## 1

### 1nc – t

#### Interp – “medicines” treat or cure, whereas vaccines prevent

Vecchio 7/22 (Christopher Vecchio, [CFA, Senior Strategist,], 7-22-2021, “Delta Variant Concerns Won't Cripple Markets, US Economy“, DailyFX, accessed: 8-9-2021, https://www.dailyfx.com/forex/video/daily\_news\_report/2021/07/22/market-minutes-delta-variant-concerns-wont-cripple-markets-us-economy.html) ajs

Let’s stick to the facts. The COVID-19 vaccines are not medicines, which by definition “treat or cure diseases.” Vaccines “help prevent diseases,” an important distinction. Why does this matter? Because data coming out of some of the world’s developed economies with high adult vaccination rates suggest that the vaccines are working as intended: tail-risks have been reduced, with hospitalizations and deaths falling relative to the recent spike in infections (which have been occurring primarily among the unvaccinated at this point). Put another way, vaccines are like a Kevlar vest for the immune system; while they don’t make you bulletproof, they dramatically increase the odds of surviving an adverse event.

#### Violation – they specify COVID

#### Negate –

#### 1] Limits – expanding the topic to preventative treatment or medical interventions allows anything from surgery to medical devices to education strategies or mosquito repellent to prevent malaria. Destroys core generics like innovation which are exclusive to disease curing – core of the topic is about proprietary information.

#### Voters:

#### Topicality is a voting issue that should be evaluated through competing interpretations – it tells the negative what they do and do not have to prepare for—there’s no way for the negative to know what constitutes a “reasonable interpretation” when we do prep – reasonability is arbitrary and causes a race to the bottom, proliferating abuse

#### No RVIs—it’s your burden to be topical.

#### Evaluate T before 1AR theory – norms – we only have a couple months to set T norms but can set 1AR theory norms anytime,

## 2

### 1nc – t

#### Interp – reductions are permanent

Reynolds 59. Judge (In the Matter of Doris A. Montesani, Petitioner, v. Arthur Levitt, as Comptroller of the State of New York, et al., Respondents [NO NUMBER IN ORIGINAL] Supreme Court of New York, Appellate Division, Third Department 9 A.D.2d 51; 189 N.Y.S.2d 695; 1959 N.Y. App. Div. LEXIS 7391 August 13, 1959)

Section 83's counterpart with regard to nondisability pensioners, section 84, prescribes a reduction only if the pensioner should again take a public job. The disability pensioner is penalized if he takes any type of employment. The reason for the difference, of course, is that in one case the only reason pension benefits are available is because the pensioner is considered incapable of gainful employment, while in the other he has fully completed his "tour" and is considered as having earned his reward with almost no strings attached. It would be manifestly unfair to the ordinary retiree to accord the disability retiree the benefits of the System to which they both belong when the latter is otherwise capable of earning a living and had not fulfilled his service obligation. If it were to be held that withholdings under section 83 were payable whenever the pensioner died or stopped his other employment the whole purpose of the provision would be defeated, i.e., the System might just as well have continued payments during the other employment since it must later pay it anyway. The section says "reduced", does not say that monthly payments shall be temporarily suspended; it says that the pension itself shall be reduced. The plain dictionary meaning of the word is to diminish, lower or degrade. The word "reduce" seems adequately to indicate permanency. Aside from the practical aspect indicating permanency other indicia point to the same conclusion. From 1924 (L. 1924, ch. 619) to 1947 (L. 1947, ch. 841) a provision appeared in the Civil Service Law which read substantially as follows: "If the pension of a beneficiary is reduced for any reason, the amount of such reduction shall be transferred from the pension reserve fund to the pension accumulation fund during that period that such reduction is in effect." (See L. 1924, ch. 619, § 2 [Civil Service Law, § 58, subd. 4]; L. 1947, ch. 841 [Civil Service Law, § 66, subd. e].) This provision reappears in the 1955 Retirement and Social Security Law as subdivision f of section 24. This provision is useful for interpretative purposes. Since it prescribes that moneys not paid because of reduction should be transferred back to the accumulation fund the conclusion is inescapable that such reductions were meant to be permanent. If temporary suspensions were intended this bookkeeping device would result in a false picture of the funds, i.e., the reserve fund would be depleted when it would contain adequate funds to meet eventual payments 57\*57 to present pensioners. Likewise, the accumulation fund would be improperly inflated with respect to the present pensioners. Section 64 of the Retirement and Social Security Law (§ 85 under the 1947 act) provides that any disability pension must be reduced by the amount payable pursuant to the Workmen's Compensation Law if applicable. In Matter of Dalton v. City of Yonkers (262 App. Div. 321, 323 [1941]) this court interpreted "reduce" to mean "offset" in holding that under then section 67 (relating to Workmen's Compensation benefits as do its successors sections 85 and 64), pensions were to be offset by compensation benefits. This is merely another indication that "reduce" means a diminishing of the pension pursuant to a given formula rather than a mere recoverable, temporary suspension during the time other benefits or salaries are being received by the pensioner. (Also, cf., Retirement and Social Security Law, § 101 [§ 84 under the 1947 act].)

#### Violation – the aff uses a temporary waiver – that was cx

#### Negate –

#### Limits and topic lit – their model allows adding on infinite random suspensions to IP protections, anything from conditioning IP protections on human rights to monopolistic tendencies – the core of the debate is reducing IP protections, not temporarily suspending them

## 3

### 1nc – t

#### Interpretation—the aff may not specify medicines

#### Bare plurals imply a generic “rules reading” in the context of moral statements

Cohen 1 — (Ariel Cohen, Professor of Linguistics @ Ben-Gurion University of the Negev, PhD Computational Linguistics from Carnegie Mellon University, “On the Generic Use of Indefinite Singulars”. Journal of Semantics 18: 183-209, Oxford University Press, 2001, accessed 12-7-20, HKR-AM) \*\*BP = bare plurals

According to the rules and regulations view, on the other hand, generic sentences do not get their truth or falsity as a consequence of properties of individual instances. Instead, generic sentences are evaluated with regard to rules and regulations, which are basic, irreducible entities in the world. Each generic sentence denotes a rule; if the rule is in effect, in some sense (different theories suggest different characterizations of what it means for a rule to be in effect), the sentence is true, otherwise it is false. The rule may be physical, biological, social, moral, etc. The paradigmatic cases for which this view seems readily applicable are sentences that refer to conventions, i.e. man-made, explicit rules and regulations, such as the following example (Carlson 1995: 225):

(40) Bishops move diagonally.

Carlson describes the two approaches as a dichotomy: one has to choose one or the other, but not both. One way to decide which approach to choose is to consider a case where the behavior of observed instances conflicts with an explicit rule. Indeed, Carlson discusses just such a case. He describes a supermarket where bananas sell for $0.49/lb, so that (41a) is true. One day, the manager decides to raise the price to $1.00/lb. Immediately after the price has changed, claims Carlson, sentence (41a) becomes false and sentence (41b) becomes true, although the overwhelming majority of sold bananas were sold for $0.49/lb.

(41) a. Bananas sell for $0.49/lb.

b. Bananas sell for $1.00/lb.

Consequently, Carlson reaches the conclusion that the rules and regulations approach is the correct one, whereas the inductivist view is wrong.

While I share Carlson’s judgements, I do not accept the conclusion he draws from them. Suppose the price has, indeed, changed, but the supermarket employs incompetent cashiers who consistently use the old price by mistake, so that customers are still charged $0.49/lb. In this case, I think there is a reading of (41a) which is true, and a reading of (41b) which is false. These readings are more salient if the sentence is modified by expressions such as actually or in fact:

(42) a. Bananas actually sell for $0.49/lb.

b. In fact, bananas sell for $1.00/lb.

BP generics, I claim, are ambiguous: on one reading they express a descriptive generalization, stating the way things are. Under the other reading, they carry a normative force, and require that things be a certain way. When they are used in the former sense, they should be analysed by some sort of inductivist account; when they are used in the latter sense, they ought to be analysed as referring to a rule or a regulation. The respective logical forms of the two readings are different; whereas the former reading involves, in some form or another, quantification, the latter has a simple predicate-argument structure: the argument is the rule or regulation, and the predicate holds of it just in case the rule is ‘in effect’.

#### Rules readings are always generalized – specific instances are not consistent. Cohen 01

Ariel Cohen (Ben-Gurion University of the Negev), “On the Generic Use of Indefinite Singulars,” Journal of Semantics 18:3, 2001 https://core.ac.uk/download/pdf/188590876.pdf

In general, as, again, already noted by Aristotle, rules and definitions are not relativized to particular individuals; it is rarely the case that a specific individual¶ forms part of the description of a general rule.¶ Even DPs of the form a certain X or a particular X, which usually receive¶ a wide scope interpretation, cannot, in general, receive such an interpretation in the context of a rule or a definition. This holds of definitions in general, not¶ only of definitions with an IS subject. The following examples from the Cobuild¶ dictionary illustrate this point:¶ (74) a. A fanatic is a person who is very enthusiastic about a particular¶ activity, sport, or way of life.¶ b. Something that is record-breaking is better than the previous¶ record for a particular performance or achievement.¶ c. When a computer outputs something it sorts and produces information as the result of a particular program or operation.¶ d. If something sheers in a particular direction, it suddenly changes¶ direction, for example to avoid hitting something.

#### That outweighs—only our evidence speaks to how bare plurals are interpreted in the context of normative statements like the resolution. This means throw out aff counter-interpretations that are purely descriptive

#### Violation—they specified the US—

#### Vote neg:

#### 1] Precision – if we win definitions the aff is not topical. The resolution is the only predictable stasis point for dividing ground—any deviation justifies the aff arbitrarily jettisoning words in the resolution at their whim which decks negative ground and preparation because the aff is no longer bounded by the resolution.

**2] Limits:**

**unlimited topics incentivize obscure affs that negs won’t have prep on – limits are key to reciprocal prep burden– also means there is no universal DA to spec affs**

**3] TVA solves – read the aff as advantage – most authors advocate for a change in WTO policy or TRIPS**

**4] No PICs offense – potential neg abuse doesn’t justify aff abuse because that would permit infinite 1AC abuse**

## 4

### 1nc – cp

#### CP: France, Germany, Sweden, and Italy should:

* substantially increase COVID vaccine production to meet the global demand
* sign bilateral intellectual property licensing contracts with low and middle-income countries to share vaccines
* donate all necessary vaccines at no cost to low and middle-income nations unable to license intellectual property rights

#### Global donations and increased domestic production solve

Yamey 21 [Gavin, Directs the Center for Policy Impact in Global Health at Duke University in Durham, North Carolina. “Rich Countries Should Tithe Their Vaccines” https://www.nature.com/articles/d41586-021-00470-9]

As I write this, 191 million vaccination shots against COVID-19 have been administered; more than three quarters were given in just 10 nations that account for 60% of the global gross domestic product. In some 130 nations with 2.5 billion people, not a single shot has been administered. High-income countries represent only 16% of the world’s population, but they have purchased more than half of all COVID-19 vaccine doses.

The US$4 billion that the White House pledged towards equitable vaccine distribution this month is a huge help in paying for doses for poorer nations. Reframing how vaccine deals are structured — and explained to the public in rich countries — could make this pledge even more powerful.

I live in the United States, so even though I am at low risk, I will be able to get vaccinated well ahead of many health workers and high-risk people in poorer nations.

This is unfair, and will prolong the pandemic. When SARS-CoV-2 transmission is wildly uncontrolled, the virus has more scope to evolve into dangerous variants. A COVID-19 outbreak anywhere could become an outbreak everywhere.

Why a pioneering plan to distribute COVID vaccines equitably must succeed

To help, rich countries should tithe their vaccine supply to poorer places and negotiate direct purchasing deals with vaccine manufacturers to increase supplies.

Many public-health workers strived to avoid the disparities we are seeing now. We knew that rich nations had hoarded vaccines during past outbreaks, such as the 2009 swine-flu pandemic. So, dozens of us working in global health tried — in long weekly Zoom calls for many months — to at least mitigate the hoarding and put a global sharing mechanism for COVID-19 vaccines in place. The result was COVID-19 Vaccines Global Access (COVAX) — co-led by Gavi, the Vaccine Alliance; the Coalition for Epidemic Preparedness Innovations; and the World Health Organization. It is a first-of-its-kind ‘buyers’ pool’ in which richer nations can collectively purchase vaccines, fund vaccine development and manufacturing and ensure that some of the supply will go to poorer countries.

Although around 190 nations have joined COVAX, about 3 dozen rich nations ended up buying most of their doses by way of direct deals with vaccine companies rather than through the COVAX pool. COVAX still expects to secure some 2 billion doses by the end of 2021, but richer countries have already bought 5.8 billion doses, often purchased before clinical trials were completed, through bilateral deals. COVAX is still getting pushed to the back of the queue.

What to do now? Richer nations should share their doses, stat. Perhaps for every nine doses they administer, they can donate one dose to COVAX. This falls far short of ‘equitable’, but it is within what is possible. This will help beyond dimming the chance of an outbreak from an imported variant that hoarded vaccines might have reduced efficacy against.

One analysis of vaccine nationalism (see go.nature.com/37wr), in which people in rich nations receive immediate vaccination and poorer nations are left behind for years, suggested that the global economy could lose US$9 trillion. Rich nations, whose exports would be suppressed, would bear half the cost. Disruption of global supply chains that provide parts for industry would continue.

COVID-19 vaccines: how to ensure Africa has access

Some nations are taking the lead. Norway is the first rich nation to have pledged to donate doses to the COVAX pool in parallel with vaccinating its citizens (the United Kingdom plans to donate superfluous doses after all its citizens have been vaccinated).

My colleagues and I used game theory to project what would happen if rich nations reconfigured their purchasing deals to increase the global vaccine supply (D. McAdams et al. BMJ Glob. Health 5, e003627; 2020). Currently, each vaccine purchase is a zero-sum game. But deals could include provisions that require vaccine makers to share knowledge and technology to boost production by other manufacturers. As a real-world example, the Serum Institute of India can manufacture the AstraZeneca–University of Oxford vaccine, providing doses for low- and middle-income countries.

An advanced purchase agreement might also finance risky investments that would speed up vaccine manufacturing. If one candidate fails in trials, the facility could be used for a different, successful vaccine, with a portion of the doses going to poorer countries. These deals create what economists call ‘positive spillovers’. With such collaboration, global vaccine distribution would no longer be a zero-sum game.

Some in rich countries might push back against sharing doses, arguing that a government needs to put its own citizens first and that no politician would risk giving doses away. But public polling in many of these nations shows that citizens want their governments to be more collaborative. A UK poll found that almost two-thirds of the public does not want rich countries to be prioritized for COVID-19 vaccination over poorer countries. And if the rich world continues to hoard vaccines, the global pandemic will drag on for perhaps as long as seven more years.

Another argument is that many poorer countries — such as Mongolia and Vietnam — have already curtailed their COVID-19 outbreaks using non-pharmaceutical interventions such as testing, contact tracing and mask-wearing. It is unfair to penalize nations that have used these measures by denying them vaccines. How will citizens respond to public-health advice in the next pandemic if they think it will deprive them of vaccine access?

It is in everybody’s interests to act collectively to boost vaccinations. It is self-defeating to act otherwise.

#### Eliminating IPR for vaccines gives China a massive competitive edge on innovation broadly – tanks pharma, undermines pandemic response, and tech leadership – BUT domestic production and distribution solves

Okutsu & Sharma 21 [Akane, staff writer for Nikkei International, and Kiran, LPC, The College of Law, Guildford, 1997 BA (Hons), Law, Gonville & Caius College, Cambridge University, 1996. “Vaccine Patent Waiver: COVID Stopper or Innovation Killer?” https://asia.nikkei.com/Spotlight/Coronavirus/COVID-vaccines/Vaccine-patent-waiver-COVID-stopper-or-innovation-killer]

Western pharmaceutical companies are telling U.S. officials that they fear exposing their technologies to China, the Financial Times reported. The still-under-wraps expertise could be used not only for COVID-19 shots but other vaccines and therapeutics, stripping the companies of their competitive edge.

Pfizer and Moderna have produced what are called messenger RNA vaccines, a new technology that does not contain live virus and instead instructs cells to produce a protein found in the coronavirus, creating immunity. China's vaccine producers, meanwhile, have relied on conventional methods using weakened virus.

The Pharmaceutical Research and Manufacturers of America released a statement that the U.S. stance on the waiver means "handing over American innovations to countries looking to undermine our leadership in biomedical discovery."

But some say the waiver would not be an automatic win for China.

One reason is that its pharmaceutical companies would not be immune if prices fall. "There would be competitive pressure and a negative impact on pharmaceutical companies in and outside of the U.S." including China, said Banri Ito, professor at Japan's Aoyama Gakuin University.

The stock market seems to agree. Chinese vaccine makers including CanSino Biologics and Shanghai Fosun Pharmaceutical Group fell after the U.S. announcement, just like the shares of Pfizer and Moderna.

China's state media has been lukewarm toward the U.S. move, calling it a "political tactic."

How would it affect the pharmaceutical industry over the long term?

One major concern is a loss of incentives for costly research and development.

Pharmaceutical research has a low success rate and requires enormous sums of money. Without the profits generated from intellectual property rights, "there would be no new drugs," as companies would have no hope of recouping their investments, a JPMA spokesperson said.

Ito said this raises "concerns about how to respond to future pandemics." Speedy vaccine development, he said, is driven in part by the chance to corner the market.

If the patents are to be waived, Ito suggested other steps to spur innovation will be needed, such as establishing a fund to buy such knowledge. But setting prices and deciding how to deal with the technical secrets would be no easy task.

Ito said a quicker solution might be for Group of Seven countries to "consider policies to expand production capacity and strengthen the [World Health Organization's] COVAX initiative to purchase and distribute vaccines to developing countries."

#### Biopharma innovation is key to overall competitiveness – US still has a razor thin lead but IP is uniquely key

Ezell 20 [Stephen Ezell, Director of Global Innovation Policy at the Information Technology and Innovation Foundation (ITIF). "Ensuring U.S. Biopharmaceutical Competitiveness." 7/16/20. https://itif.org/publications/2020/07/16/ensuring-us-biopharmaceutical-competitiveness]

Nations are competing for increased market share in a wide array of advanced-innovation industries, understanding that these industries are the key to competitiveness, national security, and good jobs. China’s “Made in China 2025” strategy is perhaps the most visible of these efforts, but by no means the only one.

Many nations, including China, have targeted the biopharmaceuticals industry—an industry which the United States has long led—especially in drug innovation. One result has been that over the last decade U.S. biopharmaceutical manufacturing value-added output has fallen by almost one-third, as the U.S. trade deficit in drugs and inputs has increased. Fortunately, America still leads in innovation and drug development, in large part due to effective life-science policies, including significant federal investment in life-sciences basic research, robust intellectual property (IP) protections, effective technology transfer policies, investment incentives, and, importantly, drug pricing policies that enable companies to invest in high-risk drug development.

But if the story of the past decline, and even loss, of other critical U.S. industries provides any guide, loss of U.S. production will ultimately lead to the loss of innovation capabilities as well. It is not enough for the United States to lead in drug development, it must also at least hold its own in drug production. This is especially true given the coming challenge from China, which intends to dominate the global drug industry, at all phases, from innovation to production to marketing.

Now is not the time for free-market complacency, hoping that America’s entrepreneurial spirit and rule of law will somehow suffice (the United States didn’t gain its biopharma lead from a laissez faire approach, and it certainly won’t keep its lead with it alone). Nor is it the time for drug populism, a political movement that both sides of the aisle, but especially progressives, have unfortunately embraced. Drug populism and its accompanying policies of weaker IP protections and draconian drug price controls would likely result in cheaper drugs. But there should be no confusion that it will lead to a hollowing out of U.S. capabilities, not just in production but also in innovation (and, not to mention, fewer new lifesaving drugs). If the United States is serious about competitiveness overall, and competitiveness in the biopharma sector specifically, an industry that the United States still has strong capabilities in—unlike the telecom equipment or flat-panel display industries, to name just two—then it’s time for Washington to articulate and embrace a robust national biopharmaceutical competitiveness strategy.

#### Chinese tech leadership causes nuke war

Kroenig & Gopalaswamy 18, \*Associate Professor of Government and Foreign Service at Georgetown University and Deputy Director for Strategy in the Scowcroft Center for Strategy and Security at the Atlantic Council. \*\*Director of the South Asia Center at the Atlantic Council. He holds a PhD in mechanical engineering with a specialization in numerical acoustics from Trinity College, Dublin. (Matthew & Bharath, 11-12-2018, "Will disruptive technology cause nuclear war?", *Bulletin of the Atomic Scientists*, https://thebulletin.org/2018/11/will-disruptive-technology-cause-nuclear-war/)

Rather, we should think more broadly about how new technology might affect global politics, and, for this, it is helpful to turn to scholarly international relations theory. The dominant theory of the causes of war in the academy is the “bargaining model of war.” This theory identifies rapid shifts in the balance of power as a primary cause of conflict.

International politics often presents states with conflicts that they can settle through peaceful bargaining, but when bargaining breaks down, war results. Shifts in the balance of power are problematic because they undermine effective bargaining. After all, why agree to a deal today if your bargaining position will be stronger tomorrow? And, a clear understanding of the military balance of power can contribute to peace. (Why start a war you are likely to lose?) But shifts in the balance of power muddy understandings of which states have the advantage.

You may see where this is going. New technologies threaten to create potentially destabilizing shifts in the balance of power.

For decades, stability in Europe and Asia has been supported by US military power. In recent years, however, the balance of power in Asia has begun to shift, as China has increased its military capabilities. Already, Beijing has become more assertive in the region, claiming contested territory in the South China Sea. And the results of Russia’s military modernization have been on full display in its ongoing intervention in Ukraine.

