#### Bipartisan infrastructure bill passing now but PC is needed – there is no margin for error.

Kapur et al 9/8 [Sahil, Frank Thorp, and Leigh Ann Caldwell; 9/8/21; Sahil Kapur is a national political reporter for NBC News, Frank Thorp V is a producer and off-air reporter covering Congress for NBC News, managing coverage of the Senate, Leigh Ann Caldwell is an NBC News correspondent; “*Democrats plow 'full speed ahead' on sweeping Biden budget, despite tensions*,” <https://www.nbcnews.com/politics/congress/democrats-plow-full-speed-ahead-sweeping-biden-budget-despite-tensions-n1278722>] Justin

WASHINGTON — The top two Democrats said they’re pushing forward with President Joe Biden’s sweeping safety net expansion, as House committees circulate legislative text with hearings scheduled Thursday to start advancing major sections of the bill. “We're moving full speed ahead,” Senate Majority Leader Chuck Schumer told reporters on a call Wednesday. The New York Democrat effectively cast aside calls by Sen. Joe Manchin, D-W.Va., for a “strategic pause” in the process of crafting the bill, as he voiced concerns about inflation and debt in a recent op-ed for the Wall Street Journal. Schumer is navigating demands by Manchin, as well as Sen. Kyrsten Sinema, D-Ariz., to reduce the price tag that Democrats set at a maximum of $3.5 trillion in the budget resolution. “There are some in my caucus who believe $3.5 trillion is too much; there are some in my caucus who believe it's too little,” Schumer said. “We're going to work very hard to have unity, because without unity, we're not going to get anything.” Speaker Nancy Pelosi said Wednesday the House is moving forward at the $3.5 trillion level. But she left open the possibility of a lower final price tag before the bill becomes law, while promising that “we will get the job done” with “a great bill” that honors Biden’s vision. “We will have our negotiations,” Pelosi, D-Calif., said, when asked by NBC News if the House could pass a bill at a lower amount. “I don’t know what the number will be. We are marking at 3.5 [trillion]. ... We will pay for more than half, maybe all of the legislation.” The remarks by Schumer and Pelosi point to a complicated balancing act, facing a broad range of opinions from centrist lawmakers skeptical of the price tag to progressives who believe $3.5 trillion should be the minimum. Democratic leaders are also juggling an aggressive timeline by seeking to ready the bill by Sept. 27 — the self-imposed House deadline to vote on the separate infrastructure bill — to ensure progressives will support the latter. They are betting Manchin can ultimately be won over on the substance of the package. Lawmakers and committees are keeping options open in case the price tag needs to be cut: For instance, they’ve privately discussed setting some provisions to expire sooner. Manchin has been somewhat vague in his demands. He has not specified what price tag he would support or what provisions of the emerging bill he wants to cut. His office did not have a comment when asked those questions Wednesday. In June, he said on ABC's "This Week" that he wants to “make sure we pay for” the bill. A source close to Manchin said he is a big proponent of targeting benefits on the basis of income and capping them so the money reaches people who need it the most — principles he believes are critical for Democrats' proposals on community college subsidies and on home-based care provisions for the disabled and elderly. Manchin also has issues with the climate change proposals in the legislation, the source said. As chairman of the Senate Energy and Natural Resources Committee, Manchin has major influence over the climate provisions. His committee was instructed to write legislation costing $198 billion for a clean electricity payment program, consumer rebates to weatherize and electrify homes, the creation of financing for domestic manufacturing of clean energy and auto supply chain technologies and climate research. “He’s not opposed to the overall bill,” the source said. “He’s going to shape the bill to what he feels is closer to the needs. People shouldn’t read into it more than that.” Senate Budget Chair Bernie Sanders, I-Vt., has said if the safety net package does not pass, the $550 billion bipartisan infrastructure package — which Manchin co-wrote — will fail as well. He told reporters the $3.5 trillion level was too low. “To my mind, this bill, that $3.5 trillion, is already the result of a major, major compromise,” Sanders said. “And at the very least, this bill should contain $3.5 trillion.” Pelosi said slashing the cost would require making difficult policy choices. “We have to talk about: What does it take? Where would you cut?” she asked. “Child care? Family medical leave paid for? Universal pre-K? Home health care?” On Thursday, the House committees on ways and means and education and labor will hold hearings on major portions of the bill they released this week. That includes 12 weeks' paid family and medical leave for all workers; expanding Medicare to cover dental, vision and hearing benefits; universal pre-K for 3- and 4-year-olds; and two years' tuition-free community college. Republicans are unified against the effort, leaving Democrats to pass the bill alone under narrow majorities. The package can bypass a Senate filibuster. Senate Minority Leader Mitch McConnell, R-Ky., said Wednesday that he hopes Manchin and Sinema “will dig in their heels” against some of the tax increases Democrats are eyeing to finance the package. “It comes down to — in the Senate — to two people,” he said. “Either one of them could kill the whole bill. I don't expect that to happen,” he said. “Either one of them could make dramatic changes in it — that could happen. Or either one of them could basically make a few cosmetic changes and throw in the towel.”

