# R6 NC

## 1

#### Counter-plan text: Low- and Middle-Income Countries should implement a public-private partnership

#### Public-private partnerships solve net better.

Rubin and Saidel 8-31 Harvey Rubin and Nicholas Saidel, 8-31-2021, "Innovation beyond patent waivers: Achieving global vaccination goals through public-private partnerships," Brookings, <https://www.brookings.edu/blog/up-front/2021/08/31/innovation-beyond-patent-waivers-achieving-global-vaccination-goals-through-public-private-partnerships/> //Nato // Re-Cut Justin

\*\*Chart moved to bottom for ease of reading.

The international effort to achieve global COVID-19 vaccination goals faces a dilemma. Stakeholders in this space are at odds over how to treat intellectual property (IP) rights now that viable vaccines are on the market but are inaccessible to vulnerable populations in low- and middle-income countries (LMICS). A key aspect of this debate is whether to grant patent waivers for COVID-19 vaccines and therapeutics. We suggest looking beyond patent waivers with an innovative solution based on public-private partnerships (PPPs), an approach that could be more effective in combating the on-going COVID-19 pandemic and simultaneously help prepare LMICS for future health crises. BACKGROUND Created in 1995, the World Trade Organization (WTO) provides a [forum](https://www.jhsph.edu/covid-19/articles/wto-trips-waiver-for-covid-19-vaccines.html) for member states to lower barriers to international trade. The WTO also [serves](https://www.wto.org/english/thewto_e/whatis_e/wto_dg_stat_e.htm) as a legal and institutional framework for executing multilateral agreements related to the global trading system. One of these agreements is known as Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS governs the protection of IP rights, such as patents and trademarks. Technologies that prevent, contain, and treat COVID-19—the death toll from which exceeds [4.3 million people](https://www.cnn.com/interactive/2020/health/coronavirus-maps-and-cases/) with [over 200 million](https://www.nytimes.com/2021/08/04/world/europe/coronavirus-200-million-cases.html) infected—are protected under TRIPS. This intersection of global public health and international trade regulations has spurred a debate as to whether an exception to TRIPS for COVID treatments is warranted. The two schools of thought on the patent waiver issue can be roughly characterized as follows: Pro-patent protection: The first school that patent protections on COVID-19 vaccines are necessary because pharmaceutical companies will otherwise be disincentivized to innovate and invest in vaccine research and development, and they will unfairly lose market share to competitors and adversarial nations such as China. This theory also that removing IP protections will not serve the intended objective of increasing vaccination rates as the developing world lacks the infrastructure and expertise to roll out effective domestic production. Advocates of patent protection argue that the WTO already allows countries to apply for “compulsory licensing,” which waives IP during emergencies such as the COVID-19 pandemic. Proponents of continued patent protection see voluntary commitments from industry, developed world governments, and large NGOs as a more effective means of addressing the problem. Pro-patent waiver: Conversely, others removing IP protections is a necessity as companies located in high-income countries hold most, if not all, of the COVID-19 vaccine IP and sell the vaccines to governments mostly in the developed world. According to this view, the price of these vaccines, combined with export restrictions and the inability of LMICs to manufacture their own vaccines at a lower price and without fear of litigation from patent holders, are among the main reason why vaccines are not reaching the world’s most vulnerable communities. They further that the compulsory license process is both time consuming and cumbersome and that providing basic medical services for these vulnerable communities should be prioritized over industry profits. Finally, a more diffuse global vaccine manufacturing architecture would be more effective and in line with health as a human right. The patent waiver issue gained traction in response to the stark disparity in global health outcomes as COVID-19 vaccines and therapeutics were brought to market. Data from May 2021 [indicates](https://www.oxfam.org/en/press-releases/more-million-covid-deaths-4-months-g7-leaders-failed-break-vaccine-monopolies) that “people living in G7 countries were 77 times more likely to be offered a vaccine than those living in the world’s poorest countries.” Data from the end of June 2021 [reflects](https://www.bmj.com/content/374/bmj.n1837.full) that “46% of people in high-income countries had received at least one dose of the COVID-19 vaccine compared with 20% in middle-income countries and only 0.9% in low-income countries.” This global health inequity is in part due to high-income countries purchasing more vaccines than they need. For example, Canada has [secured](https://www.bmj.com/content/374/bmj.n1837.full) vaccine doses for 434% of its population. Another issue is vaccine price in relation