Moreover, China may have the lead over the United States in emerging technologies that could be decisive for the future of military acquisitions and warfare, including 3D printing, hypersonic missiles, quantum computing, 5G wireless connectivity, and artificial intelligence (AI). And Russian President Vladimir Putin is building new unmanned vehicles while ominously declaring, “Whoever leads in AI will rule the world.”

If China or Russia are able to incorporate new technologies into their militaries before the United States, then this could lead to the kind of rapid shift in the balance of power that often causes war.

If Beijing believes emerging technologies provide it with a newfound, local military advantage over the United States, for example, it may be more willing than previously to initiate conflict over Taiwan. And if Putin thinks new tech has strengthened his hand, he may be more tempted to launch a Ukraine-style invasion of a NATO member.

Either scenario could bring these nuclear powers into direct conflict with the United States, and once nuclear armed states are at war, there is an inherent risk of nuclear conflict through limited nuclear war strategies, nuclear brinkmanship, or simple accident or inadvertent escalation.

This framing of the problem leads to a different set of policy implications. The concern is not simply technologies that threaten to undermine nuclear second-strike capabilities directly, but, rather, any technologies that can result in a meaningful shift in the broader balance of power. And the solution is not to preserve second-strike capabilities, but to preserve prevailing power balances more broadly.

#### Doesn’t link to the impact turns – our scenario is about us heg also being bad

## 5

### 1nc – da

#### Drug price reform coming now – fight is ramping up but Biden has the opportunity

Cancryn 9/9 Cancryn, Adam. Adam Cancryn is a health care reporter for POLITICO Pro, graduate of Washington & Lee University."Biden admin backs direct government drug price negotiations." POLITICO, 9 Sept. 2021, www.politico.com/news/2021/09/09/biden-drug-price-negotiations-510828.

A new Biden administration plan aimed at lowering prescription drug prices endorses giving the government sweeping power to directly negotiate the cost of medicines, calling it one of the key steps Congress could take to make drugs “more affordable and equitable” for all Americans.

The plan — developed by the Department of Health and Human Services and released on Thursday — largely backs Democrats’ ongoing efforts to lower drug prices as part of a $3.5 trillion reconciliation proposal, and mirrors a range of legislative options that both House and Senate lawmakers have floated in recent years.

Those include capping out-of-pocket costs in Medicare Part D, limiting how quickly pharmaceutical companies can hike prices on existing drugs and banning so-called pay-for-delay agreements aimed at blocking generic competition to brand-name drugs.

But the HHS report’s embrace of broad price negotiation is the administration’s latest signal that it’s siding with progressives who have pushed for a far more aggressive approach to slashing pharmaceutical costs.

Under the HHS plan, the government would directly negotiate prices for drugs in Medicare parts B and D, with those prices also being available to private insurance plans and any employers who want to participate.

House Democrats passed a similar provision as part of a major drug pricing bill in 2019. But it never made it into law, and some in the party’s centrist wing have since vowed to oppose drug price negotiation.

Notably, the plan stops short of supporting the use of “march-in rights” that progressives argue empower the government to pull patent rights from a drug that is deemed too expensive. Sen. Elizabeth Warren has long advocated for the approach, and urged HHS to utilize it in an August letter with Sen. Amy Klobuchar and Rep. Lloyd Doggett.

“The Biden Administration has the opportunity to lower the prices of key drugs using these authorities,” the lawmakers wrote to HHS Secretary Xavier Becerra.

The department in its report acknowledged that it has been petitioned to use march-in rights, saying only that it would give them “due consideration.”

The HHS plan also lays out a series of administration actions that the department could take to fulfill what it identified as three “guiding principles:” making drugs more affordable, improving competition within the industry and encouraging innovation.

Those options included testing value-based payment models and boosting cost-sharing support to certain low-income Medicare beneficiaries. It also suggests that improved data collection from insurers and pharmacy benefit managers could give the government better insight into drug pricing, as well as rebates and out-of-pocket spending on prescription medications.

HHS developed the report in response to an executive order that President Joe Biden issued earlier this year aimed at improving competition across a range of industries, including the drug sector.

#### Biden’s PC is key to wrangle democrats and counter pharma lobbying

Johnson 8/12 Johnson, Jake, writer for Alternet . "Joe Biden throws support behind bold reforms to slash drug prices." Alternet, August 12, 2021, www.alternet.org/2021/08/biden-medicare-negotiate-prices.

The powerful industry's public and behind-closed-doors lobbying push is likely to grow more aggressive as congressional Democrats' reconciliation package begins to take shape.

On Wednesday, the Senate approved a $3.5 trillion budget resolution setting the boundaries for the package, and the House is expected to take up and pass the resolution later this month. Once both chambers have passed an identical resolution, congressional committees will begin crafting legislative text.

"We will save taxpayers hundreds of billions by requiring that Medicare negotiate prescription drug prices with the pharmaceutical industry and we will use those savings to expand Medicare by covering the dental care, hearing aids, and eyeglasses that seniors desperately need," Sen. Bernie Sanders (I-Vt.), the chief architect of the budget resolution, said in a statement earlier this week.

But it's far from certain that a Medicare negotiation provision will survive the process of developing the final reconciliation bill, particularly given that a number of Big Pharma-backed House Democrats—including Reps. Scott Peters (D-Calif.) and Jake Auchincloss (D-Mass.)—have recently voiced skepticism about the proposal.

With Republicans unanimously opposed to the reconciliation package, Democrats can afford just a handful of defections in the House and none in the Senate.

Larry Levitt, executive vice president for health policy at the Kaiser Family Foundation, told HuffPost on Thursday that "it's not yet clear how the Democratic leadership will corral the necessary votes for a drug pricing plan, but there's no sign they're backing off."

"An epic battle with the pharmaceutical industry is coming," said Levitt.

In a series of tweets responding to Biden's prescription drug agenda, Levitt wrote that while the president's "proposal doesn't break new policy ground," it "is significant in that he is now using his political capital to push for congressional action at a pivotal moment in the debate."

#### WTO waiver takes time, energy, and political capital away from domestic legislation – big pharma and EU allies

Bhadrakumar 5/9 M K Bhadrakumar is a former Indian diplomat. "Biden’s talk of vaccine IP waiver is political theater." Asia Times, May 9, 2021, asiatimes.com/2021/05/bidens-talk-of-vaccine-ip-waiver-is-political-theater.

On the other hand, Biden, whose political life of half a century was largely spent in the US Congress, is well aware of the awesome clout of the pharmaceutical companies in American politics. From that lobby’s perspective, the patent waiver “amounts to the expropriation of the property of the pharmaceutical companies whose innovation and financial investments made the development of Covid-19 vaccines possible in the first place,” as a senior scholar at the Johns Hopkins Center for Health Security puts it. The US pharmaceutical industry and congressional Republicans have already gone on the offensive blasting Biden’s announcement, saying it undermines incentives for American innovation. Besides, the argument goes, even with the patent waiver, vaccine manufacturing is a complex process and is not like simply flipping a switch. Senator Richard Burr, the top Republican on the US Senate Health Committee, denounced Biden’s decision. “Intellectual property protections are part of the reason we have these life-saving products,” he said. “Stripping these protections only ensures we won’t have the vaccines or treatments we need when the next pandemic occurs.” The Republican senators backed by Republican Study Committee chairman Jim Banks propose to introduce legislation to block the move. Clearly, Biden would rather spend his political capital on getting the necessary legislation through Congress to advance his domestic reform agenda rather than spend time and energy to take on the pharmaceutical industry to burnish his image as a good Samaritan on the world stage. Conceivably, Biden could be counting on the “text-based negotiations” at the WTO dragging on for months, if not years, without reaching anywhere. The US support for the waiver could even be a tactic to persuade pharmaceutical firms to back less drastic steps like sharing technology and expanding joint ventures to boost global production quickly. So far Covid-19 vaccines have been distributed primarily to the wealthy countries that developed them, while the pandemic sweeps through poorer ones such as India, and the real goal is, after all, expanded vaccine distribution. Biden is well aware that there will be huge opposition to the TRIPS waiver from the United States’ European allies as well. The British press has reported that the UK has been in closed-door talks at the World Trade Organization in recent months along with the likes of Australia, Canada, Japan, Norway, Singapore, the European Union and the US, who all opposed the idea.

#### Drug price controls massively reduce healthcare costs across the board – even assuming conservative models

Gamba 6/9 Gamba, Tyler. Author at the AJMC. "Adoption of the Lower Drug Costs Now Act May Lead to Billions in Savings." AJMC, 9 June 2021, www.ajmc.com/view/adoption-of-the-lower-drug-costs-now-act-may-lead-to-billions-in-savings.

H.R.3, the Elijah E. Cummings Lower Drug Costs Now Act would improve efficiency and produce billions in savings for the commercial health care market’s employers and end consumers if fully implemented, according to a new study from Milliman commissioned by the West Health Policy Center.

Among its goals, the act’s provisions seek to reduce prescription drug costs, increase drug price transparency, lower member out-of-pocket spending, and increase potential coverage eligibility. Costs for the most expensive brand drugs in the United States would be negotiated between the manufacturers and the HHS secretary. Significant drug cost increases over the rate of inflation would need to be issued back as rebates to CMS.

To predict the effects of such reforms, the Milliman study sought quantitative estimates for the scope of these changes. Milliman’s models incorporated several variables, including current trends and projected spending based on different percentage adjustments to drug prices, rebates, and public vs private cost rates from 2023 through 2029.

The study estimates 46% of drug spending would be subject to negotiation under the legislation’s Title I by 2026, with an average 2.5% reduction in total commercial market claims by 2029.Overall, successful implementation of H.R. 3 means employers may reduce their health care expenditures by $195 billion while employees would save $61 billion. Of this latter amount, reduced premiums would account for $53 billion and out-of-pocket costs, $8 billion.

Overall, the market covered by the Affordable Care Act (ACA) could see savings of $58 billion, comprising $34 billon in reduced beneficiary premiums, $21 billion in federal savings by reduced Advance-Premium Tax Credits, and $2 billion in lower cost-sharing.

The estimates assume manufacturers could make such increases to the prices at a faster rate than the current yearly trends. This possibility still leads to stronger total savings via H.R. 3’s Title I. The study does not factor in further limitations on increases by plan sponsors and pharmacy benefit managers, which could improve savings for employers and employees, because it mainly applies to Medicare.

#### Collapses the economy

Howrigon, 16 — Ron Howrigon, M.S. in Economics with a focus on Health Economics from North Carolina State University, President and Founder of Fulcrum Strategies, 18 Years of Experience in Healthcare, 12-30-2016, “Flatlining: How Healthcare Could Kill the U.S. Economy,” Greenbranch Publishing, 1st Edition, Accessed via Minnesota Libraries, Date Accessed: 8-10

Ok, let’s shift from looking at individuals to looking at the big picture—from micro- to macroeconomics. It’s important to understand where healthcare **fits into the big picture** when it comes to the economy at large. Most people who don’t work in the industry don’t clearly understand how much of the U.S. economy healthcare makes up. In fact, given the size of the economy, healthcare in the U.S. can be impactful on the ***world* economy**. This is important to understand because future changes in healthcare not only affect ow we get care and how much we pay for it, but could also significantly affect things like **unemployment**, the **national debt**, and **interest rates**. The influences on the U.S. economy will have **a ripple effect** on other countries around the world. In 1960, healthcare as a market accounted for only 5% of the U.S. economy. For every dollar transacted, only 5 cents were spent for healthcare. The entire U.S. economy was $543 billion, and healthcare accounted for about $27 billion. By itself, in 1960, the U.S. healthcare market would rank as the 15th largest world economy, putting it just in front of the GDP (Gross Domestic Product) of Australia and just behind the GDP of Italy. Think about that for a minute: the U.S., **spent more money on healthcare** than the Australians did on everything! To put this further into perspective, in 1960, the U.S. Department of Defense was twice as large as healthcare. The Defense Department consumed 10% of the U.S. economy, which means it would rank as the 11th largest world economy just in front of Japan and just behind China. Now fast-forward 50 years. In 2010, the United States GDP was $15 trillion. The total healthcare expenditures in the United States for 2010 were $2.6 trillion. At $2.6 trillion, the U.S. healthcare market has moved up from 15th and now ranks as the **5th largest world economy**, just behind Germany and just ahead of both France and the United Kingdom. That means that while healthcare was only 5% of GDP in 1960, it has risen to over 17% of GDP in only 50 years. Over that same time, the Defense Department has gone from 10% of GDP to less than 5% of GDP. This means that in terms in terms of its portion of the U.S. economy, defense spending has been reduced by half while healthcare spending has more than tripled. If **healthcare** continues to trend at the same pace it has for the last 50 years, it will consume more than **50% of the U.S. economy** by the year 2060. Every economist worth their salt will tell you that health-care will never reach 50% of the economy. It’s simply not possible because of **all the other things** it would have to **crowd out to reach** that point. So, if we know healthcare can’t grow to 50% of our economy, **where is the breaking point?** **At what point does healthcare consume so much of the economy that it breaks the bank**, so to speak? This is the big question when it comes to healthcare. If something doesn’t happen to reverse the 50-year trend we’ve been riding, when will the healthcare bubble burst? How bad will it be and how exactly will it happen? While no one knows the **exact answers** to those questions, economists and healthcare experts agree that something needs to **happen**, because we simply **can’t continue on this trend** forever. Another way to look at healthcare is to study its impact on the federal budget and the national debt. In 1998, federal healthcare spending accounted for 19% of the revenue taken in by the government. Just eight years later, in 2006, healthcare spending had increased to 24% of federal revenue. In 2010, the Affordable Healthcare Act passed and significantly increased federal spending accounted for almost one-third of all revenue received by the government and surpassed Social Security as the largest single budget category. What makes this trend even more alarming is the fact that revenue to the federal government double from 1998 to 2016. That means healthcare spending by the federal government has almost quadrupled in terms of actual dollars in that same time period. If this trend continues for the next 20 years, healthcare spending will account for over half the revenue received by the government by the year 2035. Again, the simply can’t happen without causing significant issue for the financial wellbeing of out country. In recent history, the U.S. economy has experienced the near catastrophic failure of two major market segments. The first was the auto industry and the second was the housing industry. While each of these reached their breaking point for different reasons, they both required a significant government bailout to keep them from completely melting down. What is also true about both of **those market failures** is that, looking back, it’s easy to see the warning signs. What happens if health care is the next industry to suffer a major failure and collapse? It’s safe to say that a **health care meltdown** would make both the **auto**motive and **housing** industries’ experiences **seem minor** in comparison. While that may be hard to believe, it becomes clear if you look at the numbers. The **auto industry** contributes around 3.5 percent of this country’s GDP and employs 1.7 million people. This industry was deemed **“too big to fail”** which is the rationale the U.S. government used to finance its bail out. From 2009 through 2014, the federal government invested around $80 billion in the U.S. auto industry to keep it from collapsing. Health care is five times larger than the auto industry in terms of its percentage of GDP, and is ten times larger than the auto industry in terms of the number of people it employs. The construction industry (which includes all construction, not just housing) contributes about 6 percent of our country’s GDP and employs 6.1 million people. Again, the health care market dwarfs this industry. It’s **three times larger** in terms of GDP production and, with 18 million people employed in the health care sector, it’s three times larger than construction in this area, too. These comparisons give you an idea of just how significant a portion health care comprises of the U.S. economy. It also begins to help us understand the impact it would have on the economy if health care melted down like the auto and housing industries did. So, let’s continue the comparison and use our experience with the auto and housing industries to suggest to what order of magnitude the impact a failure in the health care market would cause our economy. The bailout in the auto industry cost the federal government $80 billion over five years. Imagine a similar failure in health care that prompted the federal government to propose a similar bailout program. Let’s imagine the government felt the need to inject cash into hospital systems and doctors’ offices to keep them afloat like they did with General Motors. Since health care is five times the size of the auto industry, a similar bailout could easily cost in excess of $400 billion. That’s about the same amount of money the federal government spends on welfare programs. To pay for a bailout of the health care industry, we’d have to eliminate all welfare programs in this country. Can you imagine the impact it would have on the economy if there were suddenly none of the assistance programs so many have come to rely upon? When the housing market crashed, it caused the loss of about 3 million jobs from its peak employment level of 7.4 million in 1996. Again, if we transfer that experience to the health care market, we come up with a truly frightening scenario. If health care lost 40 percent of its jobs like housing did, it would mean 7.2 million jobs lost. That’s more than four times the number of people who are employed by the entire auto industry — an industry that was considered too big to be allowed to fail. The loss of **7.2 million jobs** would increase the unemployment rate by 5 percent. That means we could easily top the **all-time high unemployment rate** for our country. OK, now it’s time to take a deep breath. I’m not convinced that health care is fated to **unavoidable failure** and economic catastrophe. That’s a worst-case scenario. The problem is that at even a fraction the severity of the auto or housing industry crises we’ve already faced, a health care collapse would still be devastating. Health care **can’t be allowed** to continue its current inflationary trending. I believe we are on the verge of some major changes in health care, and that how they’re **implemented** will determine their impact on the overall **economic picture** in this country and around the world. Continued failure to recognize the truth about health care will only cause the resulting market corrections to be worse than they need to be. I don’t want to diminish the pain and anguish that many people caught up in the housing crash experienced. I think an argument can be made, though, that if the health care market crashes and millions of people end up with no health care, the resulting fallout could be could be much worse than even the housing crisis.

#### Economic decline causes nuclear war

Tønnesson, 15 — Stein Tønnesson, Leader of East Asia Peace program at Uppsala University, Research Professor at the Peace Research Institute Oslo, “Deterrence, Interdependence and Sino–US Peace” International Area Studies Review, Review Essay, Volume 18, Issue 3, Pages 297-311, SAGE Journals, Minnesota Libraries, Date Accessed: 8-4

Several recent works on China and Sino–US relations have made substantial contributions to the current understanding of how and under what circumstances a combination of nuclear deterrence and economic interdependence may reduce the risk of war between major powers. At least four conclusions can be drawn from the review above: first, those who say that interdependence may **both inhibit and drive conflict** are right. Interdependence raises the **cost of conflict** for all sides but asymmetrical or unbalanced dependencies and **negative trade expectations** may generate tensions leading to trade wars among inter-dependent states that in turn increase the risk of military conflict (Copeland, 2015: 1, 14, 437; Roach, 2014). The risk may increase if one of the interdependent countries is governed by an inward-looking socio-economic coalition (Solingen, 2015); second, the risk of war between China and the US should not just be analysed bilaterally but include their allies and partners. Third party countries could drag China or the US into confrontation; third, in this context it is of some comfort that the three main economic powers in Northeast Asia (China, Japan and South Korea) are all deeply integrated economically through production networks within a global system of trade and finance (Ravenhill, 2014; Yoshimatsu, 2014: 576); and fourth, decisions for war and peace are taken by very few people, who act on the basis of their future expectations. International relations theory must be supplemented by foreign policy analysis in order to assess the value attributed by national decision-makers to economic development and their assessments of risks and opportunities. If leaders on either side of the Atlantic begin to seriously fear or **anticipate their own nation’s decline** then they may blame this on **external dependence**, appeal to anti-foreign sentiments, contemplate the use of force to gain respect or credibility, adopt protectionist policies, and ultimately **refuse to be deterred by** either **nuclear arms** or prospects of socioeconomic calamities. Such a dangerous shift could happen **abruptly**, i.e. under the instigation of actions by a third party – or against a third party.

Yet as long as there is both nuclear deterrence and interdependence, the tensions in East Asia are unlikely to escalate to war. As Chan (2013) says, all states in the region are aware that they cannot count on support from either China or the US if they make provocative moves. The greatest risk is **not** that **a territorial dispute** leads to war under present circumstances but that **changes in the world economy** alter those circumstances in ways that render **inter-state peace** more precarious. If China and the US fail to rebalance their financial and trading relations (Roach, 2014) then a trade war could result, interrupting transnational production networks, provoking social distress, and exacerbating nationalist emotions. This could have **unforeseen consequences** in the field of security, with nuclear deterrence remaining the only factor to **protect the world from Armageddon**, and **unreliably so**. Deterrence could **lose its credibility**: one of the two great powers might gamble that the other yield in a cyber-war or conventional limited war, or third-party countries might engage in conflict with each other, with a view to obliging Washington or Beijing to **intervene**.

## Case

### Adv 1

#### Squo solves – plan increases price of scarce materials and results in costly, ineffective facilities

Mcmurry-Heath 8/18 (Michelle Mcmurry-Heath, [physician-scientist and president and CEO of the Biotechnology Innovation Organization.], 8-18-2021, “Waiving intellectual property rights would harm global vaccination“, STAT, accessed: 8-19-2021, https://www.statnews.com/2021/08/18/waiving-intellectual-property-rights-compromise-global-vaccination-efforts/) ajs

Covid-19 vaccines are already remarkably cheap, and companies are offering them at low or no cost to low-income countries. Poor access to clinics and transportation are barriers in some countries, but the expense of the shot itself is not. In fact, if the World Trade Organization grants the IP waiver, it could make these vaccines more expensive.

Here’s why. Before Covid-19 emerged, the world produced at most [5.5 billion doses](https://www.barrons.com/articles/a-plan-to-break-the-vaccine-manufacturing-bottleneck-51621952245) of various vaccines every year. Now the world needs an additional [11 billion doses](https://www.who.int/director-general/speeches/detail/director-general-s-opening-remarks-at-the-g7-summit---12-june-2021) — including billions of doses of mRNA vaccines that no one had ever mass-manufactured before — to fully vaccinate every eligible person on the planet against the new disease.

