# NC

We’ll concede fairness comes first but there’s no warranted argument for why 1AC theory must come first – all of their arguments are preemptive things I did – I’m calling that out – which means that our shells need to operate on the same level.

# Misdisclosure

#### A. Interp : the affirmative must disclose changes to their affs if they include arguments like: ROBs must explicitly delineate their stance on theory, how to weigh offense, and if performance is relevant, All K links must be checked in CX, No neg analytics - I don’t have time to cover 100 blippy arguments in the NC since you can read 7 min of analytics and extend any of them to win.

#### Violation – they didn’t. SS in Doc:

#### 

#### Prep skew – I have no way to prepare prep that’s going to meet all of these arguments. Prep time in round can’t solve – I don’t have enough time to formulate a strategy that can meet all of this.

#### Reciprocity – U had alllll the time in the world to prep the aff but I only had ur speech and prep time. Controls the internal link to fairness – you had an unfair route to the ballot.

#### Fairness – intrisinc to the activity, all args concede the validity

#### DTD- deters future abuse

#### Cis – reasonability invite jusdge intervention, race to the bottom

#### No RVIS- illogical, baiting

# Abolition K

## Framework

#### [Medina & ROJ] OPPPRESSION IS HERE, AND IT STOPS EDUCATION – excluding some perspectives creates a flawed epistemology that makes answering ethical questions impossible.

Medina: Medina, Jose. [Contributing author for the Oxford University Press] “Toward a Foucauldian Epistemology of Resistance: Counter-Memory, Epistemic Friction, and Guerrilla Pluralism”. *Foucault Studies*, 1(12), 9–35. 2011 DD

Foucault invites us topay attention to the past and ongoing epistemic battles among competing power/knowledgeframeworks that try to control a given field.Different fields—or domains of discursive interaction—contain particular discursive regimes with their particular ways of producing knowledge.In the battle among power/ knowledge frameworks,some come on top and become dominant while others are displaced and become subjugated.Foucault’s methodology offers a way of exploiting that vibrant plurality of epistemic perspectives which always containssomebodies ofexperiencesand memoriesthat are erased orhidden in the mainstream frameworks thatbecome hegemonic after prevailing in sustained epistemic battles.What Foucault callssubjugated knowledges are forms ofexperience and remembering that are pushed to the margins and render unqualified and unworthy of epistemic respect **by** prevailing and hegemonic discourses.Subjugated knowledges remain invisible to mainstream perspectives; they have a precarious subterranean existence that renders them unnoticed by most people and impossible to detect by those whose perspective has already internalized certain epistemic exclusions. And with the invisibility of subjugated knowledges, certain possibilities for resistance and subversion go unnoticed.The critical and emancipatory potential of Foucaultian genealogy resides in challenging established practices of remembering and forgetting by excavating subjugated bodies of experiences and memories, bringing to the fore the perspectives that culturally hegemonic practices have foreclosed. The critical task of the scholarand the activistis toresurrect subjugated knowledges—that is, to revive hidden or forgotten bodies of experiences and memories—and to help produce insurrections of subjugated knowledges. In order to be critical and to have transformative effects, genealogical investigations should aim at these insurrections, which are critical interventions that disrupt and interrogateepistemic hegemonies and mainstream perspectives(e.g. official histories, standard interpretations, ossified exclusionary meanings, etc). Such insurrections involve the difficult labor of mobilizing scattered, marginalized publics and of tapping into the critical potential of their dejected experiences and memories.An epistemic insurrection requires a collaborative relation between genealogical scholars/activists and the subjects whose experiences and memories have been subjugated: those subjects by themselves may not be able to destabilize the epistemic status quo until they are givena voice at the epistemic table (i.e. in the production of knowledge), that is, until room is made for their marginalized perspective to exert resistance, until past epistemic battles are reopened and established frameworks become open to contestation.

