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#### Pharma innovation high now – monetary incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

**Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered policies that would lower drug prices and reduce federal drug expenditures. Such policies would probably reduce the industry’s incentive to develop new drugs.** In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? T**he pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation.** The share of revenues that drug companies devote to R&D has also grown: **On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses** in 2019, which is **almost twice as large a share of revenues as they spent in 2000.** That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On averace, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. **Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients**. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), **which are costly to develop, hard to imitate, and frequently have high prices.** Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. **What Factors Influence Spending for R&D?** Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, **Expected costs to develop a new drug**, and Policies and programs that influence the supply of and demand for prescription drugs. Various considerations inform companies’ expectations about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA. In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug**. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatmentscof uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D. Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. **In particular, spending on drug R&D increased by nearly 50 percent between 2015 and 2019.** Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms**, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000**.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. **Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs,** many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

#### The aff crushes innovation in the pharma sector---incentivizes them to focus on non-important issues.

Glassman 21 [Amanda; 5/6/21; Executive vice president and a senior fellow at the Center for Global Development, a nonpartisan, nonprofit think tank in Washington and London; “*Big Pharma Is Not the Tobacco Industry*,” Barron, <https://www.barrons.com/articles/big-pharma-is-not-the-tobacco-industry-51620315693>] Justin

But here is the crux of the problem: The pharmaceutical industry is not the tobacco industry. They are not merchants of death. The companies are amoral and exist to make money, but their business is not fundamentally immoral. Big Pharma (mostly) develops and sells products that people need to survive and thrive. Their products improve health and welfare. Fights over access to medicines are possible because medicines exist in the first place—medicines that were usually developed by Big Pharma. And yes, the pharmaceutical industry benefits from public subsidy and publicly financed foundational research. But the companies also put their own capital at risk to develop new products, some of which offer enormous public benefits. In fact, several of them did just that in the pandemic: invested their own money to develop patented manufacturing technologies in record time. Those technologies are literally saving the world right now. Public funding supported research and development, but companies also brought their own proprietary ingenuity and private investments to bear toward solving the world’s singular, collective challenge. Their reward should be astronomical given the insane scale of the health and economic benefits these highly efficacious vaccines produce every day. Market incentives sent a clear signal that further needed innovation—greater efficacy, single doses, more-rapid manufacturing, updated formulations, fast boosters, and others—would be richly rewarded. Market incentives could also have been used to lubricate supply lines and buy vaccines on behalf of the entire world; with enough money, incredible things can happen. But activist lobbying to waive patents—a move the Biden administration endorsed yesterday—sends exactly the opposite signal. It says that the most important, valuable innovations will be penalized, not rewarded. It tells innovators, don’t bother attacking the most important global problems; instead, throw your investment dollars at the next treatment for erectile disfunction, which will surely earn you a steady return with far less agita. It is worth going back to first principles. What problem are we trying to solve? We have highly efficacious vaccines that we would like to get out to the entire world as quickly as possible to minimize, preventable disease and deaths address atrocious inequities, and enable the reopening of society, trade, and commerce. Hundreds of millions of people have been plunged into poverty over the past year; in the developing world, the pandemic is just getting started. What is the quickest way to get this done? Vaccine manufacturing is not just a recipe; if you attack and undermine the companies that have the know-how, do you really expect they’ll be eager to help you set up manufacturing elsewhere? Is the plan to march into Pfizer and force its staff to redeploy to Costa Rica to build a new factory? Do the U.S. administration or activists care that this decision could take years to negotiate at the World Trade Organization, and will likely be litigated for years thereafter? Does it make sense to eliminate the incentive for private companies to invest in vaccine R&D or in the response to the next health emergency? And if the patent waiver is only temporary and building a factory takes months or years, will anyone bother to do so, even if they could? No, none of it makes sense. Worse still, we could solve the policy problem more easily by harnessing market incentives for the global good by ponying up cash to vaccinate the entire world. No confiscation necessary.

#### Pharma Innovation prevents Extinction – checks new diseases.

Engelhardt 8, H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine)

Many are suspicious of, or indeed jealous of, the good fortune of others. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceutical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge. Profit in the market for the pharmaceutical and medical-device industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for research and development spurs innovation in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of **profit is one of the most effective ways not only to acquire resources but productively to direct human energies** in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such innovation is both necessary to maintain the human species in an ever-changing and always dangerous environment in which new microbial and other threats may at any time emerge to threaten human well-being, if not survival (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industries.