Even as Covid-19 vaccines were still being developed, pharmaceutical companies began retrofitting and upgrading existing facilities to produce Covid-19 vaccines, at a cost of $40 to $100 million each. Vaccine developers also licensed their technologies to well-established manufacturers, like the Serum Institute of India, to further increase production. As a result, almost every facility in the world that can quickly and safely make Covid-19 vaccines is already doing so, or will be in the next few months.

The cutting-edge mRNA vaccines from Moderna and Pfizer-BioNTech face an even bigger capacity issue. Since the underlying technology is new, there are no mRNA manufacturing facilities sitting idle with operators just waiting for licensing agreements to turn on the machines. Nor are there trained personnel to run them or ensure safety and quality control. Embedding delicate mRNA vaccine molecules inside lipid nanoparticle shells at temperatures colder than Antarctica isn’t as easy as following a recipe from Bon Appetit.

Another big barrier to producing more shots is a shortage of raw materials. Suspending intellectual property protections and allowing any manufacturer to try to produce these vaccines, regardless of preparedness or experience, would increase the demand for scarce raw materials, driving up prices and impeding production.

Nor could all companies that suddenly get a green light due to suspended intellectual property rights produce vaccines as cheaply or quickly as existing manufacturers. Building a new vaccine manufacturing facility costs about $700 million, takes many months — if not years — to build and, once opened, requires another [four to six months](https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/) to start producing vaccine doses. And because negotiations surrounding the WTO waiver, which began this summer, could take until December before they are completed, it wouldn’t be until well into 2023 or later that any additional doses would become available.

That’s slower than our current production rate. According to a report from Duke University’s [Global Health Innovation Center](https://launchandscalefaster.org/covid-19/vaccinemanufacturing), companies are on track to manufacture enough shots in 2021 to fully vaccinate at least 70% of the global population against Covid-19 — the level required to achieve herd immunity.

Covid-19 vaccines are saving millions of lives and protecting trillions of dollars of economic activity for an exceptionally low cost. Israel, for example, which has one of the world’s highest vaccination rates, paid [$23.50 per dose](https://www.timesofisrael.com/israel-said-to-be-paying-average-of-47-per-person-for-pfizer-moderna-vaccines/) for early shipments, for a total of about $315 million. That’s approximately equal to the gross domestic productivity losses incurred during [just two days of shutdowns](https://www.bmj.com/content/372/bmj.n281) in the country.

Many countries are buying shots for under $10 per dose. India and South Africa — the two countries leading the petition to gut IP rights — are paying just $8 and $5.25 per dose, respectively. For reference, a regular flu shot costs about $14 in the United States, and pediatric vaccines average about $55 per dose.

Meanwhile, low-income countries that can’t afford even modest prices are getting their vaccines at no charge. [COVAX](https://www.who.int/initiatives/act-accelerator/covax), the international nonprofit vaccine distributor, aims to deliver 2 billion doses to developing nations by the end of the year.

President Biden vowed to make America the world’s [“arsenal of vaccines.”](https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/05/17/remarks-by-president-biden-on-the-covid-19-response-and-the-vaccination-program-4/) The U.S. has already committed $4 billion to COVAX, has donated more than 100 million vaccine doses abroad, and is on track to donate [500 million more](https://www.npr.org/sections/goatsandsoda/2021/08/03/1023822839/biden-is-sending-110-million-vaccines-to-nations-in-need-thats-just-a-first-step) by the end of summer. Other countries are following the administration’s leadership and ramping up their donations.

#### IPR hasn’t harmed access – manufacturing capacity alt cause

Mercurio 2/12 (Bryan Mercurio, [Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.], 2-12-2021, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review“, No Publication, accessed: 8-8-2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3789820) ajs

2. Intellectual property rights have not hampered access to COVID-19 vaccines

A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licencing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement. 25 This was also the case with the Kimberley Process, which attempts to eliminate trade in “conflict diamonds”. 26

Although the IP waiver proposal states that “there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients”, 27 the sponsors did not provide further elaboration or evidence to support their declaration that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]”. 28 Instead, many of the examples used by India and South Africa point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory licence in 2003, and yet many developing countries have yet to put in place any framework to allow their country to make use of the flexibility. 29 This is not an institutional problem of the international system but rather a problem at the country level.

Two additional factors which make the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at extremely reasonable rates and several announced plans for extensive not-for-profit sales.30 Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. The De Bleeker tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: (€1.78), Johnson & Johnson (€8.50), Sanofi/GSK (€7.56), CureVac (€10), BioNTech/Pfizer (€12) and Moderna (€18).31

While much as been made of the fact that South Africa agreed to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of €4.321 per dose,32 these criticisms are directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs.

Moreover, while the disparity in pricing is concerning the overall per dosage rate South Africa is paying nevertheless represents value for money given the expected health and economic returns on investment. Despite the disparity in pricing between nations, the larger point remains that the industry has not only rapidly produced vaccines for the novel coronavirus but is making them available at unquestionably reasonable prices.

Second, the proposed waiver will do nothing to address the problem of lack of capacity or the transfer of technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries – in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.33 Patents cannot be the problem in the countries where no patent applications have been filed, but the lack of production in such countries points to the real problem – these countries lack manufacturing capacity and capability.

While advanced pharmaceutical companies will have the technology, know-how and readiness to manufacture, store and transport complex vaccine formulations, such factories and logistics exist in only a handful of countries.34 Regardless of whether an IP waiver is granted, the remaining countries will be left without enhanced vaccine access and still reliant on imported supplies. With prices for the vaccine already very low, it is doubtful that generic suppliers will be able to provide the vaccine at significantly lower prices. Under such a scenario, the benefit of the waiver would go not to the countries in need but to the generic supplier who would not need to pay the licence fee or royalty to the innovator. Thus, the waiver would simply serve to benefit advanced generic manufacturers, most of which are located in a handful of countries, including China and Brazil as well as (unsurprisingly) India and South Africa. Countries would perhaps be better off obtaining the vaccine from suppliers that have negotiated a voluntary licence from the patent holder, as such licences include provisions for the transfer of technology, know-how and ongoing quality assurance support.

#### Waivers fail – license agreements are key to access and scaling up vaccines

Crosby et al 21 [[Daniel Crosby](https://www.jdsupra.com/authors/daniel-crosby/), [Evan Diamond](https://www.jdsupra.com/authors/evan-diamond/), [Isabel Fernandez de la Cuesta](https://www.jdsupra.com/authors/isabel-fernandez-de-la-cuesta/), [Jamieson Greer](https://www.jdsupra.com/authors/jamieson-greer/), [Jeffrey Telep](https://www.jdsupra.com/authors/jeffrey-telep/), [Brian White](https://www.jdsupra.com/authors/brian-white/)] “Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products,” JD Supra, March 5, 2021, <https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/> TG

Waiver risks uncontrolled use of patented technologies, without improving vaccine access. Pharmaceutical companies can provide, and have provided, licenses to distribute or scale-up production of COVID-19 vaccines and therapies at reduced cost. Such license agreements allow for expanded access in low- and middle-income countries, while also setting reasonable parameters so that patents and other IP rights are used to address the specific medical needs of the COVID-19 pandemic at hand, and not for other purposes. License agreements also allow for orderly technology transfer, including of unpatented “trade secret” information and other critical “know-how,” that may be essential to efficiently producing and scaling-up safe and effective versions of technologically complex vaccines and biologic drug products.

Under the present TRIPS waiver proposal, however, member countries could try to exploit an extraordinarily broad scope of IP and copy patented technologies so long as they are “in relation to prevention, containment or treatment of COVID-19.” For example, under an expansive reading of the proposed waiver language, a member country could try to produce patented pharmaceutical compounds that have other indicated uses predating COVID-19, if such compounds had later been studied or experimentally used for potential symptomatic relief or antiviral activity in COVID-19 patients. The same risks may be faced by manufacturers of patented materials or devices that have multiple uses predating COVID-19, but also may be used as “personal protective equipment” or components thereof, or in other measures arguably relating to COVID-19 “prevention” or “containment.”

At the same time, it is unclear how the proposed TRIPS waiver could provide the technology transfer and know-how critical for making the complex molecules and formulations constituting the various COVID-19 vaccines. Vaccine manufacture undertaken by an unauthorized party without the proper processes and controls could result in a different product that is potentially ineffective or results in unwanted health consequences. And even if an unauthorized manufacturer could overcome those substantial hurdles to reverse-engineer and scale up a safe and effective vaccine copy, it would likely take substantial time and a series of failures to do so. Notably, several of the original COVID-19 vaccine developers have recently faced low product yield and other manufacturing challenges during pre-commercial scale-up efforts and the initial months of commercial production.

#### Squo solves – voluntary licensing and other initiatives

Mercurio 2/12 (Bryan Mercurio, [Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.], 2-12-2021, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review“, No Publication, accessed: 8-8-2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3789820) ajs

3. Voluntary licensing and other initiatives are supporting access to COVID-19 vaccines Contrary to assertions the sponsors made at the TRIPS Council, pharmaceutical companies have been actively signing voluntary licensing agreements with various generic drug manufacturers to scale up the production of COVID-19 medication. For instance, Gilead’s antiviral drug named Remdesivir was approved for emergency use for COVID-19 treatment by the US Food and Drug Administration (FDA) and the European Medicines Agency in May 2020.35 As demand surged following the approvals for use in COVID-19, Gilead issued nonexclusive voluntary licences to generic producers based in India, Egypt and Pakistan in order to meet the growing demand for the product. Under the voluntary licensing agreements, these manufacturers receive the technology necessary to manufacture Remdesivir, as well as set their own prices for the generic drugs they produce. The arrangement allows the distribution of the drug in 127 countries, covering nearly all low-income and lower-middle-income countries.36 Another example of industry cooperation is the COVID-19 vaccine co-developed by AstraZeneca and University of Oxford. AstraZeneca has committed to granting voluntary licensing in developing countries and signed sublicence agreements with several generic drugs producers to increase the supply of future vaccine, including with the Serum Institute of India (one of the world’s largest vaccine producers),37 Fiocruz in Brazil,38 BioKangtai in China39 and R-Pharm in Russia,40 enabling the massive production of cheap generic vaccines and supply of over two billion doses to lower-middle-income countries once the vaccine is approved for sale in those countries.

Other initiatives set up in response to IP issues related to COVID-19 treatments and vaccines include the World Health Organization’s (WHO) COVID-19 Technology Access Pool (CTAP), launched to gather COVID-19 technology related patents and other kinds of intellectual properties, such as data, know-how and software.41 This Pool, similar to Medicines Patent Pool (MPP) – established to pool and distribute generic licences for HIV/AIDS-related treatments – aims to accelerate the scale-up of production of medical inventions to fight against COVID-19 and ensure they are available globally and equitably.42 To date, 39 WHO member states and 4 intergovernmental bodies have indicated their support43 and a coalition of 18 generic drugs manufacturers located in India, China, Bangladesh and South Africa have pledged to work together to accelerate access to millions of doses of new interventions for COVID-19 for lowand middle-income countries.

Another effort, the Access to Covid-19 Tools (ACT) Accelerator, has raised $5.8 billion from nearly forty countries and over 40 private and non-governmental sources for the deployment tests, treatments and vaccines. 44 COVAX, convened by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO, is the vaccine pillar of the ACT and acts as a global initiative to pool procurement of safe and effective COVID-19 vaccines. The objective of this accelerator collaboration is to guarantee rapid and fair access to COVID-19 vaccines for every country in the world. As of January 2021, COVAX has agreements in place to access 2 billion doses of promising COVID-19 vaccine candidates, implying that all 190 participating economies are eligible to access effective and approved vaccines in the first half of 2021.45 At least 1.3 billion donor-funded doses will be made available to 92 low- and middle-income economies.46

With the advance of reasonably priced patented treatments and vaccines, as well as the widespread and growing use of non-exclusive voluntary licence agreements and several newly established global initiatives, it is not only unnecessary to waive IPRs to ensure access to affordable medicines for all populations around the world during the pandemic but also unwise as the waiver would stifle cooperative efforts and potentially lead to less availability of needed treatments and vaccines.

**variations and adaption solve any future pandemics**

Amesh **Adalja 16**, infectious-disease physician at the University of Pittsburgh, 6/17/16, “Why Hasn't Disease Wiped out the Human Race?,” <https://www.theatlantic.com/health/archive/2016/06/infectious-diseases-extinction/487514/>

But when people ask me if I’m worried about infectious diseases, they’re often not asking about the threat to human lives; they’re asking about the threat to **human life**. With each outbreak of a headline-grabbing emerging infectious disease comes a fear of **extinction itself**. The fear envisions a large proportion of humans succumbing to infection, leaving no survivors or so few that the species can’t be sustained. I’m not afraid of this apocalyptic scenario, but I do understand the impulse. Worry about the end is a quintessentially human trait. Thankfully, **so is our resilience**. For most of mankind’s history, infectious diseases were the existential threat to humanity—and for good reason. They were quite successful at killing people: The 6th century’s Plague of Justinian knocked out an estimated 17 percent of the world’s population; the 14th century Black Death decimated a third of Europe; the 1918 influenza pandemic killed 5 percent of the world; malaria is estimated to have killed half of all humans who have ever lived. Any yet, of course, humanity continued to flourish. Our species’ recent explosion in lifespan is almost exclusively the result of the control of infectious diseases through sanitation, vaccination, and antimicrobial therapies. Only in the modern era, in which many infectious diseases have been tamed in the industrial world, do people have the luxury of death from cancer, heart disease, or stroke in the 8th decade of life. Childhoods are free from watching siblings and friends die from outbreaks of typhoid, scarlet fever, smallpox, measles, and the like. So what would it take for a disease to wipe out humanity now? In Michael Crichton’s The Andromeda Strain, the canonical book in the disease-outbreak genre, an alien microbe threatens the human race with extinction, and humanity’s best minds are marshaled to combat the enemy organism. Fortunately, outside of fiction, there’s no reason to expect alien pathogens to wage war on the human race any time soon, and my analysis suggests that any real-life domestic microbe reaching an extinction level of threat probably is just as unlikely. Any apocalyptic pathogen would need to possess a very special combination of two attributes. First, it would have to be so unfamiliar that no existing therapy or vaccine could be applied to it. Second, it would need to have a high and surreptitious transmissibility before symptoms occur. The first is essential because any microbe from a known class of pathogens would, by definition, have family members that could serve as models for **containment and countermeasures**. The second would allow the hypothetical disease to spread without being detected by even the most astute clinicians. The three infectious diseases most likely to be considered extinction-level threats in the world today—influenza, HIV, and Ebola—don’t meet these two requirements. Influenza, for instance, despite its well-established ability to kill on a large scale, its contagiousness, and its unrivaled ability to shift and drift away from our vaccines, is still what I would call a “known unknown.” While there are many mysteries about how new flu strains emerge, from at least the time of Hippocrates, **humans have been attuned to its risk**. And in the modern era, a full-fledged industry of influenza preparedness exists, with effective vaccine strategies and antiviral therapies. HIV, which has killed 39 million people over several decades, is similarly limited due to several factors. Most importantly, HIV’s dependency on blood and body fluid for transmission (similar to Ebola) requires intimate human-to-human contact, which limits contagion. Highly potent antiviral therapy allows most people to live normally with the disease, and a substantial group of the population has genetic mutations that render them impervious to infection in the first place. Lastly, simple prevention strategies such as needle exchange for injection drug users and barrier contraceptives—when available—can curtail transmission risk. Ebola, for many of the same reasons as HIV as well as several others, also falls short of the mark. This is especially due to the fact that it spreads almost exclusively through people with easily recognizable symptoms, plus the taming of its once unfathomable 90 percent mortality rate by simple supportive care. Beyond those three, **every other known disease** falls short of what seems required to wipe out humans—which is, of course, why we’re still here. And it’s not that diseases are ineffective. On the contrary, diseases’ failure to knock us out is a testament to just how resilient humans are. Part of our evolutionary heritage is our immune system, one of the most complex on the planet, even without the benefit of vaccines or the helping hand of antimicrobial drugs. This system, when **viewed at a species level**, can adapt to almost **any enemy imaginable**. Coupled to genetic variations amongst humans—which open up the possibility for a range of advantages, from imperviousness to infection to a tendency for mild symptoms—this adaptability ensures that almost any infectious disease onslaught will **leave a large proportion of the population alive to rebuild**, in contrast to the fictional Hollywood versions. While the immune system’s role can never be understated, an even more powerful protector is the faculty of consciousness. Humans are not the most prolific, quickly evolving, or strongest organisms on the planet, but as Aristotle identified, humans are the rational animals—and it is this fundamental distinguishing characteristic that allows humans to form abstractions, think in principles, and plan long-range. These capacities, in turn, allow humans to modify, alter, and improve themselves and their environments. Consciousness equips us, at an individual and a species level, to make nature safe for the species through such technological marvels as antibiotics, antivirals, vaccines, and sanitation. When humans began to focus their minds on the problems posed by infectious disease, human life ceased being nasty, brutish, and short. In many ways, human consciousness became infectious diseases’ worthiest adversary. None of this is meant to allay all fears of infectious diseases. To totally adopt a Panglossian viewpoint would be foolish—and dangerous. Humans do face countless threats from infectious diseases: witness Zika. And if not handled appropriately, severe calamity could, and will, ensue. The West African Ebola outbreak, for instance, festered for months before major efforts to bring it under control were initiated. When it comes to infectious diseases, I’m worried about the failure of institutions to understand the full impact of outbreaks. I’m worried about countries that don’t have the infrastructure or resources to combat these outbreaks when they come. But as long as we can keep adapting, **I’m not worried about the future of the human race**.

#### There are lots of covid vaccines in development now

Carl Zimmer, Jonathan Corum and Sui-Lee Wee, 9-7-2021, "Coronavirus Vaccine Tracker," No Publication, <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>  
Carl Zimmer writes the “Matter” column for The New York Times. He is the author of fourteen books, including “Life's Edge: The Search For What It Means To Be Alive.” Jonathan Corum is the science graphics editor for The New York Times. He produced the award-winning “Out There” video series, and has developed virtual-reality films about Pluto, Antarctica and Apollo 11. He joined The Times in 2005 and has a degree in Art and East Asian Studies from Yale College. Sui-Lee Wee is a China correspondent for The New York Times. She was part of the team that won the 2021 Pulitzer Prize in public service for coverage of the coronavirus pandemic. Ms. Wee has covered China since 2010, focusing on health care, gender and demographics. She was twice a part of teams that were named as finalists for the Pulitzer Prize in international reporting: in 2021 for an article that delved into the differing fates of two female medical workers who were infected with Covid-19 in Wuhan, and in 2020 for stories on the Chinese government's use of DNA surveillance against the country's Uighur Muslim minority. Ms. Wee has reported on a three-part series exploring the dysfunctions in China's health care system, which was recognized as a 2019 finalist in the public service category by the Society of Publishers in Asia. Born and raised in Singapore, Ms. Wee started her career in the city-state with Reuters in 2006. She later worked for the news agency in Hong Kong and Beijing for eight years. She was part of a team that won an Overseas Press Club award in 2016 for “The Long Arm of China,” a series that looked at China extending its influence across its borders *(Harker AM)*