**Thus,** the **Role of the Judge** is to **Promote Resistance to Oppression**, which means they endorse strategies that push back against structural denials of due – comes first, since policies mean nothing if they exclude the people who are supposed to benefit from them.

#### [Meller & Ahmed & ROB] And Big Pharma is a key cause of oppression – it consistently undermines people’s basic needs for companies’ financial gain.

Meller & Ahmed: Meller, Abby [Organizing Associate for Democracy and Government at the Center for American Progress] and Hauwa Ahmed [Research Assistant for Democracy and Government at the Center]. “How Big Pharma Reaps Profits While Hurting Everyday Americans.” Center for American Progress, August 30, 2019. americanprogress.org/issues/democracy/reports/2019/08/30/473911/big-pharma-reaps-profits-hurting-everyday-americans/ CH

Despite these taxpayer subsidies, prescription drug prices are nonetheless increasing at an alarming rate. In 2019, price increases from drug manufacturers affected more than 3,40026 drugs. For example, Allergan, a major pharmaceutical manufacturer, raised prices on 51 drugs, just more than half its portfolio. Some medications that Allergan manufactures saw a 9.5 percent jump in cost, while others saw a 4.9 percent increase in cost.27 Teva Pharmaceutical Industries Ltd., the largest generic drug manufacturer in the world, increased its drug prices by more than 9 percent.28 These sharp increases in price occur as companies continue to report millions of dollars in revenue. In 2018, Allergan reported $15.8 million29 in revenue, while Teva Pharmaceuticals reported $18.8 million30 in revenue. Pharmaceutical companies’ profit margins receive significant bumps when they launch new drugs, specifically specialty drugs, used to treat life-threatening conditions. These drugs often cost more than most Americans can afford. Pharmaceutical companies have stated that the prices are high because the drugs are difficult to manufacture. In 2013, for example, industry giant Gilead Sciences launched Sovaldi, a hepatitis C drug, at $1,000 per pill31, or $84,00032 per treatment, which could last 12 to 24 weeks.33 After an 18-month investigation into the company’s pricing, the Senate Finance Committee concluded that Gilead had pursued a marketing and pricing strategy designed to “maximize revenue with little concern for access or affordability.”34 Drug companies also benefit from patents, which give them monopoly power for their on-patent products. These patents ensure that prices remain high by reducing competition. Drug patents last for 20 years after the filing date. Pharmaceutical companies have also employed tactics such as evergreening and thicketing to prolong a drug’s exclusivity. When evergreening, pharmaceutical companies make certain modifications to a drug such as changing its35 chemical composition slightly or making an external change as minor as adding a stripe to a pill36 in order to preserve their patents. A 2018 study in the Journal of Law and the Biosciences found that 78 percent37 of new drug patents awarded in the past decade went to drugs that already existed. Seventy percent 38 of the nearly 100 bestselling drugs extended their exclusivity protections at least once, and 50 percent extended their patents more than once. The second tactic—thicketing—involves flooding the U.S. Patent and Trademark Office and the courts with excessive patents and applications to make it difficult for competing firms to secure patents. These tactics help preserve pharmaceutical companies’ monopolies and ensure that drug prices remain uncompetitive and thus less affordable for everyday Americans. While consumers continue to pay the price of this market manipulation, a Government Accountability Office (GAO) report on the pharmaceutical industry found that these unfair practices are significantly enriching manufacturers. As the report stated, “Among the largest 25 companies, annual average profit margin fluctuated between 15 and 20 percent.”39 The GAO contextualizes these profits by comparing the pharmaceutical industry’s profits with those of its counterparts, stating that “the annual average profit margin across non-drug companies among the largest 500 globally fluctuated between 4 and 9 percent.”

**The Role of the Ballot** is to **Endorse the Interrogation of Medical Capitalism**, meaning strategies that reduce market competition to benefit corporations. Controls the link to other frameworks, since harms like disease and death can’t be addressed without access to medical care.