#### 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.

#### Infrastructure secures the grid against worsening and increasing cyberattacks.

Carney 21 [Chris; 8/6/21; Senior policy advisor at Nossaman LLC, former US Representative, former professor of political science at Penn State University; "*The US Senate Infrastructure Bill: Securing Our Electrical Grid Through P3s and Grants*," JDSupra, <https://www.jdsupra.com/legalnews/the-us-senate-infrastructure-bill-4989100/>] Justin

As we begin to better understand the main components of the Infrastructure Investment and Jobs Act that the US Senate is working to pass this week, it is clear that public-private partnerships ("P3s") are a favored funding mechanism of lawmakers to help offset high costs associated with major infrastructure projects in communities. And while past infrastructure bills have used P3s for more conventional projects, the current bill also calls for P3s to help pay for protecting the US electric grid from cyberattacks. Responding to the increasing number of cyberattacks on our nation’s infrastructure, and given the fragile physical condition of our electrical grid, the Senate included provisions to help state, local and tribal entities harden electrical grids for which they are responsible. Section 40121, Enhancing Grid Security Through Public-Private Partnerships, calls for not only physical protections of electrical grids, but also for enhancing cyber-resilience. This section seeks to encourage the various federal, state and local regulatory authorities, as well as industry participants to engage in a program that audits and assesses the physical security and cybersecurity of utilities, conducts threat assessments to identify and mitigate vulnerabilities, and provides cybersecurity training to utilities. Further, the section calls for strengthening supply chain security, protecting “defense critical” electrical infrastructure and buttressing against a constant barrage of cyberattacks on the grid. In determining the nature of the partnership arrangement, the size of the utility and the area served will be considered, with priority going to utilities with fewer available resources. Section 40122 compliments the previous section as it seeks to incentivize testing of cybersecurity products meant to be used in the energy sector, including SCADA systems, and to find ways to mitigate any vulnerabilities identified by the testing. Intended as a voluntary program, utilities would be offered technical assistance and databases of vulnerabilities and best practices would be created. Section 40123 incentivizes investment in advanced cybersecurity technology to strengthen the security and resiliency of grid systems through rate adjustments that would be studied and approved by the Secretary of Energy and other relevant Commissions, Councils and Associations. Lastly, Section 40124, a long sought-after package of cybersecurity grants for state, local and tribal entities is included in the bill. This section adds language that would enable state, local and tribal bodies to apply for funds to upgrade aging computer equipment and software, particularly related to utilities, as they face growing threats of ransomware, denial of service and other cyberattacks. However, under Section 40126, cybersecurity grants may be tied to meeting various security standards established by the Secretary of Homeland Security, and/or submission of a cybersecurity plan by a grant applicant that shows “maturity” in understanding the cyber threat they face and a sophisticated approach to utilizing the grant. While the final outcome of the Infrastructure Investment and Jobs Act may still be weeks or months away, inclusion of these provisions not only demonstrates a positive step forward for the application of federal P3s and grants generally, they also show that Congress recognizes the seriousness of the cyber threats our electrical grids face. Hopefully, through judicious application of both public-private partnerships and grants, the nation can quickly secure its infrastructure from cyberattacks.

#### Cyberattacks on the grid spiral to all-out nuclear conflict.

Klare 19 [Michael; November 2019; Professor emeritus of peace and world security studies at Hampshire College; “*Cyber Battles, Nuclear Outcomes? Dangerous New Pathways to Escalation*,” Arms Control Association, <https://www.armscontrol.org/act/2019-11/features/cyber-battles-nuclear-outcomes-dangerous-new-pathways-escalation>] Justin

Yet another pathway to escalation could arise from a cascading series of cyberstrikes and counterstrikes against vital national infrastructure rather than on military targets. All major powers, along with Iran and North Korea, have developed and deployed cyberweapons designed to disrupt and destroy major elements of an adversary’s key economic systems, such as power grids, financial systems, and transportation networks. As noted, Russia has infiltrated the U.S. electrical grid, and it is widely believed that the United States has done the same in Russia.12 The Pentagon has also devised a plan known as “Nitro Zeus,” intended to immobilize the entire Iranian economy and so force it to capitulate to U.S. demands or, if that approach failed, to pave the way for a crippling air and missile attack.13 The danger here is that economic attacks of this sort, if undertaken during a period of tension and crisis, could lead to an escalating series of tit-for-tat attacks against ever more vital elements of an adversary’s critical infrastructure, producing widespread chaos and harm and eventually leading one side to initiate kinetic attacks on critical military targets, risking the slippery slope to nuclear conflict. For example, a Russian cyberattack on the U.S. power grid could trigger U.S. attacks on Russian energy and financial systems, causing widespread disorder in both countries and generating an impulse for even more devastating attacks. At some point, such attacks “could lead to major conflict and possibly nuclear war.”14