Vaccines typically require years of research and testing before reaching the clinic, but in 2020, scientists embarked on a race to produce safe and effective coronavirus vaccines in record time. Researchers are currently testing 102 vaccines in clinical trials on humans, and 33 have reached the final stages of testing. More than 75 preclinical vaccines are under active investigation in animals. Below is a list of all vaccines that have reached trials in humans, along with a selection of promising vaccines being tested in animals. For an explanation of virus variants and mutations, see our Coronavirus Variant Tracker. For treatments for Covid-19, see our Coronavirus Drug and Treatment Tracker. For an explanation of leading vaccines, see How Nine Covid-19 Vaccines Work. PRECLINICAL TESTING: Scientists test a new vaccine on cells and then give it to animals such as mice or monkeys to see if it produces an immune response. PHASE 1 SAFETY TRIALS: Scientists give the vaccine to a small number of people to test safety and dosage, as well as to confirm that it stimulates the immune system. PHASE 2 EXPANDED TRIALS: Scientists give the vaccine to hundreds of people split into groups, such as children and the elderly, to see if the vaccine acts differently in them. These trials further test the vaccine’s safety. PHASE 3 EFFICACY TRIALS: Scientists give the vaccine to thousands of people and wait to see how many become infected, compared with volunteers who received a placebo. These trials can determine if the vaccine protects against the coronavirus, measuring what’s known as the efficacy rate. Phase 3 trials are also large enough to reveal evidence of relatively rare side effects. EARLY OR LIMITED APPROVAL: Many countries have procedures for providing emergency authorizations for vaccines, based on preliminary evidence that they are safe and effective. In addition, some countries such as China and Russia began administering vaccines before detailed Phase 3 trial data was made public. Experts have warned of serious risks from jumping ahead of these results. APPROVAL: Regulators review the complete trial results and plans for a vaccine’s manufacturing, and decide whether to give it full approval. COMBINED PHASES: One way to accelerate vaccine development is to combine phases. Some vaccines are now in Phase 1/2 trials, for example, which this tracker would count as both Phase 1 and Phase 2. PAUSED or ABANDONED: If investigators observe worrying symptoms in volunteers, they can pause the trial. After an investigation, the trial may resume or be abandoned. Genetic Vaccines Vaccines that deliver one or more of the coronavirus’s own genes into our cells to provoke an immune response. RNA vaccine DNA vaccine PHASE 2 PHASE 3 COMBINED PHASES APPROVED IN SEVERAL COUNTRIES EMERGENCY USE IN U.S., ELSEWHERE Pfizer logoBioNTech logo VACCINE NAME: Comirnaty (also known as tozinameran or BNT162b2) EFFICACY: 91% DOSE: 2 doses, 3 weeks apart TYPE: Muscle injection STORAGE: Freezer storage only at –13°F to 5°F (–25°C to –15°C) On Nov. 9, 2020, New York-based Pfizer and the German company BioNTech made history by announcing that their coronavirus vaccine had an efficacy rate of over 90 percent, far surpassing expectations. It was the first time anyone had found such evidence. Just over a month later, on Dec. 11, the Food and Drug Administration granted the vaccine, known as Comirnaty, the first emergency use authorization ever given by the United States to a coronavirus vaccine. On Aug. 23, 2021, the F.D.A. granted full approval to the Pfizer-BioNTech vaccine, for people 16 and older. The companies expect to deliver 2.1 billion doses worldwide in 2021. VACCINE DEVELOPMENTThe work on Comirnaty began in January 2020, when BioNTech researchers started fashioning a genetic molecule called messenger RNA (mRNA). They created the genetic instructions for building a coronavirus protein, known as spike. When injected into cells, the vaccine causes them to make spike proteins, which then get released into the body and provoke a response from the immune system. In March, BioNTech partnered with Pfizer to scale up the research, launching a clinical trial in May. TRIAL RESULTSThe Phase 1 trials showed that Comirnaty caused volunteers to produce antibodies against SARS-CoV-2, as well as immune cells called T cells that respond to the virus. On July 27, the companies announced the launch of a Phase 2/3 trial with 30,000 volunteers. On Sept. 12, Pfizer and BioNTech announced that they would seek to expand the trial to 44,000 participants. Through the summer and into the fall, the world closely followed the Pfizer-BioNTech trial. In September, Dr. Albert Bourla, the chief executive of Pfizer, said that as soon as October the Phase 3 trial would deliver enough results to show if the vaccine worked or not. President Trump touted their progress, hinting that a vaccine would be available before the election. But on Oct. 27, Dr. Bourla announced that the volunteers in the trial had yet to experience enough cases of Covid-19 to determine if the vaccines work. Finally, on Nov. 9, Pfizer and BioNTech released their preliminary analysis of the first 94 cases of Covid-19 in their volunteers. Over the next month, Pfizer and BioNTech released more data on more cases. On Dec. 8 the FDA released their independent analysis of the clinical trials. They determined that Comirnaty has an efficacy rate of 95 percent. While Comirnaty caused no serious side effects, it frequently caused short-lived fatigue, fever, and muscle aches. In Israel, which took the lead in mass vaccination, researchers found that the vaccine was as effective in the real world as the trials had indicated. A study published by the Centers for Disease Control in March found that the vaccine is 91.3% effective after the second dose. In June 2020, researchers at Oxford announced preliminary results suggesting that a combination of AstraZeneca’s vaccine followed by Comirnaty produces strong levels of antibodies. Another study from South Korea suggested that the antibody levels generated from the same combination were six times higher than two AstraZeneca doses. AUTHORIZATIONOn Dec. 2, 2020, the United Kingdom became the first country to give Comirnaty emergency authorization, followed by many more countries. On Dec. 31, the World Health Organization gave the vaccine an Emergency Use Listing, which will speed up its authorization across the world. On May 10, 2021 the F.D.A. expanded their emergency use authorization for Comirnaty to children as young as 12. Pifzer is also running trials with younger children. Pfizer said it would request emergency approval for use in children between the ages of 5 and 11 as early as September. Results for children aged 2 to 5 could emerge shortly after that. Results for the youngest children — 6 months to 2 years old — are expected in October or November. On May 7, 2021, Pfizer and BioNTech announced they would seek full F.D.A. approval for their vaccine, which was granted at the end of August.. DISTRIBUTIONAs their clinical trials progressed, Pfizer and BioNTech also scaled up factories to produce Comirnaty. To secure a supply in advance, the Trump administration awarded Pfizer and BioNTech a $1.9 billion contract in July 2020 for 100 million doses. By July 2021, the companies had reached agreements with the United States government for a total of a billion doses: half for domestic use and half for donations to other countries. In April 2021, the European Union negotiated a deal for 1.8 billion doses, which should close up the massive shortfall they experienced early in their vaccine rollout. While Comirnaty has proven highly effective, it was initially a challenging vaccine to distribute because it had to be kept frozen at –94°F (–70°C). On Feb. 19, 2021, Pfizer and BioNTech announced that they could keep the vaccine stable at –25°C to –15°C (–13°F to 5°F). VARIANTSIn January, scientists grew concerned about the emergence of fast-spreading variants that might be able to evade antibodies. A study published in May demonstrated that Comirnaty was somewhat less effective against some variants, but still provided strong protection. A British study showed that Comirnaty had an effectiveness of 88 percent against infection with Delta, the variant first identified in India. Its effectiveness against hospitalization from Delta was 96 percent. Pfizer and BioNTech have also developed experimental boosters for the Beta and Delta variants. BOOSTERSIn April, Dr. Bourla, the chief executive, said people would “likely” need an additional shot of its vaccine within a year of receiving two doses. The Associated Press reported on July 8 that Pfizer plans to seek emergency authorization for a third dose in August, following positive preliminary results from its booster study. Pfizer launched a trial in June to combine a booster shot with Prevnar, their vaccine for pneumococcal disease. Researchers are also running a trial of Comirnaty as a booster shot for adults with cancer. In July, as the Delta variant fueled a new spike in cases, Israel began offering a booster to adults at risk. On Aug. 2, Germany announced that in September it would begin delivering boosters made by Pfizer-BioNTech and Moderna. The F.D.A. expanded its emergency authorization to include a third dose of Comirnaty in certain immunocompromised adults on Aug. 13. And on Aug. 16, Pfizer and BioNTech sent positive data from its Phase 1 trial of a third dose of Comirnaty to the F.D.A. for potential approval. For more details, see How the Pfizer-BioNTech Vaccine Works and How Pfizer Makes Its Covid-19 Vaccine. APPROVED FOR USE IN: Bahrain, Brazil, New Zealand, Saudi Arabia, Switzerland, United States NEW. EMERGENCY USE IN: Albania, Argentina, Armenia, Australia, Bangladesh, Bermuda, Bosnia and Herzegovina, Botswana, Brunei, Cabo Verde, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, European Union, Faroe Islands, French Polynesia, Greenland, Guatemala, Hong Kong, Iceland, Indonesia, Iraq, Israel, Japan, Jordan, Kuwait, Lebanon, Libya, Liechtenstein, Malawi NEW, Malaysia, Maldives, Mexico, Moldova, Monaco, Mongolia, New Caledonia, Nigeria, Norway, North Macedonia, Oman, Pakistan, Panama, Peru, Philippines, Qatar, Rwanda, Saint Vincent and the Grenadines, Serbia, Singapore, Sri Lanka, South Africa, South Korea, St. Maarten, Thailand, Trinidad and Tobago NEW, Tunisia, Turkey, Ukraine, United Arab Emirates, United Kingdom, United States, Uruguay, Vatican, Vietnam, West Bank. Emergency use validation from the World Health Organization. Recommended for emergency use by the Caribbean Regulatory System. Updated Aug. 26 Pfizer-BioNTech vaccine BRITAIN AND THE E.U. SWITZERLAND CANADA JAPAN TUNISIA MONGOLIA U.S. PHILIPPINES IRAQ BAHRAIN SAUDI ARABIA NIGERIA MEXICO OMAN BRAZIL ECUADOR BOTSWANA SINGAPORE AUSTRALIA PERU NEW ZEALAND SOUTH AFRICA ARGENTINA CHILE Approved Early, limited or emergency use PHASE 3 APPROVED IN SWITZERLAND EMERGENCY USE IN U.S., ELSEWHERE Moderna logoNational Institutes of Health logo VACCINE NAME: mRNA-1273 or Spikevax EFFICACY: More than 90% DOSE: 2 doses, 4 weeks apart TYPE: Muscle injection STORAGE: 30 days with refrigeration, 6 months at –4°F (–20°C) On Dec. 18., 2020, the F.D.A. gave emergency use authorization for a vaccine made by the Boston-based company Moderna. The Moderna vaccine, known as Spikevax, was the second to be authorized by the F.D.A., coming a week after Comirnaty, the vaccine made by Pfizer and BioNTech. VACCINE DEVELOPMENTLike Pfizer and BioNTech, Moderna makes its vaccine from mRNA. In recent years, the company has tested mRNA vaccines for a number of diseases, but they have yet to bring one to market. Last January, they began developing a vaccine for the coronavirus. The United States government bankrolled Moderna’s efforts, providing nearly $1 billion in support. In partnership with the National Institutes of Health, they found that Spikevax protects monkeys from the coronavirus. TRIAL RESULTSIn March 2020, Moderna launched the first clinical trial of a Covid-19 vaccine.. After those studies yielded promising results, Phase 3 testing on 30,000 volunteers began on July 27. On Nov. 16, Moderna announced the first preliminary data from the trial, followed by the complete data on Nov. 30. The researchers estimated that Spikevax had an efficacy rate of 94.1 percent. On May 25, 2021, Moderna announced that the vaccine safely provided strong protection to children as young as 12. The company is currently testing the vaccine in babies and young children. AUTHORIZATIONThe United States currently authorizes the use of Spikevax for people 18 and older. In June, Moderna applied to expand the authorization to children as young as 12. The Europe Medicines Agency authorized giving Spikevax to adolescents in July. On June 1, 2021, Moderna announced it would seek a full licence for their vaccine. The F.D.A. authorized a third dose of the Moderna vaccine for immunocompromised individuals on Aug. 13, 2021. DISTRIBUTIONWhile Moderna’s clinical trials were still underway in the summer of 2020, the company entered deals with several countries to supply the vaccine pending its approval. On Aug. 11, the United States government awarded the company $1.5 billion in exchange for 100 million doses if the vaccine proves safe and effective. Additional negotiations have increased the agreement to 500 million doses. The European Commission secured 460 million doses. Moderna has made similar deals with other countries including Canada, Japan, Qatar and South Korea. The company has also pledged 500 million doses to COVAX, a global vaccine initiative, to supply vaccines to low-income countries. On April 29, Moderna announced they would produce 800 million to 1 billion doses in 2021, and planned to manufacture 3 billion doses in 2022. VARIANTSTests on the Moderna vaccine indicate that it provides strong protection against dominant variants like Beta and Delta. BOOSTERSIn March 2021, Moderna began a Phase 1 trial of a new mRNA vaccine made specifically for the Beta variant. A variant-specific booster shot of the Moderna vaccine has yielded positive results in humans and mice. On Sept. 2, Moderna announced that it had sent initial data from its booster shot trials to the F.D.A. for potential authorization. In June 2021, the N.I.H. launched a clinical trial to assess Moderna’s vaccine as a booster shot, and the following month Sanofi began another trial, combining a booster shot of Moderna with their Fluzone influenza vaccine. Results from a trial of a third Moderna shot in adults who have received an organ transplant suggested that the booster improved their immune response — a finding that led the F.D.A. to authorize the booster shot in that population in August. On August 2, 2021, Germany announced that in September it would begin delivering boosters made by Pfizer-BioNTech and Moderna. For more details, see How Moderna’s Vaccine Works. APPROVED FOR USE IN: Switzerland. EMERGENCY USE IN: Andorra, Australia NEW, Bangladesh, Bhutan NEW, Botswana, Brunei, Canada, Colombia, European Union, Faroe Islands, Fiji, Greenland, Guatemala, Haiti, Honduras, Iceland, India, Indonesia, Israel, Japan, Kenya NEW, Kuwait, Libya, Liechtenstein, Malawi NEW, Malaysia NEW, Maldives, Mexico NEW, Moldova, Mongolia, Nigeria, Norway, Pakistan, Palestinian Authority, Philippines, Qatar, Saint Vincent and the Grenadines, Saudi Arabia, Singapore, South Korea, Sri Lanka, Taiwan, Thailand, Trinidad and Tobago NEW, United Arab Emirates, United Kingdom, United States, Vietnam. Emergency use validation from the World Health Organization. Updated Sept. 2 Moderna vaccine U.K. AND E.U. SWITZERLAND CANADA JAPAN MONGOLIA U.S. ISRAEL NIGERIA QATAR VIETNAM INDIA GUATEMALA SINGAPORE AUSTRALIA BOTSWANA Approved Early, limited or emergency use PHASE 3 EMERGENCY USE IN INDIA Zydus Cadila logo VACCINE NAME: ZyCoV-D EFFICACY: 66.6% DOSE: 3 doses, 4 weeks apart TYPE: Skin injection STORAGE: Stable at room temperature for three months In July 2020, the Indian vaccine-maker Zydus Cadila began testing a DNA-based vaccine delivered by a skin patch. After getting promising results in their Phase 1 trial, they launched a Phase 2 trial on ZyCoV-D on Aug. 6. On Jan. 3, 2021 the Indian government gave Zydus Cadila permission to advance to a Phase 3 trial with 30,000 volunteers. The company announced on July 1 that the vaccine had an efficacy of 66.6% and that none of the vaccinated volunteers in the trial developed severe disease or died, making ZyCoV-D the first DNA-based vaccine shown to work against Covid-19. Zydus Cadila received emergency authorization from the Indian government on Aug. 20. EMERGENCY USE IN: India. Updated Sept. 7 Zydus Cadila vaccine INDIA Approved Early, limited or emergency use PHASE 3 CureVac logo VACCINE NAME: CVnCoV EFFICACY: 48% DOSE: 2 doses, 4 weeks apart TYPE: Muscle injection STORAGE: Stable at least 3 months at 36–46°F (2–8°C) In March 2020, the Trump administration unsuccessfully tried to entice CureVac to move its research on their mRNA vaccine from Germany to the United States. The company plowed ahead with its work in Germany, seeing responses to the vaccine in mice and monkeys before launching clinical trials in July. Their vaccine showed promise in several respects: it can remain stable in a refrigerator rather than a freezer, and preliminary studies suggested it would work well at a low dose, reducing its cost. In December, CureVac launched a Phase 3 trial, recruiting up to 36,500 volunteers in Germany. The European Union began a rolling review in February, intended to speed up approval if the Phase 3 trial delivers positive results. Meanwhile, CureVac prepared for mass production of the vaccine. The company negotiated a deal to provide the European Union with up to 400 million doses of their vaccine. They projected manufacturing up to 300 million doses in 2021 and up to a billion doses the following year. Starting in January 2021, CureVac forged a series of partnerships with pharmaceutical giants Bayer, Celonic, GSK, and Novartis, to support the production of their vaccine and develop new ones against coronavirus variants. In June 2021, CureVac reported disappointing results from the trial. Overall, their vaccine had an efficacy of just 48 percent against Covid-19. It proved somewhat better for younger volunteers: For those between the ages of 18 and 60, the efficacy rose to 53 percent. In that group, the researchers also found the vaccine provided 100 percent protection against hospitalization and death. Researchers later pointed to the vaccine dosage along with the rise of new variants as potential reasons for the low efficacy. Despite the disappointing results, the company moved ahead with plans to complete their application to the European Union for authorization by the end of September. CureVac also developed a second-generation version that is more potent than the first. Known as CV2CoV, it generates a stronger immune response in animals compared to the first. Updated Sept. 3 PHASE 3 Academy of Military Medical Sciences logoSuzhou Abogen Biosciences logoWalvax Biotechnology logo In June 2020, Chinese researchers at the Academy of Military Medical Sciences, Suzhou Abogen Biosciences and Walvax Biotechnology announced they would start their country’s first safety trials on an mRNA-based vaccine, called ARCoV. Earlier studies on monkeys reportedly showed protective effects, and in the Phase 1 trial indicated it was safe in people. On Dec. 21, Xinhua reported that China was building a factory to produce 120 million doses per year. Researchers launched a Phase 2 trial for the vaccine in January 2021, and registered a Phase 3 trial in April. In September, Bloomberg reported that the trial would soon be launched in Indonesia and Mexico, with results expected by the end of the year. Updated Sept. 3 PHASE 2 PHASE 3 COMBINED PHASES Arcturus logoDuke-NUS Medical School logo The California-based company Arcturus Therapeutics and Duke-NUS Medical School in Singapore have developed an mRNA vaccine called ARCT-021. It has a “self-replicating” design that leads to a greater production of viral proteins. Tests on animals showed that it protected them against infection. In August, Arcturus launched a Phase 1/2 trial at Singapore General Hospital. On Nov. 9, the company announced that an interim analysis of the trial showed that the vaccine produced an immune response that’s in the range of responses seen in people who recovered from Covid-19. On Jan. 6 Arcturus announced that they had permission to start the Phase 2 portion of the trial in both Singapore and the United States. Singapore reached an agreement with Arcturus to spend up to $175 million to acquire vaccines when they’re ready. In August, Arcturus received approval to begin testing its next-generation mRNA vaccine in Vietnam. The company registered a Phase 2/3 trial of the vaccine, called ARCT-154. Updated Aug. 2 PHASE 2 University of Tübingen logo In early 2020, researchers at the University of Tübingen in Germany created a vaccine made of eight parts of two viral proteins, along with an immune-stimulating adjuvant. In September they launched a Phase 1 trial. On June 21, 2021, the researchers announced that the vaccine had entered Phase 2 trials. Updated Aug. 9 PHASE 2 Inovio logo VACCINE NAME: INO-4800 EFFICACY: Unknown DOSE: To be determined TYPE: Skin injection STORAGE: Over a year at room temperature Before the pandemic, the Pennsylvania-based company Inovio developed DNA-based vaccines that are delivered into the skin with electric pulses from a hand-held device. They are running clinical trials for vaccines against a number of diseases, including HIV, Zika, and several forms of cancer. At the start of the pandemic, Inovio developed a DNA vaccine against the spike protein on the coronavirus. A Phase 1 trial, published in December, did not uncover any serious adverse effects, and measured an immune response in all 38 volunteers. Inovio became embroiled in several lawsuits with stockholders and a company partner. On Sept. 28, 2020, the F.D.A. put the vaccine on a partial hold due to questions about the delivery device. On Nov. 16, Inovio said that the F.D.A. had given them permission to move forward. Inovio went on to run Phase 2 trials in the United States as well as in China and South Korea, and posted results of the studies online on May 7, 2021. They also began testing versions of their vaccine tailored against new variants. After losing government funding for Phase 3 trials, Inovio said it would proceed with testing its vaccine outside of the United States. On June 8, the company announced that it would run its Phase 3 trials in Latin America and Asia, in a partnership with the Chinese company Advaccine Biopharmaceuticals. On Aug. 26, Inovio announced that Brazilian regulators authorized their Phase 3 trial. Their vaccine is also part of a Chinese mixed trial combined with Sinovac’s vaccine. Updated Aug. 26 PHASE 2 Providence Therapeutics logo Canada’s Providence Therapeutics specializes in messenger RNA vaccines to treat cancer. In response to the pandemic, they developed an mRNA vaccine against the coronavirus. They launched a Phase 1 study of an RNA vaccine in late January 2021, and in May announced that the vaccine appeared safe and produced promising levels of antibodies. In August, Providence Therapeutics launched a Phase 2 trial. In June, the company reached an agreement with the Indian vaccine maker Biological E to carry out further trials in India. Biological E agreed to purchase up to 30 million doses and planned to scale their production of the vaccine to as many as a billion doses in 2022. Updated Sept. 3 PHASE 1 PHASE 2 COMBINED PHASES AnGes logoOsaka University logoTakara Bio logo VACCINE NAME: AG0302-COVID19 EFFICACY: Unknown DOSE: 2 doses, 2 weeks apart TYPE: Skin injection STORAGE: Over a year at room temperature On June 30, 2020, the Japanese biotechnology company AnGes launched a Phase 1 trial to test a DNA-based vaccine, developed in partnership with Osaka University and Takara Bio. The company moved on to a Phase 2/3 trial in December. On Aug. 6, the researchers registered a new Phase 1/2 