## A. Links

#### [Links] THE AFF IS PIECEMEAL REFORM – they keep existing patent law in place, only offering temporary and limited waivers. We’ll quote from the doc: the Plan isn’t anti-Patent, just pro-innovation – breaking down secondary patents is key.

## B. Impacts

#### [Trotskyist Fraction] MASSIVE INEQUALITY – patents in ANY FORM are the problem – they appropriate public goods for private gain AND cause cycles of disease.

Trotskyist Fraction: Trotskyist Fraction. “Against Capitalist Irrationality: For the Abolition of Patents, and Vaccines for All.” Left Voice, Fourth International, February 1, 2021. https://www.leftvoice.org/against-capitalist-irrationality-for-the-abolition-of-patents-and-vaccines-for-all/ CH

At a meeting of the World Health Organization (WHO) on October 15-16, 2020, India and South Africa proposed the suspension of certain articles of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This would allow patents on vaccines and other Covid-related technologies to be released. The proposal was supported by some Latin American and African countries, but was unanimously rejected by the United States, the main EU countries (including the “progressive” government of the PSOE and Unidas Podemos in the Spanish State), Australia, and Japan. Although the United States under the Biden administration has rejoined the WHO — an institution it had left under Trump’s orders — this imperialist country is unlikely to change its position one iota when it comes to patent monopolies. An alliance of non-governmental organizations, including Doctors Without Borders, Oxfam, and others, is demanding exemptions from intellectual property rights regarding vaccines and medicines for Covid. They point out that patents in the hands of private groups is already creating outrageous situations. An antiviral treatment with remdesivir costs $3,120 in the United States, while generic versions licensed in India cost between $587 and $792 per treatment even though “the estimated minimum cost to manufacture remdesivir with a reasonable profit margin is only $9 per treatment.” The monopoly ownership of vaccine patents by a handful of capitalist multinational corporations is already causing all kinds of cruel inequalities in vaccine distribution. Whoever pays the most, gets the most — this is the motto guiding the pharmaceutical companies, even if this means leaving large swaths of the world without vaccines. This does not only mean more deaths in the poorest countries, more crises in their economies, increased migration to escape hunger, and more unemployment. It also means that if a large part of the world does not obtain vaccines, the pandemic will be more difficult to eradicate. But the logic of capitalist profit is the opposite of rationality and planning for social needs, as this crisis is tragically illustrating. Patents and intellectual property are nothing more than private appropriation of a public good: the scientific and technical knowledge that has been accumulated over years or decades, the product of extensive research in different countries, largely financed with public money in universities, hospitals, or research centers all over the planet. In the case of some vaccines like that from Moderna, the funding is almost completely public. This company used technology developed by the government as the basis for its vaccine, and then got nearly $1 billion of public money to develop it. Finally, the U.S. government paid another $1.5 billion for advanced purchases. In other words, the entire project was paid for with public money, but the patent remains in private hands. Public funding is no less important for the vaccines from Novavax, Curevac, and Johnson & Johnson. And although private funding has been important in some other cases, they have also benefited from the advance purchase of millions of doses, an indirect form of state funding. Scientific knowledge — just like art, culture, or land — is a public good of humanity. But under capitalism, it is appropriated in a rent-seeking manner by a handful of private companies using patents, intellectual property rights, trademarks, and similar mechanisms. In the case of vaccines and medicines, this is even more serious, because it is a question of life or death for millions of people. This is not only the case with Covid. For example, more than 100,000 children in India die of pneumonia each year, a disease that could be prevented with the PCV13 vaccine. But the patent is held by Pfizer, and the vaccine is prohibitively expensive in that country. The unequal distribution of patents worldwide offers a snapshot of the structure of imperialism in this field. In 2019, 3,224,200 patent applications were registered worldwide — China, the United States, Japan, Korea, and the European Patent Office accounted for 84.7 percent of the total. The combined number of registrations in Africa, Latin America and the Caribbean, and Oceania was just 3.3 percent. Vaccines for All: For the Liberation of Patents and the Nationalization of Pharmaceutical Companies and Laboratories Some European countries and the United States are already experiencing a third wave of the pandemic, which continues to ravage Latin America. Employment continues to fall, and a severe economic and social crisis is underway. However, the crisis is not the same for everyone: in the last year alone, 100 million people were pushed into poverty, while the 500 richest people on the planet — representing 0.001 percent of the world population — saw their wealth grow more than at any time in the last decade. This abysmal social inequality is part of the DNA of the deadliest virus, which is capitalism. Faced with this scenario, all governments — whether conservative or “progressive” — have responded to the crisis with mobility restrictions, curfews, and increased police presence in the streets. They claim “there are no resources” to do anything else, but they refuse to touch the capitalists’ profits. Instead, they are placing the burden of the crisis on the backs of the workers and poor nations of the world, increasing their indebtedness, which will mean more pressure from the IMF and other financial agencies for new cuts and austerity in the short term. The struggle for vaccines for everyone and for the liberation of patents is urgent in the face of the catastrophe that is the pandemic. In the same way, immediate state control of all pharmaceutical companies and laboratories is necessary, to put them under the control of health professionals and in the service of rational plans of vaccine and test production and distribution. These companies and the resources of private health care must be nationalized under workers’ control. Emergency increases in health and education budgets, as well as hiring additional healthcare personnel to give the vaccines and avoid the collapse of hospitals, should be funded with extraordinary taxes on large fortunes. Instead of paying the foreign debt, it is necessary to cancel the debt of semicolonial countries. Otherwise, the working masses will be forced to pay for the crisis. Such a program cannot be imposed on the capitalist vampires with online petitions or formal statements to the WHO. Nor can we expect anything from the (neo)reformist parties who join national governments (as in Spain) and refuse to implement emergency measures. The only way to implement these kinds of measures is to develop the common struggle of the working class, women, and youth at an international level. For this, we need to fight against the union bureaucracies that have supported reactionary “national unity” throughout the pandemic, refusing to fight for the necessary measures. The growth of reactionary nationalist tendencies in the imperialist states and the brutal speculation by the multinational corporations makes it necessary to pose an internationalist, anticapitalist, and anti-imperialist perspective. We call on all working-class organizations to campaign for urgent means of struggle, starting with the demand for the abolition of patents, vaccines for all, and the medicine, equipment, and funds necessary to combat the pandemic. There is no time to lose — our lives are worth more than their profits.