### 2

#### 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.

### 3

#### CP text: The US ought to

#### ---Ramp up funding for COVAX

#### ---Engage in an “all-out mobilization” strategy that would lead a multilateral effort consisting of allies in the G-7 and NATO for assistance in the flow of vaccine supplies

#### ---Increase focus on domestic production of vaccines including companies, nonprofits, and organizations in vaccination programs to increase and export vaccines.

#### ---Engage in a voluntary licensing strategy and help set up local hubs for manufacturing capacity

#### Solves vaccine diplomacy and covid.

Gayle et al 21 [Helene, Gordon LaForge, and Annie-Marie Slaughter; 3/19/21; President and CEO of the Chicago Community Trust and has served in global health and development roles with CARE, the Centers for Disease Control and Prevention, and the Bill & Melinda Gates Foundation; President and CEO of the Chicago Community Trust and has served in global health and development roles with CARE, the Centers for Disease Control and Prevention, and the Bill & Melinda Gates Foundation; Senior Researcher at Princeton University and a lecturer at Arizona State University’s Thunderbird School of Global Management; CEO of New America and former Director of Policy Planning at the U.S. State Department; “*America Can—and Should—Vaccinate the World*,” Foreign Affairs, <https://www.foreignaffairs.com/articles/united-states/2021-03-19/america-can-and-should-vaccinate-world>] Justin