trial of the vaccine at a higher dose after preliminary results suggested the efficacy of the original dose schedule was insufficient. Updated Aug. 6 PHASE 1 PHASE 2 COMBINED PHASES Gennova Biopharmaceuticals logoHDT Bio logo Gennova Biopharmaceuticals in India and Seattle-based HDT Bio partnered to develop a vaccine based on self-amplifying RNA. The vaccine, known as HGC019, was able to safely provoke animals to make antibodies to the coronavirus, leading India to grant the companies approval in December 2020 to start Phase 1/2 trials. On May 4, 2021 HDT announced the trial was underway in India. HDT announced on Aug. 16 that it also forged a partnership with South Korean biotech company Quratis to develop its vaccine. The Indian Ministry of Science and Technology announced on Aug. 24 that promising results from the Phase 1 trial cleared the way for further Phase 2 and Phase 3 trials. Updated Aug. 26 PHASE 1 PHASE 2 COMBINED PHASES GeneOne Life Science logo GeneOne Life Science, a South Korean biotech company, developed a DNA-based vaccine that encodes two proteins from the coronavirus. In December 2020, they launched a Phase 1/2 trial with 345 participants. After receiving positive interim results from the trial, GeneOne announced on July 8, 2021 that it would begin Phase 2. Updated Aug. 4 PHASE 1 PHASE 2 COMBINED PHASES Genexine logo The South Korean company Genexine started testing the safety of a DNA-based vaccine in June 2020. In December, the Korea Biomedical Review reported that Genexine got disappointing results from their initial formulation and decided to restart their trials with a modified vaccine. On Jan. 20, 2021, the company registered a Phase 1/2 trial, and in June they registered a Phase 1 trial for elderly volunteers. The Indonesian pharmaceutical company Kalbe Farma pledged in April to buy 10 million doses of Genexine’s vaccine if it is proven to be safe and effective. In July, Indonesian regulators gave the green light for a Phase 2/3 clinical trial. Updated Aug. 4 PHASE 1 PHASE 2 COMBINED PHASES Takis Biotech logoRottapharm Biotech logo Takis Biotech and Rottapharm Biotech, two vaccine companies in Italy, developed a vaccine called COVID-eVax. A special device uses a tiny electric pulse to deliver DNA through the skin. The DNA enters cells, which use the genetic instructions to make spike proteins. In February 2021, Takis and Rottapharm launched a Phase 1/2 trial. COVID-eVax can remain stable at room temperature. The researchers told Italian newspaper Il Giorno on July 31 that the vaccine did not produce adverse effects and that preliminary results are expected in September. Updated Aug. 24 PHASE 1 PHASE 2 COMBINED PHASES Sanofi logoTranslate Bio logo The French pharmaceutical company Sanofi is developing an mRNA vaccine in partnership with Translate Bio. They have found that it produces a strong antibody response in mice and monkeys, and protects hamsters against coronavirus infections. In March the companies launched a Phase 1/2 trial, which they anticipate delivering results in the third quarter of 2021. The vaccine, known as MRT5500, is Sanofi’s second Covid-19 candidate in clinical trials, following their protein-based vaccine. Updated April 20 PHASE 1 PHASE 2 COMBINED PHASES Daiichi Sankyo logoUniversity of Tokyo logo Japan-based researchers at Daiichi Sankyo have developed an mRNA vaccine against the coronavirus in collaboration with the University of Tokyo. They launched a Phase 1/2 trial of the vaccine, named DS-5670, on March 22, 2021. Updated March 23 PHASE 1 PHASE 2 COMBINED PHASES Elixirgen Therapeutics logo Researchers at Baltimore-based Elixirgen Therapeutics have created an RNA vaccine, named EXG-5003, that targets a small part of the coronavirus spike protein. In May 2021 they launched a Phase 1/2 trial of the vaccine in Japan. Updated May 25 PHASE 1 Chulalongkorn University logoChula Vaccine Research Center logo Researchers at Thailand’s Chulalongkorn University have been developing several potential vaccines for the coronavirus. The furthest along is an mRNA-based vaccine known as ChulaCov19. In September 2020, the Chula Vaccine Research Center registered a Phase 1 trial to test it in humans. Delays in funding and manufacturing slowed the study’s launch until June 2021. In an interview with the Bangkok Post, the leader of the project said that up to 30 million doses might be produced for Thailand and six other Asian countries if the vaccine proved to be safe and effective. Updated June 16 PHASE 1 entos logo The Canadian company Entos Pharmaceuticals has created a DNA vaccine for the coronavirus. Most other genetic vaccines carry the gene for the spike protein on the surface of the virus. Entos instead chose the gene for nucleocapsid, a protein that sits inside the virus’s membrane. They are betting it can offer long-lasting immunity. In October 2020, Entos launched a Phase 1 trial in Canada for their vaccine, called Covigenix VAX-001. They began dosing participants on April 15. Entos C.E.O. John Lewis told Canadian media on Aug. 4 that the vaccine produced a sufficient immune response without adverse reactions. He also said that a Phase 2 trial would take place outside of Canada. Updated Aug. 24 PHASE 1 symvivo logo On Nov. 2, 2020, the Canadian company Symvivo announced they had administered a DNA vaccine to their first volunteer in a Phase 1 trial. The DNA is inserted into harmless bacteria, which volunteers swallow in a frozen liquid (the company is working on putting the bacteria into a pill). When the bacteria reach the intestines, the DNA slips into cells in the gut lining, which then make viral proteins. Symvivo announced on July 19 that it received nearly $5 million in funding from the National Research Council of Canada’s Industrial Research Assistance Program to continue developing its vaccine. Updated July 26 PHASE 1 OncoSec Immunotherapies logo New Jersey-based OncoSec Immunotherapies has developed experimental cancer treatments that deliver genes into tumors. There, the injected genes produce a natural signalling molecule called IL-12, which attracts the attention of immune cells that attack the cancer. In the spring of 2020, OncoSec began adapting their technology to make a vaccine for the coronavirus. The vaccine, called CORVax12, consists of a loop of DNA that encodes both the spike protein and IL-12. Causing the body to make extra IL-12 could potentially enhance the immune system’s ability to make antibodies to the spike protein. On Jan. 27, 2021, the company began dosing participants in its Phase 1 trial to test the safety of CORVax12. Updated June 8 PHASE 1 BioNet-Asia logoTechnovalia logo Using a delivery system from PharmaJet, researchers at BioNet-Asia and Australia-based Technovalia have developed a DNA vaccine called COVIGEN that can be pushed through the skin without a needle. Instead, the dose is loaded into a handheld device and shot directly into cell tissue through a jet spray of fluid. Vaccines for the flu already use the device, which PharmaJet says is a safer alternative to needle injections. The researchers registered a Phase 1 trial in Australia on Feb. 8, 2021. Updated March 4 PHASE 1 Stemirna Therapeutics logoShanghai East Hospital logo Chinese researchers at Stemirna Therapeutics have developed an mRNA vaccine in collaboration with Shanghai East Hospital. They registered a Phase 1 trial on May 1, 2021. Updated May 20 ABANDONED Imperial College logoMorningside logo In early 2020, Imperial College London researchers developed a “self-amplifying” RNA vaccine for Covid-19, which boosted production of a viral protein to stimulate the immune system. They began Phase 1/2 trials on June 15, partnering with Morningside Ventures to manufacture and distribute the vaccine through a new company called VacEquity Global Health. On Dec. 18, the researchers announced a collaboration with Enesi Pharma to formulate a solid version of the vaccine that can be implanted in the skin without a needle. On Jan. 27, 2021, Robin Shattuck, the leader of the project, announced that “it is not the right time to start a new efficacy trial for a further vaccine in the U.K.” Instead of competing with authorized vaccines, they are turning their efforts to making candidates that will work well against emerging variants of the coronavirus. Updated March 20 PRECLINICAL Other genetic vaccines in active preclinical development include vaccines from: Batavia Biosciences and RocketVax; CureVac and GSK; DIOSynVax; Doherty Institute and Monash University; ETheRNA; EyeGene; Globe Biotech; Greenlight Biosciences; Gritstone bio and CEPI; HIPRA and Hospital Clínic de Barcelona; Infectious Disease Research Institute and Amyris; Inovio; National Research Centre, Egypt; National Health Research Institutes, Taiwan; the OPENCORONA Consortia; Scancell; the Spanish National Center for Biotechnology and the Spanish National Research Council; Stanford University. Updated Aug. 20 Viral Vector Vaccines Vaccines that contain viruses engineered to carry coronavirus genes. Some viral vector vaccines enter cells and cause them to make viral proteins. Other viral vectors slowly replicate, carrying coronavirus proteins on their surface. PHASE 3 EMERGENCY USE IN RUSSIA, ELSEWHERE Gamaleya Research Institute logo VACCINE NAME: Sputnik V (also known as Gam-Covid-Vac) EFFICACY: 91.6% DOSE: 2 doses, 3 weeks apart TYPE: Muscle injection STORAGE: Freezer storage. Developing an alternative formulation that can be refrigerated. The Gamaleya Research Institute, part of Russia’s Ministry of Health, has created a vaccine with an efficacy rate of 91.6 percent. Russia began distributing the vaccine, known as Sputnik V, in fall 2020, and it is now widely used around the world. VACCINE DEVELOPMENTGamaleya produced the vaccine, initially called Gam-Covid-Vac, from a combination of two adenoviruses called Ad5 and Ad26. Both kinds have been tested as vaccines over a number of years. By combining them, the Russian researchers hoped to avoid a situation in which the immune system could learn to recognize the vaccine as a foreign object that needed to be destroyed. TRIAL RESULTSThe researchers launched clinical trials in June 2020, and by the end of the summer, the trial became bogged down in controversy. On Aug. 11, President Vladimir V. Putin announced that a Russian health care regulator had approved the vaccine, renamed Sputnik V. Yet the Phase 3 trials had not even begun. Vaccine experts decried the move as risky, and Russia later walked back the announcement, saying that the approval was a “conditional registration certificate,” which would depend on positive results from Phase 3 trials. In addition to Russia, volunteers for the trial were recruited in Belarus, the United Arab Emirates, and Venezuela. On Oct. 17, a Phase 2/3 trial was launched in India. On Sept. 4, three weeks after Putin’s announcement, Gamaleya researchers published the results of their Phase 1/2 trial. They found that Sputnik V yielded antibodies to the coronavirus and mild side effects. On Nov. 11, the Russian Direct Investment Fund announced the first preliminary evidence from their Phase 3 trial indicating that the vaccine is effective. Based on 20 cases of Covid-19 among the trial participants, Russian scientists estimated that the vaccine demonstrated 92 percent efficacy. By December, the trial had reached its final total of 78 cases. The creators of the vaccine published the results of their Phase 3 trial on Feb. 2, 2021 in the Lancet. The study demonstrated a high efficacy after two doses, and did not uncover serious side effects. No one who got the vaccine experienced a serious case of Covid-19. In January 2021, Gamaleya researchers started a trial in which they gave people only the first dose of Ad26 adenoviruses, the same adenovirus in Johnson & Johnson’s single-dose vaccine. They dubbed this one-dose version “Sputnik Light.” On Feb. 12, the director of the Gameleya center said in a television interview that Sputnik Light would likely provide only four to five months of protection. Russia announced on May 6 that Sputnik Light provided an efficacy of 79.4 percent but did not publish the details of the study or say how long the efficacy would last. After the single-dose version of the vaccine was rolled out in Argentina, a study found that its effectiveness there was between 78.6 and 83.7 percent. Studies also remain underway to assess Sputnik V’s safety and effectiveness in children and adolescents. On July 8, researchers registered a Phase 2/3 trial for Russians aged 12 to 17. In December 2020, the Gamaleya Institute joined forces with the drugmaker AstraZeneca, which makes a vaccine based on a chimpanzee adenovirus. The two teams combined their vaccines to see if the mixture can increase the efficacy of the AstraZeneca vaccine. The trial was registered in February, and on July 30, Russian officials announced that mixing Sputnik V with the AstraZeneca shot did not cause adverse effects or new Covid-19 cases. They announced similar results on Aug. 20 after mixing Sputnik Light with the Astrazeneca shot in a trial in Azerbaijan. Mixing Sputnik Light with the AstraZeneca, Sinopharm and Moderna vaccines was also found to be safe, Russian officials announced on Aug. 4. Chinese officials announced on July 30, 2021, that Sputnik V is part of a new trial assessing its effectiveness when combined with the CanSino vaccine. Preclinical trials for an intranasal version of Sputnik V have completed, and human trials could begin soon, Russian officials said on Aug. 11. AUTHORIZATIONIn November 2020, the Russian government began offering Sputnik V within Russia in a mass vaccination campaign. But worry that the vaccine was rushed to approval led to widespread hesitancy. On Dec. 22, Belarus became the first country outside of Russia to register Sputnik V, and since then a number of other countries have followed suit. Sputnik Light received authorization for use in Russia on May 6, 2021. In Europe, regulators began a rolling review of Sputnik V on March 4. If the European Medicines Agency approved it, many European countries might take up the vaccine. In April, Brazil’s vaccine regulator rejected Sputnik V, based on a number of concerns, including the possibility that the adenoviruses in the vaccines hadn’t been properly disabled. After weeks of tense confrontation, Brazil gave Sputnk V the green light in June, but with some conditions — including limiting it only to healthy adults. Concerns over the vaccine’s effectiveness have also pushed India to deny permission for Phase 3 trials to be conducted in the country. VARIANTSA study published in July found that Sputnik antibodies can neutralize the Delta variant, although not as effectively as they worked against the original version of the virus. For more details, see How Gamaleya’s Vaccine Works. EMERGENCY USE IN: Albania, Algeria, Angola, Antigua and Barbuda, Argentina, Armenia, Azerbaijan, Bahrain, Bangladesh, Belarus (including Sputnik Light), Bolivia, Bosnian Serb Republic, Cameroon, Chile, Congo Republic (including Sputnik Light), Djibouti, Ecuador, Egypt, Honduras, Gabon, Ghana, Guatemala, Guinea, Guyana, Hungary, India, Indonesia NEW, Iran, Iraq, Jordan, Kazakhstan (including Sputnik Light), Kenya, Kyrgyzstan (including Sputnik Light), Laos, Lebanon, Maldives, Mali, Mauritius (including Sputnik Light), Mexico, Moldova, Mongolia (including Sputnik Light), Montenegro, Morocco, Myanmar, Namibia, Nepal, Nicaragua (including Sputnik Light), Nigeria, North Macedonia, Oman, Pakistan, Palestinian Authority (including Sputnik Light), Panama, Paraguay, Philippines (including Sputnik Light), Russia (including Sputnik Light), San Marino, Serbia, Seychelles, Slovakia, Sri Lanka, St. Vincent and the Grenadines, Syria, Tunisia, Turkey, Turkmenistan, United Arab Emirates, Uzbekistan, Venezuela (including Sputnik Light), Vietnam, Zimbabwe. Updated Aug. 26 Gamaleya’s Sputnik V vaccine RUSSIA HUNGARY ALGERIA MONGOLIA GUINEA MALI IRAN PAKISTAN BAHRAIN GABON U.A.E. MEXICO VENEZUELA INDIA ANGOLA INDONESIA BOLIVIA KENYA PARAGUAY ARGENTINA Approved Early, limited or emergency use PHASE 2 PHASE 3 COMBINED PHASES APPROVED IN BRAZIL EMERGENCY USE IN E.U., ELSEWHERE University of Oxford logoAstraZeneca logo VACCINE NAME: Vaxzevria (also known as AZD1222, or Covishield in India) EFFICACY: 76% in a U.S. study. DOSE: 2 doses TYPE: Muscle injection STORAGE: Stable in refrigerator for at least 6 months A vaccine designed by the University of Oxford and produced by the British-Swedish company AstraZeneca has emerged as a key element in the effort to meet the global demand for Covid-19 vaccines. With an efficacy of 76 percent, the vaccine — now known as Vaxzevria — is being produced in vast quantities at a low price. Because it only needs to be refrigerated rather than frozen, it can be used far more widely than mRNA vaccines. But Vaxzevria’s journey has been turbulent, jolted by confusing messages from AstraZeneca, high-profile worries about safety, and difficulties with manufacturing. On July 29, 2021, Oxford announced that a billion doses of Vaxzevria had been released worldwide. VACCINE DEVELOPMENTVaxvezria was based on a vaccine platform that Oxford researchers had been developing for years for other diseases. They began with an adenovirus that normally infects chimpanzees and genetically engineered it to carry viral genes. In early 2020, the scientists developed Vaxvezria by endowing the adenovirus with the spike gene from the coroanvirus. When they gave the vaccine to monkeys, they found that it protected the animals from the disease. TRIAL RESULTSThe United States supported the development of Vaxvezria in May 2020, with $1.2 billion provided as part of Operation Warp Speed. The money helped AstraZeneca and Oxford embark on large late-stage trials in the United States, United Kingdom, South Africa, and elsewhere. But the researchers ran the trials independently, making it difficult to combine their results into a single clear picture of how well the vaccine worked. Making matters murkier, they gave different amounts of the vaccine to different people and also waited anywhere from four to twelve weeks to deliver the second dose. On Dec. 8, 2020, AstraZeneca and Oxford published the first scientific paper on a Phase 3 clinical trial of a coronavirus vaccine. The trial demonstrated that the vaccine can protect people from Covid-19, but it left many questions unresolved about the results. Nevertheless, the vaccine’s low cost and ease of storage made it attractive to countries looking for a way out of the pandemic. On Feb. 14, 2021, AstraZeneca announced they would start trials on children as young as six. Researchers at Oxford reported preliminary results suggesting that a combination of AstraZeneca’s vaccine followed by Comirnaty produces strong levels of antibodies. AstraZeneca also launched a similar trial with Russia’s Sputnik V vaccine, but no results have yet been released from that study. In September 2021, Imperial College London launched a trial of an inhaled form of the vaccine. AUTHORIZATIONThe United Kingdom and Argentina were the first countries to give the vaccine emergency authorization, on Dec. 30, 2020. On Jan. 3, India approved a version called Covishield, made by the Serum Institute of India. On Feb. 16 the World Health Organization recommended the vaccine for emergency use in adults 18 or older. Brazil gave full approval to the vaccine on March 13. In the summer of 2020, Astrazeneca promised it would distribute Vaxzevria in the United States as soon as that October. But a concern about the health of a volunteer in the U.S. clinical trial stalled the study for seven weeks. AstraZeneca did not deliver the results of the trial until March 2021 — only to be rebuked by its expert advisors for cherry-picking data. These speed bumps slowed the company down, while other vaccines were getting authorized and meeting the demand in the United States. As of July 2021, the company was planning on seeking full regulatory approval by December. DISTRIBUTIONVaxzexria promised at first to be a cheap, robust vaccine that would go a long way to meeting the world’s need for protection from Covid-19. But it has suffered a number of setbacks. Even while it was running clinical trials in 2020, AstraZeneca reached agreements with a number of manufacturers in order to produce billions of doses of Vaxzevria. But in January 2021, it admitted that it would fall short of its promised delivery of vaccines to the European Union. Its shortfall grew only worse in March when India, facing an explosion of new cases, blocked export of the vaccine from its factories. On April 26, the European Commission filed a lawsuit against the company for breach of contract. The court ordered AstraZeneca on June 18 to deliver 50 million additional doses of Vaxzevria, substantially less than the 90 million the European Commission had demanded. AstraZeneca met the revised deadline on July 26. In September, AstraZeneca and the European Commission settled their dispute, with an agreement for the company to supply 200 million doses by March 2022. In the spring of 2021, as other countries struggled with devastating new waves of Covid-19, the United States came under intense criticism for holding back raw materials India needed to make its own supply of Covishield. On April 25, the Biden administration announced it would partially lift its ban. Later, it promised to distribute AstraZeneca vaccines to other countries. But due to concerns about the facility where the vaccines were made in Baltimore, the vaccines have yet to be released. In South Africa, a small trial failed to demonstrate that it protected people against the Beta variant, which has become predominant in the country. On Feb. 7, 2021, South Africa halted plans for a rollout of 1 million doses of the AstraZeneca vaccine and switched to Johnson & Johnson. In March 2021, Covax began delivering doses of the vaccine to low- and middle-income countries. But manufacturing bottlenecks have slowed the pipeline. The company expects a total annual manufacturing capacity of two billion doses. VARIANTSA British study found that the AstraZeneca vaccine provides 67 percent effectiveness against infection with the Delta variant. A Canadian study found that it had an effectiveness of 87 percent against hospitalization and death from the variant. AstraZeneca and Oxford are working on a new version of the vaccine tailored to the Beta variant and are testing a version that can be delivered as a nasal spray. On June 28, participants received doses of the Beta variant vaccine, called AZD2816, in a new Phase 2 / 3 trial. BOOSTERSIn June, Oxford researchers reported that a third booster of the AstraZeneca vaccine generated strong immune responses in volunteers. SIDE EFFECTSIn March 2021, European medical regulators became concerned about a small number of cases of blood clots in younger people who received Vaxzevria. The European Medicines Agency concluded that the vaccine had a very rare side effect in which people suffered blood clots in large veins combined with low platelets. The regulators emphasized that the vaccine is effective and the benefits it provided outweighed the small risk of its side effects. In response some countries chose to minimize the risk by restricting the vaccine to older people. In May, Norway permanently removed Vaxzevria from their vaccination program. In August, a team of British researchers reported that the risk of blood clots is far higher from Covid-19 than from the Vaxzevria vaccine. For more details, see How the Oxford-AstraZeneca Vaccine Works. APPROVED FOR USE IN: Brazil. STOPPED USE IN: Denmark, Norway. EMERGENCY USE IN: Albania, Algeria, Angola, Anguilla NEW, Antigua, Argentina, Armenia, Australia, Bahamas, Bahrain, Bangladesh, Barbados, Barbuda NEW, Belize, Bermuda, Bhutan, Bosnia and Herzegovina, Botswana, Brazil, Brunei, Burkina Faso NEW, Cabo Verde, Cambodia, Canada, Chile, Colombia, Comoros NEW, Costa Rica, Cyprus, Dominica NEW, Dominican Republic, Ecuador, Egypt, El Salvador, Eswatini, Ethiopia, European Union, Fiji, Gambia, Georgia, Ghana, Greenland, Grenada, Guatemala, Guinea-Bissau