## Thus, The Alt:

#### [Rizvi] Reject the aff’s waiver to reduce IPP and instead *abolish patents.*

**Rizvi:** Rizvi, Husna. [Writer at New Internationalist] “WHAT IF…DRUG PATENTS WERE SCRAPPED?” *New Internationalist,* June 24th, 2020. JP

**It’s a broken system, not delivering the drugs we need at prices we need**. At the time of writing, the world death toll from Covid-19 is 350,000. Economist Joseph Stiglitz asks: what if a global network of laboratories, without Intellectual Property (IP) lawyers breathing down their necks, ‘monitored for emerging strains of a contagious virus, periodically updated an established formula for vaccinating against it, and then made that information available to companies and countries around the world?’ It’s not pie in the sky. It’s how flu vaccine research already operates. The World Health Organization (WHO) convenes world experts twice a year to add emerging flu strains in order to update flu vaccines. **Researchers from across 110 countries, funded largely by governments, are committed to this open-source science**. The infrastructure to gather, interpret and distribute actionable knowledge for the development of vaccines already exists. **This system could be funded through prizes, Stiglitz suggests, rewarding companies that invent necessary new medicines. Companies would need to agree to make products patent-free, be transparent over pricing and costs and share clinical trial data so that other countries can develop the same capacity**. Researchers at Global Justice Now also propose modelling democratically owned start-up firms with workers, clinicians and patients on their boards and on the Medicines Patent Pool (MPP), a UN body set up to increase access to drugs in the Global South. Governments would retain a controlling interest in these bodies. **Abolishing the IP burden would incentivize knowledge-sharing across borders, with open-source data that any WHO member could access**. With increasing vulnerability to pandemics what is needed is an ambitious strategy to compel industry to manufacture the drugs we need at scale. Transitional steps, proposed by Washington University professors Michele Boldrin and David Levine, include shortening patent terms to slowly but surely ‘decrease the strength of intellectual property interventions’. **They hasten to add: ‘the final goal cannot be anything short of abolition.’**