After a virtual “Quad summit” last Friday, the leaders of the United States, India, Japan, and Australia announced that they would cooperate to deliver one billion vaccine doses in the Indo-Pacific, directly countering China’s lead in distributing vaccines to the region. The agreement brings together Indian manufacturing and U.S., Japanese, and Australian financing, logistics, and technical assistance to help immunize hundreds of millions of people by the end of 2022. Headlines over the weekend proclaimed that the administration of U.S. President Joe Biden was preparing to catch up in global vaccine diplomacy. Yesterday the administration took a further step in this direction, leaking to reporters that it would lend four million AstraZeneca doses to Mexico and Canada. These initiatives come not a moment too soon. In tackling the worst global crisis of a lifetime, the United States has so far been upstaged. Russia and China have aggressively marketed and distributed their vaccines to foreign countries, largely to advance foreign policy goals. Russia is using the jab to bolster its image and investment prospects and to drive a wedge between EU countries. China is donating doses to gain leverage in territorial disputes and expand its influence under the Belt and Road Initiative. Both Moscow and Beijing have moved to undercut the United States in its own backyard by supplying vaccines to Latin America. The Biden administration is right to want to take the lead in vaccinating the world, for a host of reasons both self-interested and altruistic. But it should not fall into the trap of trying to beat Russia and China at their own game—handing out vaccines to specific countries based on their geostrategic importance and the amount of attention they are receiving from rival powers. Rather, Biden should pursue abroad the sort of “all in” unity approach that he has proclaimed at home. His administration should focus less on strategic advantage than on vaccinating the largest number of people worldwide in the shortest amount of time. In so doing, the United States would concentrate on what the world’s peoples have in common—susceptibility to this and many other viruses—regardless of the nature of their governments. ALL IN AND ALL OUT The United States has successfully mobilized its own and international resources to respond to regional crises in the past. In 2003, President George W. Bush started the U.S. President’s Emergency Plan for AIDS Relief, the largest global health program focused on a single disease in history. PEPFAR brought together U.S. agencies, private companies, and local civil society groups to help sub-Saharan Africa and Southeast Asia get the AIDS crisis under control, saving millions of lives. In 2004, a tsunami in the Indian Ocean caused more than 220,000 deaths and billions in damage, and the United States led an urgent, similarly inclusive humanitarian relief and recovery effort that rescued victims, hastened reconstruction, and built lasting goodwill in South and Southeast Asia. Biden can improve on Bush’s precedent by going global, and he has already taken steps toward doing so. Under President Donald Trump, the United States refused to participate in the COVID-19 Vaccine Global Access (COVAX) Facility, an international partnership that aims to guarantee COVID-19 vaccine access for the entire world. The Biden administration reversed this stance immediately and contributed $4 billion, making the United States the largest donor to the effort. Still, even if COVAX meets the ambitious target of delivering two billion doses to developing nations by the end of 2021, it will be able to vaccinate only 20 percent of those countries’ populations. Just imagine, however, what could happen if Washington were to treat COVID-19 as the equivalent of the enemy in a world war or the pandemic as a global version of the regional AIDS and Ebola epidemics of years past. Imagine, in other words, what all-out mobilization would look like if the United States treated the COVID-19 pandemic like the global threat that it is. The Biden administration is right to want to take the lead in vaccinating the world. Washington would lead a multilateral, whole-of-society effort to help COVAX vaccinate the world. The government would activate the military and call upon allies in the G-7 and NATO for a major assistance operation that speeds the flow of vaccine supplies and strengthens delivery systems. As it has pledged to do in the Quad summit deal, the U.S. government would use the State Department, U.S. Agency for International Development (USAID), Centers for Disease Control and Prevention (CDC), and other civilian agencies and development programs to help countries with their national vaccination programs. And it would enlist companies, nonprofits, and civil society organizations to help increase vaccine production, raise funding, and provide technical assistance to foreign counterparts. The U.S. government should undertake exactly such an effort, right now: an all-out response for an all-in global vaccination campaign. Such a campaign would advance U.S. economic and security interests and reboot American global leadership after years of decline. Rather than perpetuate the transactional, friend-by-friend vaccine diplomacy of China and Russia, a U.S.-led vaccine effort could invigorate a new multilateralism that is more pragmatic and inclusive than the twentieth-century international order and better adapted to tackling twenty-first-century global threats. Washington would do well to remember that if COVID-19 does come back, authoritarian governments will be able to lock down their populations more quickly and effectively than democracies will, so even in competitive terms, America’s best bet really is to eradicate the novel coronavirus. The United States has a momentous opportunity to prove both that democracy can deliver and that American ideals truly are universal. By offering a model of global cooperation that draws on a far wider range of resources than any one government can provide, the United States can lead a vaccine effort that builds on the strengths of its open and pluralist society. President Biden would demonstrate unequivocally that the United States is not only “back” but looking—and leading—far ahead. THE CASE FOR GOING REALLY BIG The COVID-19 pandemic is the most extensive humanitarian and economic catastrophe of modern times. Though it lacks the cataclysmic impact of a natural disaster, its toll is far worse and more widespread. A reported 2.6 million have died from COVID-19, though that is certainly an undercount; one analysis of premature and excess mortality estimates 20.5 million years of life have been lost. According to the World Bank, the pandemic pushed as many as 124 million into extreme poverty in 2020, the first year of increase in two decades. The Economist estimates that two years of COVID-19 will cost the world $10.3 trillion—a downturn the World Bank says is twice as deep as the Great Recession. Ultimately, the only way to arrest, let alone reverse, this collapse is global vaccination. The Biden administration