs and shorter-range ballistic missiles, as well as advanced naval vessels. The People’s Liberation Army has reached a critical point of confidence and now feel they can match competitors like the United States in combat. This has implications for the security of Taiwan, Japan, other US allies in the region as well as to America itself. To make matters worse, there are a growing number of experts that see China developing asymmetric technologies, combined with conventional and nuclear systems that could create an existential threat to the U.S. pacific based assets. It is in the wake of these growing threats to our national security American industry will likely be expected to shoulder an even larger responsibility concerning investment in defense-related R&D. One of the ways we can empower companies to make these additional investments and lead next-generation defense innovation is to allow commonsense mergers between important defense and aerospace companies. Horizontal consolidation eliminates the redundancy of enormous fixed costs, leading to savings passed down to customers. Mergers can also create economies of scale and existing synergies that help the combined company realize access to larger numbers of engineers and innovators, while keeping costs low and improving the timeline for taking a product from concept to development. FA recent example of how this can work is the proposed Raytheon and United Technologies merger. The two parties project that the new combined company will employ more than 60,000 engineers, hold over 38,000 patents and invest approximately $8 billion per year in research and development. This will allow the development of new, critical technologies more quickly and efficiently than either company could on its own. Such private sector investments in innovation will be critical in the face of the growing challenges to American military dominance. America’s R&D advantage, crucial to maintaining military superiority, is increasingly at risk. As China and Russia continue to challenge America’s military dominance and pressures on the defense budget continue to mount, the federal government will likely turn more and more to contractors and commercial companies to develop next-generation defense capabilities. Strengthening U.S. industry, therefore, will be critical to countering our national security challenges.

### 3

#### Member nations of the WTO should:

#### Institute value-based pricing for new medicines

#### Allow health service agencies to negotiate over drug prices

#### Institute price increase caps on existing drugs to an international reference price

#### Set aside public funding in the form of Development Impact Bonds and cash-on-delivery tied to health gain and encourage risk-sharing for NTD research

#### Engage in health diplomacy where richer nations share medicines and information to poorer nations to combat neglected diseases

#### Planks 1-3 solve drug prices but avoids the patent good turns.

**Rajkumar 2020** (S. Vincent Rajkumar, MD, Division of Hematology, Mayo Clinic, Rochester, MN (S.V.R.). “The high cost of prescription drugs: causes and solutions” *Blood Cancer Journal* volume 10, Article number: 71 2020)DR 21

Value-based pricing

Unlike other developed countries, the United States does not negotiate over the price of a new drug based on the value it provides. This is a fundamental problem that allows drugs to be priced at high levels, regardless of the value that they provide. Thus, almost every new cancer drug introduced in the last 3 years has been priced at more than $100,000 per year, with a median price of approximately $150,000 in 2018. The lack of value-based pricing in the United States also has a direct adverse effect on the ability of other countries to negotiate prices with manufacturers. It greatly reduces leverage that individual countries have. Manufacturers can walk away from such negotiations, knowing fully well that they can price the drugs in the United States to compensate. A governmental or a nongovernmental agency, such as the Institute for Clinical and Economic Review (ICER), must be authorized in the United States by law, to set ceiling prices for new drugs based on incremental value, and monitor and approve future price increases. Until this is possible, the alternative solution is to cap prices of lifesaving drugs to an international reference price.

Medicare negotiation

In addition to not having a system for value-based pricing, the United States has specific legislation that actually prohibits the biggest purchaser of oral prescription drugs (Medicare) from directly negotiating with manufacturers. One study found that if Medicare were to negotiate prices to those secured by the Veterans Administration (VA) hospital system, there would be savings of $14.4 billion on just the top 50 dispensed oral drugs[17](https://www.nature.com/articles/s41408-020-0338-x#ref-CR17).

Cap on price increases

The United States also has a peculiar problem that is not seen in other countries: marked price increases on existing drugs. For example, between 2012 and 2017, the United States spent $6.8 billion solely due to price increases on the existing brand name cancer drugs; in the same period, the rest of the world spent $1.7 billion less due to decreases in the prices of similar drugs[18](https://www.nature.com/articles/s41408-020-0338-x#ref-CR18). But nothing illustrates this problem better than the price of insulin[19](https://www.nature.com/articles/s41408-020-0338-x#ref-CR19). One vial of Humalog (insulin lispro), that costs $21 in 1999, is now priced at over $300. On January 1, 2020, drugmakers increased prices on over 250 drugs by approximately 5%[20](https://www.nature.com/articles/s41408-020-0338-x#ref-CR20). The United States clearly needs state and/or federal legislation to prevent such unjustified price increases [21](https://www.nature.com/articles/s41408-020-0338-x#ref-CR21).

#### Plank 4 and 5 solves NTDs and Health diplomacy BUT pharma profits are key—NTD research is high-risk and capital-intensive

**Barofksy and Schneider 2017** (Jeremy Barofsky, Sc.D., M.A. is a non-resident Fellow in Governance Studies at the Brookings Institution and a Research Associate at Tulane University’s Commitment to Equity (CEQ) Institute. He received his doctorate from Harvard University’s T.H. Chan School of Public Health in Global Health and Population (Economics) and holds an M.A. in Economics from Boston University. and Jake Schneider, Research Assistant - The Brookings Insitution “Promoting Private Sector Involvement in Neglected Tropical Disease Research and Development” *The Brookings Private Sector Global Health R&D Project* https://www.brookings.edu/wp-content/uploads/2017/12/br\_health4\_optimized\_final.pdf December 2017)DR 21

Based on this analysis, we make several recommendations for future action:

1. Alignment of public funding with social return. Our analysis shows the restricted circumstances in which private sector R&D generates a positive return on investment in the current policy environment. To increase the range of activities that receive private funding, **we propose public funding that is explicitly tied to health gain** (disability adjusted life years [DALYs] averted). There are various financing mechanisms that have been developed that would allow governments to pay for results, including Development Impact Bonds and cash-on-delivery models. These arrangements allow public funders to provide financing contingent on results, as verified by a third party, and do not require outlays otherwise.
2. Private sector late-stage investment and risk sharing. Our quantitative analysis finds that the most important drivers of private sector development cost are long development timelines and failure risk. Complementary to recommendation #1, we therefore propose additional private sector investment focused on phase III clinical trials to minimize risk-adjusted, capitalized private sector costs. In addition, to further minimize risk, private sector **biopharmecutical firms could enter into investment agreements that would spread the risk** and benefits of these trials. This risk-sharing arrangement would be particularly oriented toward social impact investors that want to both diversify market risk (R&D risk being orthogonal to market risk) and generate positive social returns.
3. Public funding coordination and stewardship. Our case studies indicated the importance of stewardship and coordination of product development partnerships by non-profit entities. Greater stewardship from governments to determine priority areas for NTD investment as well as coordinate joint funding of early stage R&D with nonprofit actors would both increase the likelihood of private sector involvement in late stage R&D as well as increase the likelihood that innovation maximizes public health.
4. Advanced market commitment for hookworm and schistosomiasis: Our analysis highlighted the challenges for NTD vaccine development and the mismatch in scale between current resources compared to the funding necessary for successful development. The creation of an advanced market commitment ensuring a set price for certain number of treatments purchased would increase the likelihood of private involvement in vaccine development.
5. Tiered PRV based on social return and clinical stage: One specific policy change that may be more feasible in the near term to align financial incentives and health impact includes an adjustment to the PRV such that the PRV varies based on the level of innovation produced compared to current clinical practice.