NEW, Guyana, Haiti, Honduras, Hungary, Iceland, India, Indonesia, Iran, Iraq, Ivory Coast, Jamaica, Japan, Jordan, Kenya, Kiribati, Kosovo, Kuwait, Lebanon, Lesotho, Liberia NEW, Libya, Liechtenstein, Madagascar NEW, Malawi, Malaysia, Maldives, Mali, Mauritius, Mexico, Moldova, Mongolia, Montserrat NEW, Morocco, Namibia, Nauru, Nepal, New Zealand, Niger NEW, Nigeria, North Macedonia, Norway, Oman, Pakistan, Panama, Papua New Guinea, Peru, Philippines, Republic of Congo, Rwanda, Sao Tome and Principe, Saudi Arabia, Senegal, Serbia, Seychelles, Sierra Leone, Solomon Islands, South Africa, South Korea, Sri Lanka, Saint Vincent and the Grenadines, St. Kitts and Nevis, St. Lucia NEW, Sudan, Suriname, Taiwan, Tajikistan, Thailand, Timor-Leste, Tonga, Trinidad and Tobago NEW, Tuvalu, Uganda, Ukraine, United Kingdom, Uruguay, Vanuatu, Vietnam, Yemen, Zambia. Emergency use validation from the World Health Organization. Endorsed by the Africa Regulatory Taskforce. Recommended for emergency use by the Caribbean Regulatory System. Updated Sept. 7 Oxford-AstraZeneca vaccine NORWAY BRITAIN AND THE E.U. MOROCCO CANADA MONGOLIA SOUTH KOREA ALGERIA BAHAMAS EGYPT PHILIPPINES IRAN PAKISTAN NIGERIA INDIA MEXICO BRAZIL INDONESIA COSTA RICA KENYA AUSTRALIA NAMIBIA MALDIVES SEYCHELLES CHILE SOUTH AFRICA ARGENTINA Approved Stopped use in favor of other vaccines Early, limited or emergency use PHASE 3 APPROVED IN CHINA EMERGENCY USE IN OTHER COUNTRIES CanSino Biologics logoAcademy of Military Medical Sciences logo VACCINE NAME: Convidecia (also known as Ad5-nCoV) EFFICACY: 65.28% DOSE: Single dose TYPE: Muscle injection STORAGE: Refrigerated The Chinese company CanSino Biologics developed Convidecia in partnership with the Institute of Biology at the country’s Academy of Military Medical Sciences. The one-shot vaccine is based on an adenovirus called Ad5. Last May, researchers published promising results from a Phase 1 safety trial on Convidecia, and in July they reported that their Phase 2 trials demonstrated the vaccine produced a strong immune response. In an unprecedented move, the Chinese military approved the vaccine on June 25 for a year as a “specially needed drug.” On Nov. 28, the Chief Executive of CanSino Biologics said in an interview that about 40,000 to 50,000 people had received Convidecia. Starting in August 2020, CanSino began running Phase 3 trials in a number of countries, including Pakistan, Russia, Mexico and Chile. On Feb. 25, China announced the approval of the CanSino vaccine for general use. The company announced that its one-shot vaccine had an efficacy rate of 65.28 percent at preventing all symptomatic Covid-19 cases. The details of the trial have yet to be published. But on April 1, CanSino’s chief scientific officer said that the efficacy of its vaccine could drop over time. He also floated the idea of using a booster shot six months after the first dose, though more clinical trial data is needed. Reuters reported on Aug. 5 that this drop could be as much as around 30 percent after six months. On March 23, CanSino announced that it had won approval for a clinical trial of an inhaled version of the vaccine. Chief Executive Yu Xuefeng said on June 2 that this version is now in Phase 2 trials. Preliminary findings from the Phase 1 trial suggest that the inhaled vaccine was effective at stimulating an immune response, and that an injected dose followed by an inhaled dose may yield the best results. Researchers have also begun to test whether giving alternating doses of vaccines from CanSino and Anhui Zhifei Longcom can boost their effectiveness. On June 9, Reuters reported that the CanSino vaccine is being tested as a booster shot. Results from a Chinese study, released on Sept. 7, suggested that getting the CanSino booster shot after the Sinovac vaccine produced a stronger antibody response compared to a third shot of the Sinovac vaccine. APPROVED FOR USE IN: China. EMERGENCY USE IN: Argentina, Chile, Ecuador, Hungary, Malaysia, Mexico, Moldova, Pakistan. Updated Sept. 7 CanSino vaccine HUNGARY CHINA PAKISTAN MEXICO ECUADOR ARGENTINA CHILE Approved Early, limited or emergency use PHASE 3 EMERGENCY USE IN U.S., ELSEWHERE Johnson & Johnson logoBeth Israel Deaconess Medical Center logoJanssen Pharmaceutica logo VACCINE NAME: Ad26.COV2.S EFFICACY: 72% in United States, 68% in Brazil and 64% in South Africa DOSE: 1 dose TYPE: Muscle injection STORAGE: Up to two years frozen at –4° F (–20° C), and up to 6 months refrigerated at 36–46° F (2–8° C). On Feb. 27, 2021, the F.D.A. issued an emergency use authorization for Johnson & Johnson’s vaccine, making it the third coronavirus vaccine available in the United States. It was also the first to be shown to be safe and effective with just one dose rather than two. VACCINE DEVELOPMENTThe work that led to the vaccine started a decade ago at Beth Israel Deaconess Medical Center in Boston, where researchers developed a method for making vaccines out of a virus called Adenovirus 26, or Ad26 for short. Johnson & Johnson used Ad26 to develop vaccines for Ebola and other diseases with Ad26. In January 2020, the company and Beth Israel researchers collaborated on creating a coronavirus vaccine. In March they received $456 million from the United States government to support their move towards production. That spring, resarchers found that the vaccine provided protection in experiments on monkeys. TRIAL RESULTSJohnson & Johnson began Phase 1/2 trials in July 2020. Based on promising results in these studies, Johnson & Johnson launched a Phase 3 trial in September using just one dose rather than two. Although Johnson & Johnson initially set out to recruit 60,000 volunteers, it capped the trial at 45,000 in December as cases rose. On Jan. 29, 2021, Johnson & Johnson announced that the trial had proven that the vaccine was safe and effective, and the F.D.A. released a similar analysis on Feb. 24. Johnson & Johnson published a paper on the trial in the New England Journal of Medicine on April 21, 2021. With a single shot, the vaccine had an efficacy of 66 percent, although it varied from country to country, likely due to variants and other factors. Efficacy against severe disease was higher, at 76 percent. On Nov. 16, 2020, Johnson & Johnson announced that they were also launching a second Phase 3 trial to observe the effects of two doses of their vaccine, instead of just one. Although the results were initially expected in the summer of 2021, they have yet to be released. In February, the company also launched a trial for pregnant women and in March it announced it would soon start trials on children. Johnson & Johnson’s chief executive said in a March 4 interview that the vaccine could become available for children by September. AUTHORIZATIONBahrain became the first country to authorize the vaccine for emergency use on Feb. 25. Two days later, the United States followed suit. South Africa dropped plans to use AstraZeneca’s vaccine for their health care workers after a small trial failed to show it was effective against the Beta variant that had grown dominant across the country. They began using Johnson & Johnson’s instead. DISTRIBUTIONIn August 2020, the federal government agreed to pay Johnson & Johnson $1 billion for 100 million doses if the vaccine was authorized. Most of the U.S. supply was supposed to be made by Baltimore-based Emergent Solutions. But the company struggled to get the vaccine’s complex manufacturing up and running. In April 2021, the F.D.A. issued a scathing report about the company’s lax standards. At least 15 million doses of Johnson & Johnson’s vaccine were contaminated at the factory. As a result, the company only delivered 4 million doses to the United States after authorization, shipping them from its factory in the Netherlands. On June 11, the New York Times reported that the F.D.A. told the company to throw out 60 million doses. The following month, Emergent announced that it would resume production of the vaccines from its Baltimore plant after it receives authorization from the F.D.A. On March 2, Merck announced it would assist Johnson & Johnson with manufacturing the vaccine, but it will take several months to spin up its production. The European Union reached a similar deal on Oct. 8, 2020 for 200 million doses. But after concerns about rare blood clots emerged, reports surfaced that the E.U. might not renew its contract with the company. Meanwhile, on March 29, a coalition of African countries announced that it had secured up to 400 million doses of the Johnson & Johnson vaccine through 2022. Shipments could begin as soon as the third quarter of 2021. COVAX, an international collaboration to deliver the vaccine equitably across the world, secured 500 million doses. But as of August, manufacturing problems had prevented the company from providing COVAX with any of the promised vacccines. Johnson & Johnson is aiming for production of a billion doses in 2021. VARIANTSJohnson & Johnson found that its vaccine only had an efficacy of 52 percent in South Africa, where the Beta variant was dominant during the trial. As the Delta variant emerged in the summer of 2021, Johnson & Johnson released results of experiments indicating that their vaccine provided durable protection against it. But another study from outside scientists suggested that the vaccine only weakly protects against Delta. BOOSTERSJohnson & Johnson gave 17 trial volunteers a booster shot six months after their initial vaccination. On Aug. 25, the company announced that the boosters lifted levels of antibodies against the coronavirus nine times higher than their initial peak. SIDE EFFECTSOn April 13 the U.S. government recommended a pause in using the vaccine while it investigated reports of rare blood clots. Ten days later, C.D.C. researchers reported 15 cases of the unusual clots in nearly 8 million people who received the vaccine. The government decided to lift the pause and add a warning to the vaccine that younger women may run a slight risk of the severe side effect. At a May 12 meeting, C.D.C. researchers reported a total of 28 cases of blood clots in over 9 million vaccinations. Among women between the ages of 30-39, the rate is 12.4 cases per million doses. In women between 40 and 49, the rate is 9.4 cases per million doses. Among older women and men of all ages, there were fewer than 3 cases per million doses. In July 2021, the F.D.A. found that the vaccine caused a small increased risk of Guillain–Barré syndrome, a rare but potentially serious neurological condition. For more details, see How the Johnson & Johnson Vaccine Works. STOPPED USE IN: Denmark, Finland. EMERGENCY USE IN: Andorra, Australia, Bahrain, Bangladesh, Botswana, Brazil, Canada, Chile, Colombia, European Union, Ghana, Greenland, Iceland, Kuwait, Libya, Liechtenstein, Malaysia, Maldives, Mexico, Moldova, New Zealand, Nigeria, Norway, Philippines, South Africa, South Korea, Saint Vincent and the Grenadines, Switzerland, Syria, Thailand, Tunisia, Ukraine, United Kingdom, United States, Vietnam, Zambia, Zimbabwe. Emergency use validation from the World Health Organization. Endorsed by the Africa Regulatory Taskforce. Updated Sept. 3 Johnson & Johnson vaccine EUROPEAN UNION FINLAND CANADA SOUTH KOREA U.S. LIBYA BAHRAIN MEXICO BRAZIL ZAMBIA AUSTRALIA SOUTH AFRICA CHILE Stopped use in favor of other vaccines Approved Early, limited or emergency use PHASE 2 PHASE 3 COMBINED PHASES ReiThera logoLazzaro Spallanzani National Institute for Infectious Disease logo The Italian biotechnology company ReiThera has developed a Covid-19 vaccine, called GRAd-COV2, that is based on an adenovirus that infects gorillas. Working in collaboration with the Lazzaro Spallanzani National Institute for Infectious Diseases in Rome, they found that it produced strong levels of antibodies in mice and monkeys. In July 2020, they launched a Phase 1 clinical trial. In November, they announced that the vaccine was well tolerated and produced antibodies, and released a report on the trial. In March 2021, researchers launched a Phase 2 trial of the vaccine, which delivered encouraging results in July. But it remained unclear if ReiThera would be able to advance to a final Phase 3 trial. In May, Reuters reported, a court in Italy struck down the government’s plan to fund the Phase 3 trial. The government later said it was ready to support the vaccine trial, but has yet to offer up the funds. Updated July 12 PHASE 2 PHASE 3 COMBINED PHASES Israel Institute for Biological Research logo In the spring of 2020, the Israel Institute for Biological Research started work on a coronavirus vaccine based on vesicular stomatitis viruses. They engineered the viruses to carry the gene for the coronavirus spike protein. On Oct. 25, the Israeli government announced that the vaccine, called Brilife, would be going into a Phase 1 trial. In January 2021, the vaccine moved on to a Phase 2 trial. In July, Israel formed a partnership with the American company NRx Pharmaceuticals to advance research on Brilife in studies to be conducted in Israel, Georgia, and the Ukraine. The following month, NRx registered a Phase 2/3 trial, with plans to recruit 550 volunteers. Updated Sept. 7 PHASE 2 University of Hong Kong logoXiamen University logoWantai Biopharmaceutical logo In 2019, researchers at the University of Hong Kong and Xiamen University created a nasal-spray vaccine for the flu based on a genetically weakened form of the influenza virus. In early 2020, they engineered the vaccine to produce part of the coronavirus spike protein as well. On Sept. 9, they received approval to start clinical trials in partnership with Beijing Wantai Biological Pharmacy. They registered a Phase 1 trial on March 22, 2021. At a June 11 press conference, a researcher for the Chinese Center for Disease Control and Prevention said that this vaccine has completed Phase 2 trials and is expected to begin a Phase 3 trial overseas. The researchers are receiving $5.4 million in support from CEPI, the Coalition for Epidemic Preparedness Innovations. Updated June 14 PHASE 2 City of Hope logo Researchers at City of Hope, a California biomedical research institute, created a vaccine based on a weakened form of a virus called Modified Vaccinia Ankara, or MVA for short. They added two coronavirus genes to the virus — one for the spike protein, and one for another protein called nucleocapsid. They hope the combination will enable the vaccine to produce immunity that’s both fast and long-lasting. On Nov. 24, 2020, they announced the start of a Phase 1 trial. Eight months later, in August 2021, the researchers registered a Phase 2 trial, recruiting patients who have received stem cell transplants. Updated Aug. 9 PHASE 1 PHASE 2 COMBINED PHASES Cellid logoLG Chem logo In April 2020, the South Korean biotech company Cellid began to develop a vaccine for Covid-19. The vaccine is based on a combination of two strains of adenoviruses, called Ad5 and Ad35. After testing the vaccine on monkeys, Cellid entered into a partnership with the South Korean chemical manufacturer LG Chem to manufacture the vaccine. In December 2020, they registered a Phase 1 trial. Korean news outlets reported that Cellid received government approval to begin a Phase 1 trial of a new formulation of the vaccine on July 23, 2021. The Phase 2 trial of the original vaccine concluded on June 18, 2021, and the company shared initial results in August. Cellid plans to run the Phase 3 trial as a comparison between Cellid’s vaccine and Johnson & Johnson’s, but the company is having difficulty securing enough J&J doses to run the study. Updated Sept. 3 PHASE 1 Vaxart logo While many vaccines are given as injections, some vaccines can be taken as a pill. Oral vaccines have been approved for diseases including polio, cholera, and typhoid fever. The small San Francisco company Vaxart specializes in developing oral vaccines. They have created and tested pills for influenza and other diseases. Last spring Vaxart began work on an oral vaccine for Covid-19. It contains an adenovirus called Ad5 (the same viral vector in CanSinoBio’s vaccine and in Russia’s Sputnik V). When Vaxart gave the pill to mice, they produced antibodies against the coronavirus. Mice don’t suffer symptoms of Covid-19, however, so the researchers then switched to hamsters, which do. In an unpublished study, they found that the vaccine pill not only dramatically reduced the amount of coronavirus in sick hamsters, but also protected them from two important symptoms of the disease: weight loss and swollen lungs. The company’s stock price increased 3,600 percent in the first half of 2020. In June, The New York Times reported, a hedge fund that partly controlled the company sold off most of its shares, netting over $200 million in profits. In the wake of that reporting, the Department of Justice began investigating the company, while a number of shareholder lawsuits were brought against Vaxart, its executives and its board. In October, the company began giving the pill to volunteers in a Phase 1 clinical trial. On Feb. 3, 2021, Vaxart announced that the trial revealed no serious safety concerns. While the pill produced a response from T cells, it didn’t produce encouraging neutralizing antibodies. Its stock price plunged 60 percent on the news. On Feb. 25, the company announced it would advance to a Phase 2 trial in the second quarter of 2021, but manufacturing problems forced them to push the launch to the second half of 2021. Updated July 20 PHASE 1 German Center for Infection Research logo Three decades ago, the German Center for Infection Research developed a smallpox vaccine from a harmless virus called Modified Vaccinia Ankara, or MVA for short. In recent years, they adapted it to create a vaccine for MERS, a disease caused by another coronavirus. In the spring of 2020, they made an MVA-based vaccine for SARS-CoV-2, the coronavirus that is causing the Covid-19 pandemic. It carries the gene for the spike protein, which is produced inside cells that it invades. On Sept. 29, the center and a consortium of German universities registered a Phase 1 trial. In January 2021, the center announced that their initial formulation provided disappointing results and are postponing the trial until they update it. They said that they resumed the trial with an updated version of the vaccine on July 16, 2021. Updated Aug. 4 PHASE 1 ImmunityBio logo The California-based company ImmunityBio created a vaccine using the Ad5 adenovirus, the same one used by CanSinoBio and the Gamaleya Institute in Russia. ImmunityBio engineered the Ad5 virus to carry genes for two genes from the coronavirus. In addition to the spike protein, it also carries the gene for a protein called nucleocapsid. The company hopes that this combination will provoke a strong immune response. The company found that the vaccine protects monkeys from the coronavirus. ImmunityBio launched a Phase 1 trial of a Covid-19 vaccine in October 2020 in the United States and another in South Africa in January. In February 2021, the company registered a Phase 1 trial of an oral version of the vaccine. On May 25, the company announced that it would study how well their candidate works as a booster shot for those who already received other vaccines. They are also testing a nasal spray version. They said on July 14 that trials of the booster shot would begin in South Africa later this year.The chairman, C.E.O. and Global Chief Scientific and Medical Officer of ImmunityBio is billionaire Patrick Soon-Shiong, the owner of the Los Angeles Times. Updated Aug. 20 PHASE 1 Bharat Biotech logo On Feb. 11, 2021, Indian regulators gave Bharat Biotech approval to launch a Phase 1 trial of a vaccine delivered as a nasal spray. The spray, called BBV154, contains a chimpanzee adenovirus developed by researchers at Washington University. They found that it could produce coronavirus antibodies in mice with just a single dose. BBV154 is Bharat Biotech’s second foray into coronavirus vaccine clinical trials. Their vaccine Covaxin, made of inactivated coronaviruses, is already in emergency use in India. Government officials announced on Aug. 11 that they will allow Bharat to perform a trial that mixes BBV154 with Covaxin. Updated Aug. 12 PHASE 1 Icahn School of Medicine at Mount Sinai logoMahidol University logo Government Pharmaceutical Organization logoAvi-Mex logo In 2020, researchers at the Icahn School of Medicine at Mount Sinai in New York developed a Covid-19 vaccine based on a virus called Newcastle Disease Virus, or NDV for short. NDV is a bird pathogen and does not cause symptoms in humans. The researchers engineered NDV to carry the gene for a modified version of the coronavirus spike protein called HexaPro, developed at the University of Texas. They then grew the modified virus in chicken eggs. The researchers inactivated the NDVs with chemicals and combined them with immune-boosting chemicals called adjuvants. The researchers found that the vaccine produced high levels of coronavirus antibodies in mice and hamsters. They published the results of their experiments in November. On Feb. 22, Mahidol University in Thailand registered a Phase 1 trial of the vaccine, called NDV-HXP-S. They are running the trial in collaboration with the Government Pharmaceutical Organization, a Thai state-run drug manufacturer. Avi-Mex in Mexico also licensed NDV-HXP-S under the name Patria and launched its own Phase 1 trial. The Institute of Vaccines and Medical Biologicals in Vietnam has done the same, dubbing the vaccine Covivac. In June, Brazil’s Butantan Institute launched a Phase 1 trial of the vaccine, known there as Butanvac, with the hopes of distributing it in Brazil by the end of 2021. The vaccine could potentially help low- to middle-income countries secure their own supplies of Covid-19 vaccines. The Newcastle Disease Virus can be safely grown in large quantities in chicken eggs, the same way influenza vaccines have been produced since the 1950s. As a result, the vaccine could be very cheap to make. Updated July 20 PHASE 1 Gritstone Oncology logoNational Institute of Allergy and Infectious Diseases logo Gritstone Oncology has developed experimental vaccines in recent years that teach the immune system to attack tumors. In 2020, they constructed a vaccine for Covid-19 that presents a number of targets in the coronavirus for attack. The researchers constructed a piece of DNA that encodes the entire spike protein of the coronavirus. In addition, it encodes instructions for building small pieces of other viral proteins called nucleocapsid and ORF3a. They then inserted this cassette into the genes of a chimpanzee adenovirus. The spike protein provokes the body to make antibodies, while the pieces of other proteins train the immune system to recognize infected cells and kill them. In addition, the researchers created an RNA molecule with the same genetic instructions, which they put in a shell. Once the shell slips into a cell, the RNA molecule can make copies of itself, and the cell then makes proteins from those copies. In a Phase 1 trial launched in March 2021, the National Institute of Allergy and Infectious Diseases is testing how well these two vaccines work together, with the chimpanzee adenovirus serving as the first dose and the self-amplifying RNA as the second. The researchers hope that this combination will produce a better immune response than two doses of either vaccine. Updated March 4 PHASE 1 Meissa Vaccines logo Meissa Vaccines has developed a vaccine that can be delivered as a spray or drops into the nose. To make the vaccine, researchers started off with another virus, called respiratory syncytial virus (RSV for short). The researchers introduced mutations into the RSV virus’s genes so that it replicated too slowly to cause disease. Then they added a gene for the coronavirus spike protein, so that the weakened RSV viruses could present it to the immune system. Data from its preclinical trial in monkeys, released in July, suggested that the vaccine was effective at generating immunity in the nose. Meissa registered a Phase 1 trial for the vaccine on March 15, 2021. Updated Aug. 20 PHASE 1 Tetherex Pharmaceuticals logo