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## Regulation DA

#### [Silver et al] Safety regulations are up – governments oversee all drug trials.

**Silver et al 8/27:** Silver, Caleb [Editor in Chief]Attkisson, Anna [Senior Editorial Director] Siew, Walden [Editorial Director, Trading and Investing] Woolsey, Ben [Associate Editorial Director] Kagan, Julia [Senior Editor] Cornfield, Jill[Senior Editor] Wrenn, Sienna [Special Project Editor] Halton, Clay [ Associate Editor] Alpert, Gabe [Associate Editor] William, Ward [Associate Editor] “How Government Regulations Impact the Drug Sector,” *Investopedia,* August 27, 2021, https://www.investopedia.com/ask/answers/032315/how-does-government-regulation-impact-drugs-sector.asp AA

**Most governments around the world impose regulations on pharmaceutical companies,** in an effort to protect their public from harmful drug effects. **These regulations often prolong the process for bringing new pharmaceuticals to market.** **In the United States**, the [Food and Drug Administration (**FDA**)](https://www.investopedia.com/terms/f/fda.asp) **ensures that new drugs are rigorously tested for safety and efficacy**, with an aim towards minimizing side effects. **As a result of this testing, most new drugs are researched and investigated for 10 years before they are brought to market and made readily available to consumers.** Specifically, **drugs must undergo human trials intended to discover potential**[**side effects**](https://www.investopedia.com/articles/analyst/112702.asp)**and accurately gauge treatment efficacy.**3 During any point in the multi-iterative testing process, **if a new drug lacks effectiveness or triggers undesirable side effects, the company may elect to conduct further laboratory research** in an effort to achieve superior results. Since this can be rather costly, **companies often consider whether it makes fiscal sense to continue their attempts to achieve desirable results, or** whether they should **shift their resources elsewhere.** Throughout the [research and development](https://www.investopedia.com/terms/r/randd.asp) process, pharmaceutical companies must cultivate reliable sources of financing. This typically comes from loans, investments, or revenue from the sale of products that have already been approved. Generally speaking, long-established drug manufacturers with profitable product lines do not need to rely on outside investors, unlike smaller [startups](https://www.investopedia.com/terms/s/startup.asp) drug companies, which frequently raise [venture capital](https://www.investopedia.com/terms/v/venturecapital.asp) funds to bankroll their efforts.

#### [Durand & Milberg] Without strict IP regimes, companies move to secrecy to circumvent business regulations.

**Durand & Milberg:** Durand, Cédric [Associate Prof. Political Economy at U-Geneva] Milberg, William [Dean at The New School for Social Research] “Intellectual Monopoly in Global Value Chains,” 2018, <https://hal.archives-ouvertes.fr/hal-01850438> AA