learned an important lesson from the government’s response to the 2008 financial crisis: do not be afraid to go big. The American Rescue Plan does just that, funneling $1.9 trillion into many different parts of the economy. The administration should heed the same advice when it comes to vaccinating the world. An all-out effort will have the greatest and quickest impact on the fight against COVID-19—and the impact it will have is squarely in America’s self-interest. The United States has much to gain from an accelerated recovery of the global economy. A study from the Eurasia Group estimated that vaccinating low- and middle-income nations would generate at least $153 billion for the United States and nine other developed economies in 2021 and up to $466 billion by 2025. Even if the United States vaccinates its entire population, its economic recovery will still drag so long as its trading partners don’t have full access to the vaccine and the pandemic continues. As Biden has said, “We’re not going to be ultimately safe until the world is safe.” Moreover, today’s pandemic will not be the last. The partnerships and public health infrastructure that the United States builds to inoculate the world from this coronavirus will also defend it against the next deadly pathogen or health threat. Protecting the nation against disease cannot be separated from protecting the world. In 2018, the United States issued a National Biodefense Strategy that seemed to recognize this interdependence. The strategy called for developing agreements and partnerships to help foreign countries prepare for and respond to bio-incidents. Such collaborations not only prevent emerging threats but also contribute to a spirit of openness that can pay off in profound ways. There was no such openness between China and the United States when COVID-19 emerged in 2019. Had China swiftly shared its data and genome information with the World Health Organization and other countries, the initial outbreak might have been slowed. HOW TO END A PANDEMIC Ending a pandemic and vaccinating the entire world is an extraordinary undertaking. It will depend a great deal on the COVAX Facility and Gavi, the Vaccine Alliance, which is the facility’s execution arm. Gavi was established with funding from the Bill & Melinda Gates Foundation two decades ago and is a crowning achievement of a whole-of-society approach to global problem-solving. It was specifically designed to deliver vaccines globally by combining the speed and flexibility of the private and civic sectors with the scale of the public sector. Still, the job before it is monumental and will require the kind of networked support that the United States brought into play in earlier humanitarian crises, such as the AIDS pandemic, the Ebola epidemic in 2014, and the Indian Ocean tsunami. The United States could bring the formidable logistics capabilities of its military to bear on the effort to supply and deliver vaccines globally, including in difficult and remote locations. The U.S. military excels at exactly such tasks and has a global footprint, along with long-standing partnerships in countries ranging from Colombia to Egypt to the Philippines. As was the case in the 2004 Indian Ocean tsunami relief effort, U.S. forces could partner with foreign militaries to help expand and administer national vaccination programs. Washington could call upon allies in the G-7 and NATO to build a broad coalition that shares the costs. And in contrast to the interminable stabilization operations in the Middle East, this humanitarian assistance mission would be straightforward, with concrete objectives. The United States already has thousands of civilian officials and locally employed staff with experience in humanitarian assistance operations and immunization campaigns stationed around the world, representing such agencies as USAID, the CDC, and the State Department. Because of past initiatives, such as PEPFAR and the Global Health Security Agenda, the United States has strong public health partnerships in dozens of low- and middle-income nations. As Samantha Power, former ambassador to the United Nations, has argued in these pages, that presence could be directed toward helping countries manage logistics and supply chains, initiate public information campaigns, train local health-care workers, and increase vaccine access for marginalized and isolated communities. A serious global campaign would mark the beginning of a very different era of American leadership. In the same spirit, the United States should work with countries to help develop and increase local vaccine-manufacturing capacity. Several Latin American countries turned to China and Russia for vaccines because they could not meet the strict terms or pay the high prices that Western drug companies demanded. Just as the Biden administration brokered a deal between Johnson & Johnson and Merck—two fierce industry competitors—to increase production of the one-shot vaccine, so **should** it push U.S. **companies to** establish production arrangements with foreign manufacturers. China and Russia have already made deals for local manufacturers to produce their vaccines. Companies in Argentina, Brazil, and Italy all plan to begin producing the Sputnik V vaccine. Open, democratic societies have tremendous resources to mobilize in the effort to vaccinate the world. Sister cities, universities, religious denominations, corporations with global supply chains, charities with global networks, diaspora groups—all could be encouraged to reach out to partners abroad and figure out how best to contribute. Involving such diverse actors would help animate a new, more dynamic multilateralism. The Biden administration is right to prioritize vaccinating every American. Ending the pandemic abroad won’t matter if the United States doesn’t vaccinate everyone at home, any more than the reverse. But the country absolutely has the ability to do both at the same time. A serious global campaign to vaccinate everyone as soon as possible would mark the beginning of a very different era of American leadership. The United States would demonstrate its ability to lead through global institutions rather than against them—and those institutions would include more nimble ones than the bureaucratic behemoths of the twentieth century. The United States, alongside as many nations as it can convince to join it, would lead with all its resources and talent, whether public, private, or civic. It would focus more on people than on power games and measure its success in lives saved more than in governments recruited to “our side.” Call it a strategy of all for all. The success of such an effort would undoubtedly confer enormous strategic advantage on the United States. PEPFAR, for example, dramatically improved the perception of the United States in many African and Asian countries. But the United States will have earned that advantage by living up to the universal commitments in its highest ideals—by being, in the words of Biden’s inaugural address, “a strong and trusted partner for peace, progress, and security” for everyone.