Researchers at Oklahoma-based Tetherex Pharmaceuticals have created a vaccine that uses genetically engineered viruses to develop immunity. They registered a Phase 1 trial in Australia on April 9, 2021. Mayo Clinic announced a deal to develop and market the vaccine technology worldwide on July 6. Updated July 6 PHASE 1 CyanVac logo Scientists at the University of Georgia and the University of Iowa have developed a vaccine based on canine parainfluenza virus, which has never been found to cause disease in humans. They engineered it to carry proteins from the coronavirus. The vaccine, called CVXGA1, is administered as a nasal spray. In July 2021, the researchers published a study showing that a single dose of the vaccine could protect mice and ferrets against Covid-19. A spin-off company called CyanVac took the intranasal vaccine, called CVXGA1, to Phase 1 trials the same month. Updated July 15 ABANDONED Merck logoThemis logoInstitut Pasteur logo The American company Merck acquired the Austrian firm Themis Bioscience in June to develop their vaccine, which had been originally developed at Institut Pasteur. The vaccine used a weakened measles virus that carries a gene for the coronavirus spike protein. Researchers launched a Phase 1 trial in August 2020. On Jan. 25, Merck announced it was abandoning the effort, because the vaccine provoked a response that was weaker than a natural infection. In March they entered into a partnership with Johnson & Johnson to help produce their vaccine instead. Updated March 4 ABANDONED Merck logoInternational AIDS Vaccine Initiative logo In addition to its project with Themis, Merck partnered with IAVI on a second viral vector vaccine. It was based on vesicular stomatitis viruses, the same approach Merck successfully used to produce the first approved vaccine for Ebola. They designed their coronavirus vaccine as a pill, which could have made it easier to distribute than syringes for injections. Merck and IAVI received $38 million from the United States government to support their research, and on September 30, 2020, they registered a Phase 1 trial. But on Jan. 25, they announced they were abandoning the effort because the vaccine failed to trigger an immune system comparable to what happens in a natural infection of Covid-19. Updated Jan. 25 ABANDONED Altimmune logo VACCINE NAME: AdCOVID EFFICACY: Unknown DOSE: 1 dose TYPE: Nasal spray STORAGE: Refrigerated Maryland-based Altimmune is a biopharmaceutical company that focuses on developing vaccines delivered by nasal spray. They developed a nasal spray vaccine for Covid-19, delivering the Ad5 adenovirus to the airway. Studies on the immune system suggests that a nasal spray could be more effective for blocking the transmission of the virus than vaccines given by injection. In a study on mice, Altimmune researchers found that a single dose of the vaccine gave complete protection from a lethal infection of coronaviruses. On Dec. 22, 2020, the company registered a Phase 1 clinical trial of a single dose of the vaccine. But on June 29, 2021, Altimmune announced they were abandoning their Covid-19 vaccine. In their Phase 1 trial, they gave the spray to 80 volunteers and found that they produced substantially lower levels of antibodies than produced by Covid-19 vaccines that have already been authorized. Updated June 30 PRECLINICAL Other viral vector vaccines in active preclinical development include vaccines from: ID Pharma; KU Leuven and Batavia Biosciences; Smorodintsev Flu Research Institute; the Spanish National Center for Biotechnology and the Spanish National Research Council; Thomas Jefferson University and Bharat Biotech; Tonix Pharmaceuticals; University of Helsinki, University of Eastern Finland, and Rokote Laboratories Finland; University of Pittsburgh; University of Western Ontario; Valo Therapeutics and University of Helsinki; Vivaldi Biosciences; Walvax Biotechnology, Tsinghua University, and Tianjin Medical University; Zydus Cadila. Updated Sept. 3 Protein-Based Vaccines Vaccines that contain coronavirus proteins but no genetic material. Some vaccines contain whole proteins, and some contain fragments of them. Some pack many of these molecules on nanoparticles. PHASE 3 APPROVED IN TURKMENISTAN EARLY USE IN RUSSIA Vector Institute logo VACCINE NAME: EpiVacCorona, Aurora-CoV EFFICACY: Unknown DOSE: 2 doses, 3 weeks apart TYPE: Muscle injection STORAGE: Stable in refrigerator for up to two years On Aug. 26, 2020, the Vector Institute, a Russian biological research center, registered a Phase 1/2 trial for a coronavirus vaccine they call EpiVacCorona. The vaccine contains small portions of viral proteins, known as peptides. Less than two months later, on Oct. 14, Vladimir Putin announced that Russia has granted regulatory approval to the vaccine, making it the second one to receive that designation after the Gamaleya Institute’s Sputnik V vaccine. The following month, a Phase 3 trial began. In January 2021, without any results yet from the trial, Russia launched a mass vaccination campaign that included EpiVacCorona. In February, Tass reported that the immune response from EpiVacCorona lasted “for approximately a year,” but the vaccine’s creators did not publish the scientific details behind this claim. On March 3, the Vector Institute registered their trial on an international registry, indicating that they expected to deliver preliminary results by September 2021. Results from EpiVacCorona’s Phase 1/2 trial were published in an obscure Russian journal in late March 2021, but the data has concerned outside experts, who have pointed out serious flaws in the study. Critics in Russia have asked the government there to stop administering the vaccine until the Phase 3 trial results are published. On July 5, Tass reported that the Vector Institute is registering the vaccine under the name Aurora-CoV. APPROVED FOR USE IN: Turkmenistan. EARLY USE IN: Russia. Updated Sept. 3 Vector Institute vaccine RUSSIA TURKMENISTAN Approved Early, limited or emergency use PHASE 3 EMERGENCY USE IN CHINA, UZBEKISTAN Anhui Zhifei Longcom logoInstitute of Medical Biology at the Chinese Academy of Medical Sciences logo VACCINE NAME: ZF2001 EFFICACY: 81.76% DOSE: 3 doses, 4 weeks apart TYPE: Muscle injection The Chinese company Anhui Zhifei Longcom and the Institute of Medical Biology at the Chinese Academy of Medical Sciences partnered to make a vaccine. Their candidate is composed of an adjuvant, along with a section of the spike protein called the receptor-binding domain. They launched Phase 2 trials in July 2020, followed by a Phase 3 trial with 29,000 volunteers in December. China authorized the vaccine for emergency use on March 15, 2021. On July 14, researchers registered a Phase 1 trial for the vaccine in children and adolescents. The company announced on Aug. 27 that their vaccine had an efficacy rate of 82 percent against Covid-19 of any severity. EMERGENCY USE IN: China, Uzbekistan. Updated Sept. 3 Anhui Zhifei Longcom and IMCAS vaccine CHINA UZBEKISTAN Approved Early, limited or emergency use PHASE 3 EMERGENCY USE IN IRAN, CUBA Finlay Vaccine Institute logo VACCINE NAME: Soberana 2, or Pasteur (in Iran) EFFICACY: 62% with two doses, 91.2% with Soberana Plus Cuba’s Finlay Vaccine Institute developed a vaccine known as Soberana 2. It contains a part of the coronavirus spike protein, fused to a standard tetanus vaccine to make it stable. Soberana 2 also contains aluminum hydroxide as an adjuvant to boost the immune system. After testing Soberana 2 in animals, Finlay researchers started a Phase 1 trial in October 2020, followed by a Phase 2 trial in December. On March 3, 2021, the Finlay Vaccine Institute registered a Phase 3 trial for Soberana 2, with plans to recruit 44,010 participants in Havana. Researchers began dosing trial participants in Iran on April 26. On June 19, Cuban officials said that Soberana 2 has an efficacy of 62% with just two doses. Before the Phase 3 trial delivered its results, however, the Cuban government began rolling out Soberana 2 on May 12 in a mass vaccination campaign. The government announced plans to make 100 million doses of Soberana 2 in order to vaccinate its entire population, pinning hopes on the vaccine as a source of economic benefit to the island. Cuban scientists are also testing a combination of Soberana 2 and a boost of another Cuba-made vaccine called Soberana Plus. On July 9, Cuban officials said that this combination has an efficacy of 91.2%. The Finlay Vaccine Institute announced on June 10 that it had received approval to begin a trial of the combined vaccines in children. Preliminary results from the pediatric trial suggest the combination may be more effective in children than adults. Cuba expanded its Soberana 2 vaccination campaign to include children in September. On June 29, Iran’s health minister announced that Soberana 2 has received emergency use approval. The Finlay Vaccine Institute said that the Pasteur Institute of Iran would market the vaccine under the name Pasteur. On Aug. 20, 2021, the Cuban government announced the emergency authorization of both Soberana 2 and Soberana Plus. Just two weeks later, on September 2, Cuba authorized Soberana 2 for children between the age of 2 and 18. In their announcement, Cuban regulators said that the immune response in children was similar to adults who received Soberana 2. EMERGENCY USE IN: Cuba, Iran. Updated Sept. 7 Soberana 2 vaccine CUBA IRAN Approved Early, limited or emergency use PHASE 3 EMERGENCY USE IN CUBA Centro de Ingeniería Genética y Biotecnología de Cuba logo VACCINE NAME: Abdala EFFICACY: 92.28% In November 2020, the Center for Genetic Engineering and Biotechnology of Cuba launched a trial on a coronavirus vaccine called Abdala. The name is from a poem by the nineteenth-century poet José Marti. The Abdala vaccine consists of a piece of the coronavirus spike protein called the receptor binding domain, and is delivered in three doses. On Feb. 1, the center held a press conference to announce the start of a Phase 2 trial. A Phase 3 trial involving up to 48,000 participants was launched on March 18. On May 12, while the Phase 3 trial was still underway, the Cuban government began rolling out Abdala in a mass vaccination campaign, in the hopes of reining in a surge of cases. Venezuela began using the vaccine in late June. On June 21, Cuban officials reported that Abdala had an efficacy of 92.28 percent. Cuban officials approved a trial for Abdala in young people on July 1. On July 9, the Cuban government granted emergency use authorization for the vaccine. Abdala is one of two Cuban vaccines tested in a Phase 1/2 clinical trial to assess their ability to increase immunity in those who have already had Covid-19. EMERGENCY USE IN: Cuba, Venezuela. Updated Aug. 4 Abdala vaccine CUBA VENEZUELA Approved Early, limited or emergency use PHASE 3 EMERGENCY USE IN TAIWAN Medigen logoDynavax logo Taiwan-based vaccine maker Medigen created a vaccine containing a combination of spike proteins and an adjuvant from Dynavax. After a series of promising experiments on animals, they began injecting volunteers for a Phase 1 trial in early October, which showed that the vaccine provoked strong immune responses. On Dec. 30, Medigen announced that it had received permission to commence a Phase 2 trial. The first volunteers in the trial were injected in late January 2021. In July, Medigen started another Phase 2 trial on children between 12 and 18 years old. Medigen received permission to begin a Phase 3 trial in Paraguay on July 20. Taiwan granted emergency use authorization to the vaccine on July 19. Results from the Phase 2 trial suggested that volunteers were producing strong levels of antibodies and did not have serious adverse reactions. Taiwan started administering Medigen’s vaccine on Aug. 23. EMERGENCY USE IN: Taiwan. Updated Aug. 24 Medigen vaccine TAIWAN Approved Early, limited or emergency use PHASE 3 Novavax logo VACCINE NAME: NVX-CoV2373 EFFICACY: 89.7% DOSE: 2 doses, 3 weeks apart TYPE: Muscle injection STORAGE: Stable in refrigerator Maryland-based Novavax makes vaccines by sticking proteins onto microscopic particles. They were the first company to release Phase 3 trials showing that a protein-based vaccine provides strong protection against Covid-19. In a study on nearly 30,000 volunteers in the United States in Mexico, they estimated the vaccine’s efficacy at 90.4 percent. Currently, the company plans to apply for emergency use authorization in the third quarter of 2021. Before the pandemic, Novavax developed a number of vaccines for diseases based on their nanoparticle technology. In 2019, their flu vaccine finished Phase 3 clinical trials, but they had yet to deliver a single vaccine to market. In May 2020, the company launched trials for a Covid-19 vaccine, and the Coalition for Epidemic Preparedness Innovations invested $384 million to support research on the vaccine. In July the U.S. government awarded Novavax another $1.75 billion to support the vaccine’s clinical trials and manufacturing. After getting promising results from preliminary studies in monkeys and humans, Novavax launched a Phase 2 trial on 2,900 people in South Africa in August 2020, and the next month it launched a Phase 3 trial with up to 15,000 volunteers in the United Kingdom. The Phase 3 trial in the United States was delayed because of problems with manufacturing the doses required for the study. It finally launched on Dec. 28. On March 11, 2021, Novavax reported that their United Kingdom trial determined an efficacy rate of 96 percent against the original coronavirus, and an efficacy of 86 percent against Alpha. But in South Africa, where volunteers were exposed to the Beta variant, the efficacy was only 49 percent. The company is developing a new version of the vaccine that is tailored to that variant. The company announced in August that a booster shot dramatically raised antibody levels in vaccinated people. Novavax reached an agreement in September 2020 with the Serum Institute of India, a major vaccine manufacturer, that could enable them to produce as many as 2 billion doses a year. They have an agreement with other countries, including the United Kingdom, Canada, Australia and South Korea. On Feb. 18, 2021, Novavax announced it would supply 1.1 billion doses to COVAX, a consortium that seeks to distribute vaccines to all countries across the world. Yet Novavax has been dogged by delays in manufacturing and testing the quality of their vaccines. In August, the federal government said that it would not fund further production of Novavax’s vaccine until the company resolves concerns of regulators about its work. Meanwhile, Novavax has continued to expand trials of its vaccine. In May 2021, the company expanded its U.S. Phase 3 trial to include volunteers as young as 12. Novavax’s vaccine is one of several being tested in an Oxford study that gauges how well alternating doses can increase immunity. It’s also part of another United Kingdom trial to assess the effectiveness of vaccines as boosters. The company announced on Aug. 25 that its vaccine would be part of another booster study in patients with impaired immune systems. Novavax has also found that its vaccine can work in combination with a seasonal flu shot. For more details, see How the Novavax Vaccine Works. Updated Aug. 26 PHASE 3 Medicago logoGSK logo VACCINE NAME: CoVLP EFFICACY: Unknown DOSE: 2 doses, 3 weeks apart TYPE: Muscle injection STORAGE: Stable in refrigerator Canada-based Medicago, partly funded by the cigarette maker Philip Morris, grows vaccines in a plant called Nicotiana benthamiana, a wild species related to tobacco. They deliver virus genes into leaves, and the plant cells then create protein shells that mimic viruses. In July 2020, Medicago launched a Phase 1 trial. In that study, they found that their plant-based vaccine, combined with an adjuvant made by GSK, produced promising levels of antibodies in volunteers. A Phase 2 trial also provided encouraging results. A Phase 3 trial, launched on March 16, 2021, is still underway. Medicago announced in October 2020 that it had reached an agreement with the government of Canada to supply 76 million doses. In April 2021, the Canadian government announced a rolling review of the company’s vaccine. A Medicago official announced at a conference in May that the company expected to seek authorization for their vaccine in Canada in the third quarter of 2021. Updated May 18 PHASE 3 Baylor College of Medicine logoTexas Children’s Hospital Center for Vaccine Development logo Biological E logoDynavax logo VACCINE NAME: Corbevax After the SARS epidemic in 2002, Baylor College of Medicine researchers began developing a vaccine that could prevent a new outbreak. Despite promising early results, support for the research disappeared. Because the coronaviruses that cause SARS and Covid-19 are very similar, the researchers revived the project in 2020, working in partnership with the Texas Children’s Hospital. The Indian company Biological E licensed it in August 2020 and launched a Phase 1/2 trial in November, combining the viral proteins with an adjuvant made by Dynavax. On Dec. 29, Biological E and the Coalition for Epidemic Preparedness Innovations announced a partnership to advance the development and manufacturing of the vaccine, known as BECOV2, with CEPI initially contributing $5 million to the effort. On April 24, 2021, Biological E announced it was starting a Phase 3 trial of the vaccine, called Corbevax. Biological E received approval for a Phase 2/3 trial of Corbevax on children on Sept. 2. The Biden administration has pledged a substantial expansion of Biological E’s manufacturing capability. The company has a target of 300 million doses ready for immediate deployment when the vaccine is approved, and plans on making 1.2 billion doses in 2022. On Sep. 3, the Hindustan Times reported that Corbevax may be launched in India as early as October. Updated Sept. 3 PHASE 3 Sanofi logoGSK logo In addition to their mRNA vaccine, Sanofi developed a Covid-19 vaccine based on viral proteins in early 2020. They produced the proteins with engineered viruses that grow inside insect cells. GSK supplemented these proteins with adjuvants that stimulate the immune system. The vaccine, called Vidprevtyn, is based on the same design Sanofi used to create Flublok, an approved vaccine for influenza. The companies launched a Phase 1/2 clinical trial in September 2020. Vidprevtyn was widely expected to play a major role in tackling the pandemic. In the United States, Operation Warp Speed selected it as one of six vaccines to secure in large quantities, reaching a $2.1 billion agreement for 100 million doses. On Sept. 18 Sanofi closed another deal with the European Union for 300 million doses for an unspecified amount, and later reached an agreement with Canada for up to 72 million doses. In addition, Sanofi agreed to provide 200 million doses to COVAX, an international collaboration to deliver the vaccine equitably across the world. The company expected to move to a Phase 3 trial in December and potentially seek emergency use authorization for Vidprevtyn in the United States by spring 2021. Sanofi announced plans to make up to one billion doses in 2021. But on Dec. 11, Sanofi and GSK announced that Vidprevtyn was proving disappointing. While it provided promising levels of antibodies in people under 50, older people did not respond as strongly as they had hoped. The company halted the trial. In January Sanofi decided to help Pfizer and BioNTech make 100 million doses of their vaccine, and they reached a similar agreement with Johnson & Johnson in February. Meanwhile, Sanofi developed a stronger formulation of Vidprevtyn. On Feb. 22, the company launched a new Phase 2 trial, which showed that the new version produced strong immune responses. They began enrolling participants for their Phase 3 trial on May 27, with hopes of U.S. authorization for their vaccine by the end of 2021. On July 20, 2021, the European Medicines Agency started a rolling review of Vidprevtyn in advance of their application for authorization. Updated Aug. 2 PHASE 3 West China Hospital of Sichuan University logo In July 2020, researchers at West China Hospital of Sichuan University published a study in Nature describing a vaccine made from the RBD region of the spike protein that could protect mice and monkeys from the coronavirus. To make the vaccine, researchers encoded the RBD region in a gene, which they inserted into a virus. They then infected insect cells with the virus, causing them to make the molecule in huge amounts. On Aug. 24, they launched a Phase 1 trial, and on Nov. 16 they moved to Phase 2 with a study on 960 volunteers. On Jan. 22, 2021, the researchers registered another Phase 2 trial with 4,000 volunteers. A Phase 3 trial began on June 1. Updated June 1 PHASE 3 Nanogen Biopharmaceutical logo On Dec. 10, 2020, Nanogen Biopharmaceutical in Vietnam began recruiting 60 volunteers for a Phase 1 trial of their protein-based vaccine Nanocovax. Vietnam news agencies announced that Nanocovax entered a Phase 2 trial in February, 2021. Nanogen researchers reported that in these early studies, the vaccine did not cause any dangerous side effects and promising levels of antibodies. In June, Nanogen launched a Phase 3 trial. Updated June 26 PHASE 3 Vaxine logo The Australian company Vaxine developed a vaccine that combines viral proteins with an adjuvant that stimulates the immune system. A Phase 1 trial began in June 2020, and the company announced promising results in April 2021. In June, 2021, Vaxine launched a Phase 2 trial in Iran, followed by a Phase 3 trial, registered Aug. 13. If clinical trials prove successful, the vaccine, known as Spikogen, will be produced by the Iranian company CinnaGen. Updated Aug. 12 PHASE 2 EMERGENCY USE IN CUBA Finlay Vaccine Institute logo Cuban researchers at Finlay Vaccine Institute have also developed a single-dose vaccine called Soberana Plus. Like its other candidates, Soberana Plus targets the part of the coronavirus known as the RBD and contains an adjuvant. But Finlay researchers are specifically tailoring this vaccine to people who have already had Covid-19 — a first of its kind. They say that such a strategy can help prevent reinfection and limit the spread of new variants. After positive results from a Phase 1 trial, Finlay received approval to begin a Phase 2 trial among Covid-19 survivors on April 9. Cuban scientists have reported that combining two doses of Soberana 2 with one dose of Soberana Plus has yielded solid results. On Aug. 20, 2021, the Cuban government announced the emergency authorization of both Soberana 2 and Soberana Plus. Reuters reported later that month that Cuba would begin importing Sinopharm vaccines to make up for their lagging vaccination campaign, combining it with a Soberana Plus booster. EMERGENCY USE IN: Cuba. Updated Sept. 3 Soberana Plus vaccine CUBA Approved Early, limited or emergency use PHASE 3 University of Washington logoSK Bioscience logoGSK logo Last spring, researchers at the University of Washington developed a nanoparticle studded with pieces of the coronavirus spike protein. Experiments on mice showed a strong immune response. The South Korean vaccine company SK Bioscience licensed the vaccine, called GBP510. After partnering with GSK, they launched a Phase 1/2 trial of the vaccine in February 2021. It is the second vaccine SK Bioscience has put into trials, after launching a study on another protein-based vaccine called NBP2001. SK Bioscience has received $210.1 million from the Coalition for Epidemic Preparedness Innovations for the development of GBP510. In August, the company launched a Phase 3 trial, comparing GBP510 to AstraZeneca’s Vaxzevria vaccine. Updated Sept. 3 PHASE 3 Livzon Pharmaceutical Group logoInstitute of Biophysics logo A subsidiary of Chinese company Livzon Pharmaceutical Group has developed a protein vaccine in collaboration with the Institute of Biophysics at the Chinese Academy of Sciences. Called V-01, the vaccine completed Phase 1 and 2 trials earlier in 2021. A Phase 3 trial began in the Philippines on