The late 20th century internationalization of IPRs and the expansion of GVC trade have each been driven by a separate set of factors, but there is a link and we see it in the growing role of intangible assets in international trade. GVC trade is qualitatively different from the traditional exchange of final goods or primary products. It requires intense information flows to coordinate the labor process in parts across countries (see section 2.2). Moreover, the density of these information flows entails a risk of appropriation by would-be competitors, even more than in traditional trade of finished products, where a costly process of reverse engineering is required prior to any imitation (Mansfield et al., 1981). In GVCs, lead firms thus have to weigh the advantages of disaggregating the production process and the cost reduction this can bring against the risk of losing control over some of their proprietary intangible assets. 21 Management studies and transaction costs economists have stressed the importance of the IP institutional context for business decisions when there are international alliances, investment and sourcing due to the risk of so called “appropriability hazards” (Oxley, 1997; Teece, 1986). This risk seems to have expanded since the 1990s, although there are some early testimonies from chemical and information industries reporting a reluctance to transfer advanced technology in countries with weak intellectual property regimes (Mansfield, 1994, pp. 26–29). From the perspective of transaction cost economics, considering the case of a relation with a foreign supplier or buyer, the risk of IP leakage due to a weak IP environment will tend to raise the cost of relying on contract-based alliances relative to equity joint venture (Oxley, 1999, pp. 287–288; Williamson, 2008, p. 12). From the perspective of management research, careful management of the flow of technology along GVCs is imperative and necessitates strict control over information flows in countries with weak IPRs (Prasad & Sounderpandian, 2003, p. 246). Adequate governance arrangements, secrecy or restraint to outsource offshore were thus considered as the main way to deal with the risk of IP leaks in GVCs: Companies can mitigate intellectual property risk by bringing, or keeping, some production in-house, or at least under direct company control. That is a major reason why Motorola owns some of the testing equipment at supplier locations. Managers also can decrease risk by limiting the flow of new intellectual property into countries with weak legal protections. Companies like Cisco, which outsources all manufacturing, also lower risk by creating business processes that cannot be easily replicated by a single manufacturer. Electronics manufacturer Sharp Corp. even repairs equipment itself, thus preventing any possibility, accidental or otherwise, that its vendors will share proprietary information with Sharp's competitors. The company goes so far as to reprogram various computer-aided machines used by its vendors without sharing the information. (Chopra & Sodhi, 2004, p. 57) In the 2010s, a new field of business research and consulting emerged around the management of IP in global value chains. Its purpose is to circumvent the difficulty of using formal IP protection channels and to find other ways to enforce IPRs without limiting the scope of GVC activity. A first issue is supplier selection to minimize the risk of IP leaks (Wu, Li, Chu, & Sculli, 2013). There is also an attempt to move beyond legal procedure and use the reporting procedures created for the implementation of Corporate Social Responsibility to enforce stricter IPRs standards along the chains (Gillai, Rammohan, & Lee, 2014). The Center for Responsible Enterprise And Trade (CREATe.org) was founded in 2011 with the support of start-up grants from the Microsoft Corporation with this objective of fostering “a culture of IP protection and compliance” throughout the global supply chain. This agenda is becoming mainstream, as it was endorsed by the World Intellectual Property Organization in its annual report dedicated to Intangible Capital in Global Value chains (WIPO, 2017).

#### [Szabo et al] Waiving IPPs results in unsafe manufacturing and forces trade-offs with medicines for other infectious diseases.

**Szabo et al:** Szabo, Liz [a senior correspondent and enterprise reporter who focuses on the quality of patient care, has covered medicine for two decades] Tribble, Sarah [Senior Correspondent] Allen, Arthur [editor for California Healthline] "Why Even Presidential Pressure Might Not Get More Vaccine to Market Faster." *Kaiser Health News*, January 25, 2021, AA https://khn.org/news/article/ramping-up-covid-vaccine-production-could-take-months-even-with-bidens-best-tool-to-pressure-companies