#### Pharma spills-over – has cascading global impacts that are necessary for human survival.

NAS 8 National Academy of Sciences 12-3-2008 “The Role of the Life Sciences in Transforming America's Future Summary of a Workshop” //Re-cut by Elmer

Fostering Industries to Counter Global Problems The life sciences have applications in areas that range far beyond human health. Life-science based approaches could **contribute to advances in** many industries, from energy production and pollution remediation, to clean manufacturing and the production of new biologically inspired materials. In fact, biological systems could provide the basis for new products, services and industries that we cannot yet imagine. Microbes are already producing biofuels and could, through further research, provide a major component of future energy supplies. Marine and terrestrial organisms extract carbon dioxide from the atmosphere, which suggests that biological systems could be used to help manage climate change. Study of the complex systems encountered in biology is decade, it is really just the beginning.” Advances in the underlying science of plant and animal breeding have been just as dramatic as the advances in genetic can put down a band of fertilizer, come back six months later, and plant seeds exactly on that row, reducing the need for fertilizer, pesticides, and other agricultural inputs. Fraley said that the global agricultural system needs to adopt the goal of doubling the current yield of **crops while reducing key inputs like pesticides, fertilizers, and water** by one third. “It is more important than putting a man on the moon,” he said. Doubling agricultural yields would “change the world.” Another billion people will join the middle class over the next decade just in India and China as economies continue to grow. And all people need and deserve secure access to food supplies. Continued progress will require both basic and applied research, The evolution of life “put earth under new management,” Collins said. Understanding the future state of the planet will require understanding the biological systems that have shaped the planet. Many of these biological systems are found in the oceans, which cover 70 percent of the earth’s surface and have a crucial impact on weather, climate, and the composition of the atmosphere. In the past decade, new tools have become available to explore the microbial processes that drive the **chemistry of the oceans**, observed David Kingsbury, Chief Program Officer for Science at the Gordon and Betty Moore Foundation. These technologies have revealed that a large proportion of the planet’s genetic diversity resides in the oceans. In addition, many organisms in the oceans readily exchange genes, creating evolutionary forces that can have global effects. The oceans are currently under great stress, Kingsbury pointed out. Nutrient runoff from agriculture is helping to create huge and expanding “dead zones” where oxygen levels are too low to sustain life. Toxic algal blooms are occurring with higher frequency in areas where they have not been seen in the past. Exploitation of ocean resources is disrupting ecological balances that have formed over many millions of years. Human-induced changes in the chemistry of the atmosphere are changing the chemistry of the oceans, with potentially catastrophic consequences. “If we are not careful, we are not going to have a sustainable planet to live on,” said Kingsbury. Only by understanding the basic biological processes at work in the oceans can humans live sustainably on earth.

## 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 doesn’t solve but 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

#### The member nations of the World Trade Organization except for the United States ought to reduce intellectual property protections for medicines related to the prevention, containment, and treatment of COVID-19.

#### The United States ought to reduce intellectual property protections for medicines related to the prevention, containment, and treatment of COVID-19. 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.

#### Circumvention is inevitable---the aff is unconstitutional and companies use that as a sword to prevent loss of IP.

Brown 21 [Delphine; 7/21/21; Partner in the firm's Litigation Practice Group, and a member of its Intellectual Property Practice Team. With over twenty years of trial experience, Delphine's practice focuses on complex intellectual property and technology cases, with extensive experience in the life sciences industry. Delphine has served as lead counsel for several global pharmaceutical companies in Hatch-Waxman litigation and trials involving dozens of drug products, dosage forms and delivery systems. Delphine’s lead counsel expertise also includes patent litigation involving biotech, medical device, computer hardware and software, design and business method patents, and counseling of established and emerging biotechnology companies regarding intellectual property, regulatory and litigation issues. Delphine has served as lead trial counsel in complex trademark and copyright infringement, misappropriation of trade secrets, and unfair competition cases. Delphine believes that the key to being the best litigator and trial lawyer is always keeping her "eyes on the prize" which she defines with her clients as accomplishing both legal victory and strategic objectives to get the client back to running its business as quickly as possible. A corporate client once remarked to Delphine's parents at her birthday party that "if Delphine wasn't such a good lawyer, we wouldn't have become such great friends." Delphine has three decades of experience representing both U.S. and foreign corporations in federal and state courts nationwide in pretrial proceedings, trials and appeals, and in arbitration proceedings. Delphine frequently publishes thought leadership and speaks on intellectual property issues. Delphine received her bachelors degree from Princeton University and her J.D. from St. John's University School of Law. In her spare time, she serves on the boards of several private foundations, and the CT Selection Committee for the Princeton Prize in Race Relations, as well as a USA swimming official. Delphine also enjoys skiing, golf, tennis and classic wood boats; “*Powerhouse Points: Will TRIPS Waiver of IP Protection for COVID-19 Vaccines Serve Global Need*,” Freeborn, <https://www.freeborn.com/perspectives/powerhouse-points-will-trips-waiver-ip-protection-covid-19-vaccines-serve-global-need>] Justin