### Case

#### Aff gets circumvented- powerful countries use bilateral agreements to force other countries to accept their IPR protections- its empirically proven

DC = developing country

NIT = Net Importers of Technology (this references developing countries)

NET = Net Exporters of Technology (countries with advanced economies)

Marcellin 16 Marcellin, Sherry (Professor, London School of Economics). The political economy of pharmaceutical patents: US sectional interests and the African Group at the WTO. Routledge, 2016./SJKS

In July 1988, prior to the Montreal Mid-Term Review, DCs had sensed that the approach being proposed by industrialised countries was desirable on the grounds that the alternative would be a proliferation of unilateral or bilateral actions (MTN.GNG/NG11/8: 31). These NITs maintained that acceptance of such an approach would be tantamount to creating a licence to force, in the name of trade, modifications in standards for the protection of IP in a way that had not been found acceptable or possible so far in WIPO (ibid). Brazil subsequently informed the Group that on October 20, 1988, unilateral restrictions had been applied by the US to Brazilian exports as a retaliatory measure in connection with an IP issue; that this type of action seriously inhibited Brazil’s participation in the work of the Group, since ‘no country could be expected to participate in negotiations while experiencing pressures on the substance of its position’ (MTN.GNG/NG11/10: 27). The Brazilian delegate maintained that such action by the US constituted a blatant infringement of GATT rules and was contrary to the Standstill commitment of the Punta del Este Declaration. ‘The United States action was an attempt to coerce Brazil to change its intellectual property legislation, and furthermore represented an attempt by the United States to improve its negotiating position in the Uruguay Round’ (ibid). A US delegate countered that the measures had been taken with regret and as a last resort after all alternative ways of defending legitimate US interests had been exhausted, and that the US further believed that the adoption of effective patent protection was in Brazil’s own interest (ibid: 28). The US had therefore applied its strategy of coercive unilateralism against one of the two most important players championing the cause of the South in the TRIPS negotiations, the other being India. Apprehensive about the resistance of this dominant Southern duo, the United States sought to utilise its market size as a bargaining tool to secure changes to national IP regimes. It therefore decided to impact the more powerful of the two at the time, thereby indirectly admonishing India and the entire coalition against strengthened IP rules, as well as their domestic export constituencies who would be affected by US decisions to restrict imports. Moreover, because Brazil and India appeared to be collaborating extensively in maintaining a united front, a resulting strain on Brazil’s economy would likely affect their co-operation. However, since market opening and closure have been treated as the currency of trade negotiations in the post-war period (Steinberg 2002: 347), the move to place restrictions on Brazilian exports by the largest consumer market in the GPE should not have been entirely unanticipated. Brazil was also the regional leader in South America and disciplining it would send an unequivocal warning to other South American countries (Drahos and Braithwaite 2002: 136), including Argentina, Chile and Peru who were also active participants in the negotiations. This would mark the start of a series of coercive strategies aimed at compliance with the US private-sector envisioned GATT IPP.

#### Companies will just obtain a patent in a different sector.

Thomas 15 [John R; Visiting Scholar, CRS; “Tailoring the Patent System for Specific Industries, Congressional Research Service,” CRS; 2015; <https://crsreports.congress.gov/product/pdf/R/R43264/7>] Justin

In view of the concerns noted above, commentators have gone so far to say that “it has become increasingly difficult to believe that a one-size-fits-all approach to patent law can survive.”75 To the extent the current patent system creates a blanket set of rules that apply comparably to distinct industries, it likely over-encourages innovation in some contexts and under-incentivizes it in others.76 Further, some observers have asserted that the need of firms to identify and access the patented inventions of others may differ among industries.77 As a result, the case can be made that distinct industrial, technological, and market characteristics that exist across the breadth of the U.S. economy compel industry-specific patent statutes. However, others have questioned the wisdom and practicality of such line-drawing.78 The following concerns, among others, have been identified:

• Over its long history, the U.S. patent system has flexibly adapted to new technologies such as biotechnology and computer software. Legislative adoption of technology-specific categories may leave unanticipated, cutting-edge technologies outside the patent system.79

• Defining a specific industry or category of technologies may prove to be a contested proposition.

80 • Over time, new industries may emerge and old industries may consolidate. The dynamic nature of the U.S. economy suggests greater need for legislative oversight within a differentiated patent regime.

81 • Even if an industry or technology remains relatively stable, the innovation environment within it might change. For example, technological or scientific advances might open new possibilities for research and development within hidebound industries—but also increase expense and risk for those firms.

82 • Distinct patent rights among industries or technologies may lead to strategic behavior on behalf of patent applicants. For example, a computer program that controls a fuel injector within an automobile could possibly be identified as either an automobile-related or a computer-related invention.

83 •The legislative effort to enact sector-specific patent laws may provide an opportunity for politically savvy firms to exert more lobbying and political power, at the possible expense of less sophisticated firms.

#### MRNA expert shortages.

Garde et al 21 [Damian Garde (National Biotech Reporter), Helen Branswell (Senior Writer, Infectious Disease)Matthew Herper (Senior Writer, Medicine, Editorial Director of Events), 5/6/21, Waiver of patent rights on Covid-19 vaccines, in near term, may be more symbolic than substantive, <https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/>] Justin

In October, Moderna vowed not to enforce its Covid-19-related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses.

That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines.

“There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple,” said Norman Baylor, who formerly headed the Food and Drug Administration’s Office of Vaccines Research and Review, and who is now president of Biologics Consulting.

While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — using messenger RNA technology — require skilled expertise that even existing manufacturers are having trouble sourcing.

“In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said.