Americans are dying of covid-19 by the thousands, but **efforts to ramp up production of potentially lifesaving vaccines are hitting a brick wall. Vaccine makers Moderna and Pfizer-BioNTech are running their factories full tilt and are under enormous pressure to expand production or collaborate with other drug companies to set up additional assembly lines.** That pressure is only growing as new viral variants of the virus threaten to launch the country into a deadlier phase of the pandemic. President Joe Biden has said he plans to invoke the Cold War-era authority of the Defense Production Act to provide more vaccines to millions of Americans. Consumer advocates — who had called for Donald Trump to use the Defense Production Act more aggressively as president — are now asking Biden to do the same. **But even forcing companies to gear up production won’t provide much-needed doses anytime soon. Expanding production lines takes time. Establishing lines in repurposed facilities can take months. “The big problem is that even if you can get the raw material and get the infrastructure set up, how do you get a company that is already producing at maximum capacity to go beyond that maximum capacity?”** said Lawrence Gostin, a professor of global health law at Georgetown University. **Ordering the companies to work 24/7 “would be a naïve solution,”** said Dr. Nicole Lurie, a senior adviser to the CEO of the Coalition for Epidemic Preparedness Innovations, an international group that finances vaccines for emerging diseases. “**They’re probably already doing that to the extent they have the raw materials.” Lurie added, “If you completely wear people out, mistakes happen. You** **have to balance speed with quality and safety.”** The technological challenges involved are daunting, and the companies haven’t been forthcoming about what’s needed to overcome any supply shortfalls. “We don’t know what the holdup is. Is it capacity? Raw materials? People? Glass vials? We just don’t know what the bottleneck is,” said Erin Fox, senior director of drug information and support services at the University of Utah Health Hospitals. Forcing other companies to start making the vaccines might not work either, Gostin said. “I’m not sure if Biden could require a private company to transfer its technology to another company,” Gostin said. “That is highly questionable legally. … President Biden’s room for maneuvering isn’t as great as people think.” Drug companies define “trade secrets” broadly, Fox said. “In general, drug companies don’t have to tell me who is making their product, where it’s made, the location of the factory. … That’s considered proprietary.” Part of the challenge relates to how these vaccines are made. The first two authorized products use lipid nanoparticles to deliver a snippet of the coronavirus’s genetic material — called messenger RNA, or mRNA — into cells. The viral genes teach our cells how to make proteins that stimulate an immune response to the novel coronavirus. Messenger RNA is fragile and breaks down easily, so it needs to be handled with care, with specific temperatures and humidity levels. The vaccines “are not widgets,” said Lurie, who served as assistant secretary for preparedness and response at the Department of Health and Human Services during the Obama administration. Every step, experts say, to get vaccines to market has its complexities: obtaining raw materials; building facilities to precise specifications; buying single-use products, such as tubing and plastic bags to line stainless steel bioreactors; and hiring employees with the requisite training and expertise. Companies also must pass safety and quality inspections and arrange for transportation. The Defense Production Act, for instance, would allow the government to commandeer a plant that already has a fermenter — there are plenty in the biotech industry — to expand production. But that’s just the first stage in making an mRNA vaccine and, even then, it would take about a year to get going, said Dr. George Siber, a vaccine expert who is on the advisory board of CureVac, a German mRNA vaccine company. Companies would first have to do a breathtakingly thorough cleaning to prevent cross-contamination, Siber said. Next, they would need to set up, calibrate and test equipment, and train scientists and engineers to run it. Finally, Siber said, unlike a drug, whose components can be tested for purity, there’s no way to be sure a vaccine produced in a new facility is what it claims to be without testing it on animals and people. “Making vaccines is not like making cars, and quality control is paramount,” said Dr. Stanley Plotkin, a vaccine industry consultant credited with inventing the rubella vaccine. “We are expecting other vaccines in a matter of weeks, so it might be faster to bring them into use.” However, even that will require patience. Johnson & Johnson, expected to announce clinical trial results this month, has said that it won’t be able to deliver as many shots as planned because of manufacturing delays. The company did not confirm a manufacturing delay and declined to respond to questions. AstraZeneca’s vaccine, also funded in part by U.S. taxpayers, is in use already in the United Kingdom and India, but the Food and Drug Administration has raised questions about its late-stage trial, so it may not be available here until the spring. Novavax, another U.S.