Despite the current U.S. administration’s apparent support for waiving IP protection for COVID-19 vaccines, the response in the U.S. to the proposed broader waiver would most certainly involve intense lobbying by pharmaceutical companies to reverse or severely narrow its effect. The U.S. Congress has already introduced legislation to require Congressional approval of any waiver, and prohibit the use of federal funds to support a waiver.[vi] If the U.S. government seeks to enforce a TRIPS waiver, the takings clause of the Fifth Amendment to the U.S. Constitution could be used by U.S. companies as a sword to prevent the loss of intellectual property rights without compensation. In addition, compulsory licenses issued by foreign governments to U.S.-based pharmaceutical companies would be the subject of jurisdictional challenges and lack effective enforcement mechanisms.

#### CP solves better – the US has structurally undermined WTO legitimacy

Baschuk 2/22 [(Bryce, reporter for Bloomberg Economics based in Geneva, Switzerland, has been published in Bloomberg, the Washington Times, United Press International and National Public Radio) “Biden Picks Up Where Trump Left Off in Hard-Line Stances at WTO,” Bloomberg, 2/22/2021]

President Joe Biden’s administration dashed hopes for a softer approach to the World Trade Organization by pursuing a pair of his predecessor’s strategies that critics say risk undermining the international trading system. The U.S. delegation to the WTO, in a statement Monday obtained by Bloomberg, backed the Trump administration’s decision to label Hong Kong exports as “[Made in China](https://www.bloomberg.com/news/articles/2020-10-30/hong-kong-takes-formal-wto-action-on-u-s-made-in-china-order)” and said the WTO had no right to mediate the matter because the organization’s rules permit countries to take any action to protect their “essential security interests.” “The situation with respect to Hong Kong, China, constitutes a threat to the national security of the United States,” the U.S. delegation said. “Issues of national security are not matters appropriate for adjudication in the WTO dispute-settlement system.” Prior to 2016, WTO members generally steered clear of defending their trade actions on the basis of national security because doing so could encourage other nations to pursue protectionist policies that have little or nothing to do with hostile threats. That changed in 2018, when the Trump administration triggered a cold war-era law to justify tariffs on foreign imports of steel and aluminum. In response, a handful of U.S. trade partners, including Canada, the EU, and China filed disputes at the WTO and a ruling in those cases is expected later this year. Since then, more nations -- including Saudi Arabia, India, Russia and others -- have cited the WTO’s national-security exemption in regional trade fights, leading trade experts to warn that such cases could erode the organization’s ability to mediate disputes The Biden administration on Monday said the U.S. has consistently argued that national-security disputes are not subject to WTO review because it would infringe on a member’s right to determine what is in its own security interests. In spite of the U.S. objection, the WTO granted Hong Kong’s dispute inquiry and will establish a panel of experts to deliberate the matter and render a decision, which could take two to three years. At the same meeting, the Biden administration said it would not agree to appoint new members to the WTO’s appellate body, a seven-member panel of experts who until 2019 had the final say on trade disputes involving billions of dollars worth of international commerce. The Biden administration said it could not do so because the U.S. “continues to have systemic concerns” with the functioning of the appellate body as have all previous administrations over the past 16 years. Though the statement was not entirely unexpected, it confirms America’s bipartisan frustration with the functioning of the WTO appellate body and the new administration’s willingness to block new panelists until changes can be agreed. Once Katherine Tai is confirmed as the U.S. Trade Representative, her office “looks forward to working with” WTO Director-General Ngozi Okonjo-Iweala to tackle the problems with WTO dispute settlement, including the unresolved issues over appellate-body overreach, USTR spokesman Adam Hodge said in an email. “These are long-standing, bipartisan concerns that we hope our trading partners will work with us to address,” he said. The Trump administration broke precedent when it refused to consider any nominees to fill vacancies on the panel until there weren’t enough to sign off on new rulings. As a result, the WTO’s dispute-settlement system has been critically damaged because WTO members are now free to veto any adverse dispute rulings by appealing them into a legal void created by the appellate body’s paralysis.