#### Existing companies solve scale-up, but other companies don’t have the capabilities.

Lowe 21 [Derek; BA from Hendrix College and PhD in organic chemistry from Duke before spending time in Germany on a Humboldt Fellowship on his post-doc. He’s worked for several major pharmaceutical companies since 1989 on drug discovery projects against schizophrenia, Alzheimer’s, diabetes, osteoporosis and other diseases; 2/2/21; Myths of Vaccine Manufacturing; <https://www.science.org/content/blog-post/myths-vaccine-manufacturing>] Justin

Ah, but now we get back to Step Four. As Neubert says, "Welcome to the bottleneck!" Turning a mixture of mRNA and a set of lipids into a well-defined mix of solid nanoparticles with consistent mRNA encapsulation, well, that's the hard part. Moderna appears to be doing this step in-house, although details are scarce, and Pfizer/BioNTech seems to be doing this in Kalamazoo, MI and probably in Europe as well. Everyone is almost certainly having to use some sort of specially-built microfluidics device to get this to happen - I would be extremely surprised to find that it would be feasible without such technology. Microfluidics (a hot area of research for some years now) involves liquid flow through very small channels, allowing for precise mixing and timing on a very small scale. Liquids behave quite differently on that scale than they do when you pour them out of drums or pump them into reactors (which is what we're used to in more traditional drug manufacturing). That's the whole idea. My own guess as to what such a Vaccine Machine involves is a large number of very small reaction chambers, running in parallel, that have equally small and very precisely controlled flows of the mRNA and the various lipid components heading into them. You will have to control the flow rates, the concentrations, the temperature, and who knows what else, and you can be sure that the channel sizes and the size and shape of the mixing chambers are critical as well.

These will be special-purpose bespoke machines, and if you ask other drug companies if they have one sitting around, the answer will be "Of course not". This is not anything close to a traditional drug manufacturing process. And this is the single biggest reason why you cannot simply call up those "dozens" of other companies and ask them to shift their existing production over to making the mRNA vaccines. There are not dozens of companies who make DNA templates on the needed scale. There are definitely not dozens of companies who can make enough RNA. But most importantly, I believe that you can count on one hand the number of facilities who can make the critical lipid nanoparticles. That doesn't mean that you can't build more of the machines, but I would assume that Pfizer, BioNTech, Moderna (and CureVac as well) have largely taken up the production capacity for that sort of expansion as well.

And let's not forget: the rest of the drug industry is already mobilizing. Sanofi, one of the big vaccine players already (and one with their own interest in mRNA) has already announced that they're going to help out Pfizer and BioNTech. But look at the timelines: here's one of the largest, most well-prepared companies that could join in on a vaccine production effort, and they won't have an impact until August. It's not clear what stages Sanofi will be involved in, but bottling and packaging are definitely involved (and there are no details about whether LNP production is). And Novartis has announced a contract to use one of its Swiss location for fill-and-finish as well, with production by mid-year. Bayer is pitching in with CureVac's candidate.

#### The aff causes a scramble for limited resources by manufacturers with no experience – turns case.

Breuninger 21 [Kevin; Specialist at CNBC; “Pfizer CEO opposes U.S. call to waive Covid vaccine patents, cites manufacturing and safety issues,” CNBC; 5/7/21; <https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html>] Justin

“Currently, infrastructure is not the bottleneck for us manufacturing faster,” Bourla wrote in a dear colleague letter posted on LinkedIn. “The restriction is the scarcity of highly specialized raw materials needed to produce our vaccine.”

Pfizer’s vaccine requires 280 different materials and components that are sourced from 19 countries around the world, Bourla said. He contended that without patent protections, entities with much less experienced than Pfizer at manufacturing vaccines will start competing for the same ingredients.

“Right now, virtually every single gram of raw material produced is shipped immediately into our manufacturing facilities and is converted immediately and reliably to vaccines that are shipped immediately around the world,” Bourla wrote.

He predicted that the proposed waiver “threatens to disrupt the flow of raw materials.”

“It will unleash a scramble for the critical inputs we require in order to make a safe and effective vaccine,” Bourla wrote.

“Entities with little or no experience in manufacturing vaccines are likely to chase the very raw materials we require to scale our production, putting the safety and security of all at risk,” the CEO wrote.

#### Prevents distribution---causes vaccine hesitancy.

Newey et al 21 [Sarah Newey*;* Anne Gulland*;* Jennifer Rigby, (GLOBAL HEALTH SECURITY CORRESPONDENTS at the telegraph) *and* Samaan Lateef (Reporting IN INDIA) 6/1/21, Vaccinating the world: the obstacles hindering global rollout – and how to overcome them, Telegraph, <https://www.telegraph.co.uk/global-health/science-and-disease/vaccinating-the-world/>] Justin