-funded vaccine maker, has been plagued by delays and only recently began recruiting volunteers for its big trial. Merck, the most recent company to get federal support for covid vaccines, announced Monday it was scrapping its two candidates after they failed to produce adequate immune response in early tests. “None of the vaccine makers are manufacturing at the volume they ultimately want to be at,” Lurie said. “They all have manufacturing delays.” Pfizer, which has committed 200 million doses to the U.S. government by the end of July, said last week it expected “no interruptions” in shipments from its primary U.S. covid manufacturing plant in Kalamazoo, Michigan. Pfizer spokesperson Sharon Castillo said the company has expanded manufacturing facilities and added more suppliers and contract manufacturers. Those efforts, and the company’s announcement that its five-dose vials actually contain an extra dose, mean “we can potentially deliver approximately 2 billion doses worldwide by the end of 2021.” The U.S. government also has an option to acquire another 400 million doses of the Pfizer-BioNTech vaccine, though the company declined to provide details on that option when asked. But countries around the world are competing for the same supplies and raw materials, Gostin said. Biden could use the Defense Production Act “**to force Pfizer to prioritize U.S. contracts, but that would be politically risky,” given that other countries could retaliate by hoarding supplies.** Although Pfizer is an American company, it has partnered with BioNTech, of Germany, to make its covid vaccine. “That would lead to a global mess.” Trying to corner the world market on vaccine ingredients or supplies would look bad, experts say, given that the United States just this week joined Covax, an international venture to source and distribute vaccines, in an effort to ensure poor countries aren’t left behind. Paradoxically, **the rush to get vaccines to market may have resulted in a less efficient manufacturing process. Vaccine companies typically spend months making their factories run as efficiently as possible, as well as finding an ideal dose and the most effective interval between doses, Lurie said. Given the urgency of the pandemic, however, they delayed parts of this process and launched straight into mass production. Pfizer angered European countries last week when it paused vaccine production at a Belgian plant to upgrade its capacity.** Pfizer said the weeklong closure would decrease vaccine deliveries to Europe for three to four weeks before boosting supplies in February. The move doesn’t affect U.S. vaccine supplies. “The U.S can’t necessarily readily access stuff that’s being held for vaccines in other countries,” Lurie said. And **forcing other companies to make covid vaccines could jeopardize production of other important shots, such as measles,** said Dr. Amesh Adalja, a senior scholar at the Johns Hopkins Center for Health Security. **Routine childhood immunization rates have fallen during the pandemic, raising the risk of epidemics. Using the act to prioritize covid vaccine manufacturing has already disrupted supplies of at least one drug, Fox noted. In December, Horizon Therapeutics warned doctors and patients to expect a shortage of a drug called Tepezza, used to treat thyroid-related eye disease, because its manufacturer was ordered to prioritize covid shots**. Lawmakers and consumer advocates such as Public Citizen called on the government to use the Defense Production Act more aggressively. In a letter sent earlier this month, Sen. Elizabeth Warren (D-Mass.) and Rep. Katie Porter (D-Calif.) said Moderna should share its technique for stabilizing its vaccine at normal refrigerator temperatures, without “ultracold” freezers. Moderna officials have said the intrinsic differences in the two companies’ mRNA material make that technology hard to share. Besides, they say, Pfizer has declined to share data with Moderna. Pfizer has declined to comment on the issue. Since Moderna’s effort is federally funded, the government presumably has march-in rights and could take over production, said Mike Watson, former president of Moderna subsidiary Valera, in an email. “**The reality is that however far you push production capacity, you sooner or later reach a bottleneck.” Experts say it’s not as simple as demanding that glassmaker Corning step up and make glass vials, for example. Of course, the vials will need to meet rigorous requirements. But there’s also this: The U.S. is facing a shortage of mined sand, the main component needed to make glass vials.**

## Case