to cost and LMIC’s purchasing power: One report [states](https://reliefweb.int/report/world/great-vaccine-robbery-pharmaceutical-corporations-charge-excessive-prices-covid-19) that Pfizer/BioNTech and Moderna have been charging governments up to 24 times the potential cost of production. Furthermore, Pfizer/ BioNTech are charging their lowest reported price of $6.75 to the African Union, yet [one dose costs the same](https://reliefweb.int/report/world/great-vaccine-robbery-pharmaceutical-corporations-charge-excessive-prices-covid-19) as Uganda spends per citizen on health annually. These incongruities represent an injustice to the world’s underserved populations, and they demand the development of innovative ideas regarding how to overcome price and access obstacles. In October 2020, India and South Africa led a group of LMIC’s request to the WTO to waive certain TRIPS provisions. The [request](https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True), modified as of May 25, 2021, asks for a three-year waiver of IP protection for products and technologies related to COVID-19 prevention, treatment, and containment. Normally, WTO protections for IP last around 20 years. The Biden administration is [currently on board with the waiver](https://thehill.com/policy/healthcare/551992-biden-backs-covid-19-vaccine-patent-waivers), and the EU is open to negotiations. However, some EU member states like Germany remain steadfast in rejecting this idea, and the EU has [proposed](https://news.yahoo.com/eu-present-wto-plan-boost-074524190.html) its own non-waiver plan. The WTO will likely take months [deliberating](https://www.cfr.org/in-brief/debate-over-patent-waiver-covid-19-vaccines-what-know) this matter, and it usually renders decisions unanimously, though a TRIPS waiver would technically only require a three-quarters majority to pass. As it stands now, [talks](https://www.natlawreview.com/article/waiver-ip-protections-covid-19-vaccines-still-under-consideration-wto) at the WTO stalled in late July with little progress and are now on hold for the summer holiday. SOLUTION An optimal solution to the currently inequitable global distribution of COVID-19 vaccines requires more innovation than a temporary waiver of patents. A process is needed whereby LMICs can take some level of ownership over the manufacturing and distribution of critical vaccines and medicines without the bureaucratic red tape associated with compulsory licensing. We suggest that PPPs between pharmaceutical companies and relevant governmental ministries that are well-funded by access to the capital markets through impact bonds is a comprehensive, sustainable solution to the problem of achieving global vaccination goals. A PPP can be [defined](https://www.cambridge.org/core/journals/health-economics-policy-and-law/article/abs/publicprivate-partnerships-in-the-health-sector-the-danish-experience/B3EB8135E4303250D7DE4870899593A2) as: Co-operation of some sort of durability between specific public and private actors in which they jointly develop infrastructure, products, and services (including knowledge and dissemination of information) and share risks (financial and/or prestige), cost and resources, which are applied in the development and delivery process. This solution has three essential components: first, identifying the incentives for the private sector to participate in the partnership; second, inducing the public sector to transfer some of its mission and responsibilities to the partnership; and third, access to capital markets. As the current authors [wrote](https://www.sciencedirect.com/science/article/abs/pii/S0030438716000089) in 2016: Private sector entities can profit from PPPs—especially with LMICs that present a new or unsaturated market for a wide range of a pharmaceutical company’s products. Increased brand recognition, increased market penetration, entry into new markets, preserving the existing customer base, gaining new customers, and garnering favorable status for introduction of new products are all attractive concepts for private sector partners. Relaxed barriers to market entry (e.g., tariffs and taxes) and access to LMIC raw data would also motivate a private sector entity to forge a relationship with public entities. The public sector can be incentivized to formalize a PPP for pharmaceutical and vaccine-related issues like supply chain management, data capture and analysis, quality control, and inventory optimization. PPPs would assist in speeding up the scaling required to develop sufficient quantities of COVID-19 vaccines and medicines, and LMICs would be better prepared for future pandemics. Access to the capital markets through “impact bonds” can provide a source of sustainable funds. Impact bonds work in a series of steps (see Figure 1. below): Investors purchase bonds and provide up-front risk capital to finance the program(s). Prior to issuance of the bonds, well-defined metrics leading to specific sets of outcomes for success of the partnership need to be negotiated. The progress toward fulfilling these outcomes will be monitored and rigorously measured by an independent organization at every stage. When the partnership demonstrates that it has met its