## 4

#### CP text: The member nations of the WTO should:

#### ---Loan an additional 4 billion dollars of additional funding to close the pre-purchase gap of 350 million vaccines to achieve world-wide immunity

#### ---The World Bank should relax the conditions to receive a loan as per Goldberg 21

#### ---Eliminate export restriction on critical medicines during pandemics.

#### The CP solves pandemics better – the aff misidentifies the problem.

Goldberg 20 [PINELOPI KOUJIANOU; Former World Bank Group chief economist and editor-in-chief of the American Economic Review, Professor of Economics at Yale University; “Forget the Vaccine Patent Waiver,” Project Syndicate; 5/13/21; <https://www.project-syndicate.org/commentary/wto-vaccine-waiver-is-beside-the-point-by-pinelopi-koujianou-goldberg-2021-05>] Justin

What’s the issue, then? According to Agarwal and Reed, it is that companies are reluctant to activate their existing production capacity without pre-purchase commitments. There is currently a large gap between the number of doses that could be produced and the number that have been pre-ordered. And, as one would expect, this gap is unevenly distributed. High-income countries have ordered more doses than they need and thus will end up with a surplus, whereas lower-income countries are far behind in pre-purchasing vaccines.

Under these circumstances, efforts to increase capacity by relaxing patent protections would do nothing to accelerate vaccinations in lower-income countries. A far more promising strategy is to help lower-income countries purchase vaccines, while channeling surplus doses from richer countries to wherever they are needed most.

To a large extent, this strategy is already being implemented, thanks to the efforts of the COVAX Advanced Market Commitment facility, together with concessional loans by multilateral institutions such as the World Bank, and regional initiatives such as the one being led by the African Union. Remarkably, Agarwal and Reed show that the COVAX AMC facility and the AU initiative already have ensured that most African countries have ordered enough vaccines to cover at least 50% of their populations.

Still, three critical challenges remain. First, closing the pre-purchase gap of 350 million vaccines will requires an additional $4 billion – a trivial cost relative to the potential benefit of achieving worldwide immunity. Providing this support, either through additional funding for the COVAX AMC facility or by sending surplus vaccines to developing countries as soon as possible, should not be too difficult or costly for high-income countries to manage.

Second, the World Bank needs to relax its conditions for extending loans for vaccine pre-purchases. Currently, such loans can be used only for vaccines approved by three stringent regulatory authorities (SRAs) in three different regions. Among these are Japan and certain Western countries, which naturally prioritize approval of vaccines intended for their own populations. They have little incentive to grant emergency-use authorization to alternative vaccines that have shown high efficacy in Phase 3 clinical trials, such as Bharat Biotech’s Covaxin (India), and Gamaleya’s Sputnik V (Russia), and Sinovac Biotech’s CoronaVac (China). Extending the list of national regulators classified as SRAs would go a long way toward increasing lending for vaccine purchases.1

Finally, existing vaccine manufacturers will be unable to meet their production targets if vaccine nationalism gives rise to export restrictions on critical inputs and raw materials. We saw such behavior early in the pandemic with respect to personal protective equipment, but the resulting export restrictions proved short-lived. One hopes the same will be true for vaccines. International cooperation and coordination will be crucial in the coming months.

There are many ways for advanced economies to assist poorer countries in vaccinating their populations as soon as possible. But relaxing patent protections – however appealing the idea may be in other contexts – is not one of them. The focus should be on providing additional funding and less restrictive lending for pre-ordering vaccines, and on funneling surpluses from high-income countries to the rest of the world.

#### Solves legitimacy as well – 1AC Meyer says that if public perception is that WTO is solving COVID, it shores up legitimacy