[Vaccine hesitancy has also reared its head](https://www.telegraph.co.uk/global-health/science-and-disease/hesitancy-hard-wired-us-indulge-now-peril/), with concerns around rare blood clots linked to the AstraZeneca and J&J vaccines hitting public confidence in Africa. The Democratic Republic of Congo sent 1.3m unwanted doses to countries including Togo and Senegal before they expired in late June, while Malawi destroyed 20,000 unused shots last month as hesitancy hit rollout. “There were some assumptions in the public health community that this is such a bad pandemic... that this will change people’s minds if they were ever hesitant about vaccines,” Prof Heidi Larson, director of the Vaccine Confidence Project, told a Devex event. “Well, it hasn’t really – in fact, the groups and the questioning around vaccines and some of the anti sentiments have actually escalated.” There are also growing concerns that the AstraZeneca and J&J vaccines may be viewed as the “cheap relation” compared to the new mRNA vaccines produced by Pfizer and Moderna. Given the former make up the bulk of Covax’s supply and are far easier to distribute in the developing world, this is a substantial hurdle. “The AstraZeneca row has significantly impacted confidence – not just across Africa, but around the world,” says Dr Ayoade Alakija, co-chair of the Africa Union Vaccine Delivery Alliance. “But there is no choice here [to pick a different vaccine].” However, back in Kumasi, Mr Nyarko says it is supply rather than confidence that is currently undermining his district’s roll out. And with no clear picture on when more shots will arrive, he’s left with few options. “All we can do for now is pray that Ghana can secure another batch,” he says. “We are praying that the UK and Europe will help us.

#### LICs statistically cannot mass produce vaccines.

Newey et al 21 [Sarah Newey*;* Anne Gulland*;* Jennifer Rigby, (GLOBAL HEALTH SECURITY CORRESPONDENTS at the telegraph) *and* Samaan Lateef (Reporting IN INDIA) 6/1/21, Vaccinating the world: the obstacles hindering global rollout – and how to overcome them, Telegraph, <https://www.telegraph.co.uk/global-health/science-and-disease/vaccinating-the-world/>] Justin

Supply is one thing but actually getting shots into arms is a huge undertaking for any country. According to a review of low and middle income countries’ readiness to implement vaccine campaigns conducted by the World Bank, 95 per cent have developed national plans and 82 per cent have worked out which groups should be vaccinated first. However, crucial gaps remain. Only 59 per cent have plans to train vaccinators and less than half (48 per cent) have implemented communications strategies to encourage people to take up vaccines. While low and middle income countries are used to delivering childhood vaccines, so have cold chain systems in place, a mass vaccine campaign for adults is a very different beast, says Mamta Murthi, vice president for human development at the World Bank. “This is a very different population – adults may be at work, at home, they may be unwilling to travel or not be able to come to vaccine centres,” she says.

#### Patents can’t solve the vaccine problem- they don’t have enough info and manufacturers shield key replication information

Santos Rutschman 21 Santos Rutschman, Ana (Professor of Law, St. Louis University) and Julia Barnes-Weise (Executive Director of the Global Healthcare Innovation Alliances Accelerator a non-profit organization spun out of a program in Public Policy at Duke University, and a Senior Consultant to the Coalition for Epidemic Preparedness Innovations. She is a lawyer, global health policy consultant, entrepreneur and Certified Licensing Professional). "The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal." Bill of Health (2021) (2021)./SJKS

In order to understand the practical limitations of a waiver of intellectual property rights when a vaccine is involved, it may be useful to think of patents as informational mechanisms akin to the information and tools needed to turn a recipe into an edible product. One or more patents will provide a recipe for a process or a component needed to produce a vaccine. But, just as with a culinary recipe, the informational power of a patent does not cover any tips or instructions that have not been memorialized in writing, nor does it provide any access to the raw materials needed to put a vaccine together. Waivers, therefore, temporarily remove exclusionary rights, but do not address two fundamental sources of the current vaccine scarcity problem. First, we are still left with a significant informational problem: as many [commentators](https://science.sciencemag.org/content/369/6506/912) have remarked, knowledge disclosed through patents alone is often insufficient for a third party to actually be able to replicate a vaccine. From a scientific perspective, vaccines are biological products, and, as such, their relative complexity makes them highly dependent on specific manufacturing processes and practices, many of which are not disclosed in a patent — think of it as the unwritten tips or instructions for a particular recipe. Some of this information may be kept secret by a company for competitive reasons; in these cases, lifting patent rights will not result in increased informational disclosure, unless the patent holders themselves are willing to collaborate. A waiver thus solves the exclusivity problem, but not the information problem that undergirds competition in vaccine manufacturing. To revisit the analogy introduced above, a waiver allows third parties to freely use the recipe. It does not, however, provide all the information that may be needed to manufacture the desired good, nor does it provide manufacturers with the tacit knowledge that only the original manufacturer possesses and is not disclosed elsewhere.