goals, the outcome payers—who can be public sector entities (i.e., Ministries of Health or Finance), the private sector, development banks, or combinations of all three—are contractually and legally required to repay the investors. The key advantage of this approach is the additional accountability for outcomes that investment brings. Investors’ interest in achieving measurable success provides a framework that incentivizes flexible and effective program implementation. Risk is transferred to the investor, and the focus on rigorously measured outcomes ensures that scarce donor funding is only used for tangible, verifiable outcomes. The metrics, goals, and outcomes must be uniquely crafted for each country in which the impact bond is issued. Ultimately, a successful PPP might lead to healthier populations, more robust and cost-effective national healthcare systems, and economic growth. Source: [Understanding Social Impact Bonds, OECD Working Paper, 2016](https://www.oecd.org/cfe/leed/UnderstandingSIBsLux-WorkingPaper.pdf) As Brookings Institution scholars [wrote](https://www.brookings.edu/research/usaids-public-private-partnerships-a-data-picture-and-review-of-business-engagement/#:~:text=On%20a%20conceptual%20level%2C%20public-private%20partnerships%20are%20a,agency%2C%20a%20for-profit%20business%2C%20and%20a%20nonprofit%20entity.) in a review of USAID’s PPPs: “On a conceptual level, public-private partnerships are a win-win, even a win-win-win, as they often involve three types of organizations: a public agency, a for-profit business, and a nonprofit entity. PPPs use public resources to leverage private resources and expertise to advance a public purpose. In turn, non-public sectors—both businesses and nongovernmental organizations (NGOs)—use their funds and expertise to leverage government resources, clout, and experience to advance their own objectives, consistent with a PPP’s overall public purpose. The data from the USAID data set confirm this conceptual mutual reinforcement of public and private goals.” A case study is further illustrative of how PPPs play an integral role in pandemic-related solutions. Established in 2003, The U.S. President’s Emergency Plan for AIDS Relief ([PEPFAR](http://www.pepfar.gov/)) is a U.S. government foreign aid program focused on controlling the HIV/AIDS epidemic in more than 50 countries. PEPFAR has saved millions of lives; experts [note](https://www.healthaffairs.org/doi/10.1377/hlthaff.2012.0585) that PPPs played a key role in this effort, strengthening logistics, supply chains, and HIV lab practices: PEPFAR’s Supply Chain Management System took advantage of private industry’s best practices in logistics, and a partnership with the medical technology company BD (Becton, Dickinson and Company) improved laboratory systems throughout sub-Saharan Africa. We found that setting ambitious goals, enlisting both global and local partners, cultivating a culture of collaboration, careful planning, continuous monitoring and evaluation, and measuring outcomes systematically led to the most effective programs. Other examples of successful PPPs in global health include the Global Alliance for Vaccines and Immunizations (GAVI); the Global Fund to Fight AIDS, TB and Malaria; Global Alliance for TB Drug Development, Drugs for Neglected Diseases initiative (DNDi); International AIDS Vaccine Initiative (IAVI); Medicines for Malaria Venture; Harnessing Non-State Actors for Better Health for the Poor; and PPPs for Universal Health Coverage. CONCLUSION Patent waivers will not correct the lack of capacity in the majority of LMICs that is necessary to implement domestic production of vaccines. Cold chain infrastructure, logistics and data systems, robust supply chains (including access to the raw materials needed for disease testing and vaccine/medicine production), and storage and administration need to be developed. Finally, there is a desperate need to train and maintain a skilled workforce to permanently meet not only the ongoing challenges of the current pandemic and any future pandemic but also to build capacity and jobs in the biomedical sectors. Implementing an impact bond-funded PPP to fully develop, manage, and sustain a vaccine and critical medicine supply/cold chain is the most promising path forward to broaden access to COVID-19 vaccines and therapeutics in LMICs. It’s an ambitious goal that requires cooperation among entities with disparate interests, but the current alternatives are not working. The patent waiver debate could yield fruit by perhaps streamlining TRIPS’ compulsory licensing process or by granting waivers to countries that have the capacity to make generics at lower cost. However, the core long-term problem for most LMICs will remain without engagement with the private sector’s expertise and access to capital markets. PPPs are the best way these countries will be able to strengthen their infrastructure, supply chain capacity, and technical expertise sufficiently and permanently in order to respond to pandemics effectively—a result that is required for global health security and equity.

## 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

#### 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