Aug. 25. Updated Aug. 30 PHASE 2 PHASE 3 COMBINED PHASES Clover Biopharmaceuticals logoDynavax logo Clover Biopharmaceuticals developed a vaccine containing the spike protein from coronaviruses. To further stimulate the immune system, the company is testing so-called adjuvants made by British drugmaker GSK and the American company Dynavax. Investments from the Coalition for Epidemic Preparedness supported the development of manufacturing that could lead to the production of a billion doses a year. Clover’s formula looks to be especially durable; the vaccine can sit out at room temperature for a month and remain viable. Clover launched a Phase 1 trial in June 2020, , and in December the company announced that the vaccine triggered a high level of antibodies. It registered a Phase 2/3 trial with the GSK adjuvant, but in February 2021 the company announced it was cancelling the study. Instead, it has moved forward with a trial with the Dynavax adjuvant. On June 30, 2021, Clover announced an agreement to provide 400 million doses to COVAX, the initiative to deliver vaccines to low- and middle-income countries. The company expects results from its Phase 2/3 trial in the third quarter of 2021. In July 2021, Clover registered a Phase 2 trial of a vaccine tailored for the Beta variant. Updated July 9 PHASE 2 Vaxxinity logo Dallas-based Vaxxinity is testing a vaccine containing parts of several viral proteins. (Vaxxinity formed in April 2021 when the companies COVAXX and United Neuroscience combined.) On Sept. 11, 2021, COVAXX registered a Phase 1 trial in Taiwan which led to 100 percent of volunteers producing antibodies without any serious side effects. In February COVAXX launched a Phase 2 trial, also in Taiwan. A Phase 2/3 trial is planned to launch in Brazil, India and other countries. On Nov. 25, Covaxx announced agreements with countries including Brazil, Ecuador, and Peru to deliver more than 140 million doses for $2.8 billion. In January, the company announced they were also starting preclinical research on a vaccine tailored specifically to newly emerged coronavirus variants that could potentially evade conventional vaccines. In a June 21 press release, Vaxxinity said it expected to deliver the vaccine by the end of the summer, which did not come to pass. The researchers registered a Phase 1 trial on July 20 to assess the effectiveness of a third dose of its vaccine in those who have already received two. Updated Sept. 3 PHASE 2 Zhongyianke Biotech logoAcademy of Military Medical Sciences logo Researchers at Zhongyianke Biotech, Liaoning Maokangyuan Biotech and the Academy of Military Medical Sciences are using Chinese hamster ovary cells to help create immunity in humans. They registered a Phase 1 trial in China last November. On March 24, they advanced the vaccine to Phase 2. Updated March 25 PHASE 2 Razi Vaccine and Serum Research Institute logo On Feb. 7, Iran announced that it was launching a clinical trial of a second vaccine, known as Cov-Pars Razi and developed by the Razi Vaccine and Serum Research Institute. The vaccine contains fragments of coronavirus spike proteins and is delivered in three doses: two injections and one nasal spray. The researchers began dosing participants for their Phase 2 trial on May 28. Razi officials said that they would be able to produce at least one million doses of the vaccine every month. Updated Aug. 24 PHASE 2 Middle East Technical University logoBilkent University logo TUBITAK logoNobel İlaç logo A team of Turkish researchers at Middle East Technical University and Bilkent University have developed a vaccine that is made up of virus-like particles. Each particle carries four of the coronavirus proteins. On March 26, they registered a small Phase 1 trial sponsored by TUBITAK, the Scientific and Technological Research Council of Turkey. The researchers registered a Phase 2 trial of the vaccine on July 15. Updated July 15 PHASE 2 Shanghai Zerun Biotechnology logoWalvax Biotechnology logo Chinese researchers at Shanghai Zerun Biotechnology and Walvax Biotechnology have modified the structure of the coronavirus spike protein to better stimulate an immune response from their vaccine. They registered a Phase 1 trial for their prototype vaccine, called 202-CoV, in China on July 29. On Aug. 4, they registered a Phase 2 trial. ZerunBio and Walvax announced on July 21 that they are also partnering with CEPI, the Coalition for Epidemic Preparedness Innovations, to support the development of 202-CoV and to create a variant vaccine using the same technology. Updated Aug. 9 PHASE 2 Bavarian Nordic logo As part of the European Union-funded PREVENT-nCoV consortium, a team of biotechnology companies and research laboratories developed a vaccine against Covid-19. It contains a coronavirus protein called nucleocapsid. The vaccine, called ABNCoV2, uses technology from consortium members AdaptVac and ExpreS2ion, among others. After promising preclinical results in primates, Bavarian Nordic announced that it would proceed with a Phase 1/2 trial of the vaccine in the Netherlands. The first volunteers received doses of the vaccine on March 15. On Aug. 9, the researchers said that the trial showed ABNCoV2 produced high levels of antibodies without dangerous side effects. Later that month, Bavarian Nordic launched Phase 2 trials of the vaccine, both as an initial protection against Covid-19 and as a booster for other vaccines. Updated Aug. 24 PHASE 1 PHASE 2 COMBINED PHASES Finlay Vaccine Institute logo On Aug. 18, 2020, the head of epidemiology at Cuba’s public health ministry announced the country’s first trial of a vaccine of Covid-19. The Finlay Vaccine Institute in Havana began testing a vaccine called Soberana 1. It contains a part of the spike protein, called RBD, along with two extra ingredients: proteins from a bacteria and aluminum hydroxide. These ingredients, known as adjuvants, boost the immune system’s response to the coronavirus RBD. On July 26, Cuban media outlets reported that Soberana 1 had entered Phase 2 trials. Updated Aug. 2 PHASE 1 PHASE 2 COMBINED PHASES spybiotech logo SpyBiotech, a company spun off from the University of Oxford, produced a vaccine from a mixture of proteins. Some of the proteins, from hepatitis B viruses, form hollow shells. The researchers decorated these shells with part of the coronavirus spike protein. The vaccine is relatively easy to manufacture because the proteins can be produced by fermenting yeast. Once purified, the proteins then self-assemble into shells. Injected into monkeys the vaccine produced promising levels of immune responses. In September 2020, SpyBiotech announced that the first volunteers in an Australian Phase 1/2 trial were receiving their Covid-19 vaccine. The Serum Institute of India, which licensed the technology from SpyBiotech, is running the trials. Updated July 20 PHASE 1 PHASE 2 COMBINED PHASES Shionogi logoNational Institute of Infectious Diseases logoKyushu University logo Shionogi, a Japanese pharmaceutical giant, launched a Phase 1/2 trial of a coronavirus vaccine on Dec. 16. The company developed it in collaboration with the National Institute of Infectious Diseases and Kyushu University. The vaccine is based on a coronavirus protein which is produced in insect cells by genetically altered viruses. But according to a March report from The Japan Times, Shionogi has faced difficulties with recruiting enough participants for its trials, and it is unlikely that the vaccine will be ready by the end of 2021. In a slide deck from its Aug. 2 conference call with investors, Shionogi said that it is using a new adjuvant with its vaccine after receiving disappointing preliminary results from the original trial. A new Phase 1/2 trial began in July 2021, they said. Updated Aug. 4 PHASE 1 PHASE 2 COMBINED PHASES EuBiologics logo South Korean vaccine producer EuBiologics launched a Phase 1/2 trial of a protein-based vaccine in late January. Known as EuCorVac-19, the vaccine combines the spike protein with an adjuvant that stimulates the immune system. EuBiologics announced on June 10, 2021, that it had successfully completed Phase 1 and is now recruiting for the Phase 2 portion of the trial, which is expected to finish up in September. For its Phase 3 trial, EuBiologics plans on comparing its vaccine to Vaxzevria, made by AstraZeneca. But it has yet to secure enough doses for the study. Updated Aug. 4 PHASE 1 PHASE 2 COMBINED PHASES VBI Vaccines logo The Massachusetts-based company VBI Vaccines developed a coronavirus vaccine that is based on hollow, virus-like protein shells. The company added pieces of coronavirus proteins to the shells, selected for their potential both to produce antibodies and to train T cells to attack infected cells. In February 2021, VBI registered a placebo-controlled Phase 1/2 trial in Canada on 780 volunteers, comparing the effects from using one or two doses. The vaccine, called VBI-2902a, uses aluminum phosphate as an adjuvant. On June 29, VBI released preliminary results from the trial, showing that volunteers produced high levels of antibodies without any serious side effects. VBI Vaccines is also experimenting with vaccines that combine proteins from the three coronaviruses that cause severe disease in humans: Covid-19, SARS, and MERS. They are exploring the possibility that such a vaccine could someday protect against a wide swath of coronaviruses, including ones that have yet to spill over from animal hosts. Updated June 30 PHASE 1 PHASE 2 COMBINED PHASES Akston Biosciences logo Massachusetts-based Akston Biosciences has developed a vaccine that targets a part of the coronavirus spike protein called the receptor-binding domain. Researchers at Akston say that focusing on this section is an efficient way to boost immunity against new variants. They began a Phase 1/2 trial of their vaccine, known as AKS-452, on April 12. After positive results from the Phase 1 trial, Akston announced that it began dosing participants in its Phase 2 trial on Aug. 5. Updated Aug. 6 PHASE 1 PHASE 2 COMBINED PHASES Sinopharm logo Researchers at China’s Sinopharm have created a protein-based vaccine that uses a genetically engineered spike protein to help the body produce antibodies. Sinopharm’s two other vaccine candidates, one developed with the Beijing Institute and one developed with the Wuhan Institute, use inactivated coronaviruses to develop immunity. Sinopharm started a Phase 1/2 trial on April 24. Updated April 28 PHASE 1 PHASE 2 COMBINED PHASES Lanzhou Institute of Biological Products logoZhengzhou University logo Researchers at the Lanzhou Institute of Biological Products, Beijing Zhong Sheng Heng Yi Pharmaceutical Technology and Zhengzhou University are testing a vaccine that is grown in Chinese hamster ovary cells. They registered a Phase 1/2 trial on May 3. Updated May 5 PHASE 1 PHASE 2 COMBINED PHASES Icosavax logoSeqirus logo In spring 2021, researchers at the University of Washington developed a nanoparticle vaccine for Covid-19. Each nanoparticle carries numerous copies of a protein fragment called RBD, from the spike protein of the coronavirus. Seattle-based Icosavax purchased a license to test and market the vaccine, called IVX-411, from the University of Washington. On June 8, the company announced that it had begun a Phase 1/2 trial in Australia. In the trial, funded by the Bill and Melinda Gates Foundation, some of the volunteers will receive the vaccine along with an adjuvant from Seqirus. The scientists are also testing their vaccine’s potential as a booster shot. Updated June 8 PHASE 1 PHASE 2 COMBINED PHASES Kazakhstan’s Research Institute for Biological Safety Problems logo Kazakhstani scientists at the Research Institute for Biological Safety Problems have developed a second vaccine against Covid-19. Unlike the first, which is made from inactivated coronaviruses, this one uses proteins from the virus to boost immunity. They commenced a Phase 1/2 trial of the vaccine, called QazCoVac-P, on June 15. Updated June 15 PHASE 1 PHASE 2 COMBINED PHASES St. Petersburg Scientific Research Institute of Vaccines and Sera logo Russian researchers at the St. Petersburg Scientific Research Institute of Vaccines and Sera at the Federal Medical Biological Agency developed a protein subunit vaccine against the coronavirus. TASS reported that they launched a Phase 1/2 trial on July 19, 2021. Updated July 7 PHASE 1 PHASE 2 COMBINED PHASES logo Researchers at Spanish animal health company HIPRA have created a recombinant protein vaccine against the coronavirus in humans. They registered a Phase 1/2 trial for their candidate on Aug. 16. The company has predicted that it would be able to produce as much as 400 million doses of the vaccine by the end of 2022. HIPRA is also partnering with the Hospital Clínic de Barcelona to create an mRNA vaccine, which is still in preclinical trials. Updated Aug. 19 PHASE 1 Kentucky BioProcessing logo A second plant-based vaccine is in development at Kentucky BioProcessing, an American subsidiary of British American Tobacco, the maker of Lucky Strike and other cigarettes. Like Medicago, Kentucky BioProcessing engineers a wild relative of tobacco called Nicotiana benthamiana to make viral proteins. The company previously used this technique to make a drug called Zmapp for Ebola. A Phase 1 trial launched in December 2020. On July 28, 2021, Financial Times reported that British American Tobacco would update investors on the vaccine’s progress next season. Updated Aug. 6 PHASE 1 AdImmune logo Taiwan-based vaccine manufacturer Adimmune got permission to launch a Phase 1 trial on Aug. 20, 2020. The vaccine contains the RBD section of the virus’s spike protein. In December, the Taiwan press reported that Adimmune failed to find the right dose of their vaccine and needed to try a new formulation. Adimmune announced in February that it would shift vaccine research to target new variants. Updated Aug. 4 PHASE 1 SK Bioscience logo SK Bioscience, a South Korean vaccine maker, won approval on Nov. 23, 2020 from the country’s Ministry of Food and Drug Safety for a vaccine called NBP2001. The vaccine contained fragments of the spike protein. In a Phase 1 trial, researchers are now testing the vaccine on 50 volunteers. Updated Feb. 23 PHASE 1 Centro de Ingeniería Genética y Biotecnología de Cuba logo In addition to their Abdala vaccine, the Center for Genetic Engineering and Biotechnology of Cuba announced on Nov. 26, 2020 that it was beginning a Phase 1 trial of a second vaccine, this one delivered as a nasal spray. Known as Mambisa, the vaccine contains a piece of the coronavirus spike protein called the receptor-binding domain, along with a protein from the hepatitis B virus that stimulates the immune system. The name refers to women who fought in Cuba’s nineteenth-century wars of independence. Mambisa is one of two Cuban vaccines tested in a Phase 1/2 clinical trial to assess their ability to increase immunity in those who have already had Covid-19. Updated July 26 PHASE 1 Vaccine and Infectious Disease Organization logo VACCINE NAME: COVAC EFFICACY: Unknown DOSE: 2 doses, 4 weeks apart TYPE: Muscle injection The Vaccine and Infectious Disease Organization at the University of Saskatchewan has developed a vaccine candidate which uses pieces of viral proteins to develop immunity against the coronavirus. It was cleared for human testing in late 2020 by the Canadian government. VIDO registered a Phase 1/2 trial on Jan. 8, 2021. If trials proceed as expected, researchers predict that at least one of their candidates will be ready by late 2021. But as approved vaccines become easier to get in Canada, some volunteers are dropping out of the VIDO trial, Saskatoon’s CTV News reported. Updated May 18 PHASE 1 Jiangsu Rec-Biotechnology logo Scientists at Jiangsu Rec-Biotechnology have developed a vaccine, called ReCOV, that is made of viral proteins that are grown in Chinese hamster ovary cells. They registered a Phase 1 trial in New Zealand on March 26, 2021. Updated March 30 PHASE 1 PAUSED OSE Immunotherapeutics logo On April 1, 2021, French researchers at OSE Immunotherapeutics announced they had received approval to launch a Phase 1 trial of a vaccine, called CoVepiT, in Belgium. Their vaccine can teach the body to develop an immune response against 11 different proteins of the coronavirus. The researchers picked these proteins because they have a low chance of mutating — a feature, they say, that makes the vaccine “variant-proof.” They began dosing participants on May 26. But on July 19, OSE announced that it would voluntarily pause its trial after receiving preliminary news of adverse reactions to the vaccine. Updated July 20 PHASE 1 Walter Reed Army Institute of Research logo Scientists at the Walter Reed Army Institute of Research have designed a vaccine from a nanoparticle decorated with the coronavirus’s spike protein. Experiments on monkeys showed that the two-dose vaccine delivered extremely high levels of antibodies. On April 5, 2021, the army launched a Phase 1 trial. The vaccine designers hope to create a new version of the vaccine with proteins from other coronaviruses to offer protection that extends beyond Covid-19. Updated April 5 PHASE 1 VaxForm logoUS Specialty Formulations logoSyneos Health logo Researchers at Pennsylvania-based VaxForm have created a vaccine that can be taken by mouth as a liquid. The scientists say that their candidate, called CoV2-OGEN1, has an advantage over injected vaccines because it’s stable at room temperature and it doesn’t require a medical professional to be administered. Syneos Health and US Specialty Formulations registered a Phase 1 trial in New Zealand on May 19, 2021. Updated Aug. 24 PHASE 1 Baqiyatallah University of Medical Sciences logo Iranian researchers at the Baqiyatallah University of Medical Sciences developed a protein-based vaccine against the coronavirus. On June 27, 2021, the Islamic Revolutionary Guard Corps announced that the vaccine, called Noora, had entered Phase 1 trials. Updated June 30 PHASE 1 Baiya Phytopharm logo Scientists at Thai startup Baiya Phytopharm have created a vaccine that uses plant-based technology to develop immunity. They registered a Phase 1 trial on July 7, 2021. Updated July 7 ABANDONED University of Queensland logoCSL logo On Dec. 10, 2020, a vaccine from Australia’s University of Queensland was the first to be abandoned after entering a clinical trial. Cancelling the vaccine meant the collapse of a $1 billion deal with the Australian government for 51 million doses. The vaccine studies offered great promise at first. Experiments on hamsters showed that the vaccine protected them from the coronavirus. The university launched a Phase 1 trial in July, combining coronavirus spike proteins with an adjuvant made by CSL. The trial delivered encouraging results: volunteers produced a high level of antibodies with no evidence of harmful side effects. But then the researchers made an unwelcome discovery: some volunteers were getting positive tests for HIV, even though they were not actually infected with that virus. In a report released in February 2021, the researchers explained the false positives came about due to the way the researchers designed the vaccine. To ensure that spike proteins can stimulate a strong immune response, the researchers had to prevent the molecules from unfolding and changing their shape. The researchers held the proteins in place with a molecular clamp, which was based on a segment of an HIV protein. HIV tests use antibodies to probe for the presence of the virus’s proteins in people’s blood. The researchers thought that the antibodies would not grab the clamp. That assumption turned out to be wrong. Worried that false positive HIV test results would fuel hesitancy over getting Covid-19 vaccines, the Australian government decided to halt the trial. “It will no longer feature in Australia’s vaccine plan,” said Prime Minister Scott Morrison at a press conference to announce the cancellation. But Queensland researchers have still found promise in their vaccine platform. In April 2021, they published the full results from their abandoned Phase 1 trial, which suggested that the candidate could still be effective against Covid-19. The researchers are now working to re-engineer their vaccine with different proteins that will not generate false positives for HIV. They have yet to provide a timeline for the development of an updated vaccine. Updated May 18 PRECLINICAL Other protein-based vaccines in active preclinical development include vaccines from: Applied Biotechnology Institute; BiOMVis and University of Trento; BioVaxys Technology; Chulalongkorn University; City College of New York and TechnoVax; Doherty Institute and Monash University; Duke University; Dyadic; EpiVax; Eyegene and Pharmcadd; Generex; GeoVax; Heat Biologics; iBio; Iconovo and ISR; ImmunoPrecise Antibodies; IMV; Inserm, Vaccine Research Institute and Université Paris-Saclay; Instituto Buntantan; Intravacc; IrsiCaixa; Izmir Biomedicine and Genome Center; MIGAL Galilee Research Institute; Nanografi Nano Technology, Middle East Technical University, and Ankara University; Navarrabiomed; Neo7Logix; NidoVax; Novavax; OncoGen; Oragenics; Oramed; Oravax; Osaka University, BIKEN, and National Institutes of Biomedical Innovation, Japan; Osivax; PDS Biotechnology; Quadram Institute; Reliance Life Sciences; ReVacc Biotech; Saiba; Soligenix; Uvax; University of Alberta; University of Pittsburgh; University of San Martin and CONICET, Argentina; University of Sao Paulo; University of Virginia; Vabiotech; Vaxxas, University of Queensland and Griffith University; Voltron Therapeutics; Walter Reed Army Institute of Research; Yisheng Biopharma. Updated Sept. 3 Inactivated or Attenuated Coronavirus Vaccines Vaccines created from weakened coronaviruses or coronaviruses that have been killed with chemicals. Inactivated virus PHASE 3 APPROVED IN CHINA, BAHRAIN, U.A.E. EMERGENCY USE IN OTHER COUNTRIES Sinopharm logo VACCINE NAME: BBIBP-CorV EFFICACY: 78.1% DOSE: 2 doses, 3 weeks apart TYPE: Muscle injection BBIBP-CorV, a vaccine made by the Beijing Institute of Biological Products and the state-owned Chinese company Sinopharm, has emerged as China’s leading Covid-19 vaccine, both within the country and abroad. In a July 2021 interview, a Sinopharm executive said that the company was planning on producing 5 billion doses a year. VACCINE DEVELOPMENTResearchers at the institute produced BBIP-CorV by growing live coronaviruses in cells and then dousing them with chemicals to inactivate them. Injected into the body, these inactivated viruses cannot infect cells, but they can draw the attention of the immune system. In June 2020, the researchers reported that the vaccine produced promising results in monkeys. TRIAL RESULTSA Phase 1/2 trial showed that the vaccine didn’t cause any serious side effects and enabled people to make antibodies against the coronavirus. A Phase 3 trial began in the United Arab Emirates in July 2020, and in Morocco and Peru the following month. On Dec. 30, Sinopharm announced that the vaccine had an efficacy of 79.34 percent, leading the Chinese government to give it approval. On May 7, 2021, the World Health Organization put forward a similar efficacy estimate of 78.1 percent and gave the vaccine emergency use authorization. On Aug. 3, Bloomberg reported that results from a Hungarian study showed that the vaccine failed to produce enough antibodies in more than one quarter of elderly people. Results from a Peru trial suggest that the vaccine was 50.4 percent effective in preventing infections among healthcare workers, Reuters reported on Aug. 13. AUTHORIZATIONIn the summer of 2020, long before the Phase 3 trial was complete, the Chinese government gave Sinopharm emergency approval in the summer 0f 2020. Government officials, health care workers, and other select groups began receiving BBIIP-CorV. On Sept. 14, the U.A.E. gave emergency approval for Sinopharm’s vaccine to use on health care workers, and soon government officials and others were also receiving it. Less than two months later, on Dec. 9, the U.A.E. gave full approval to BBIBP-CorV. Since then a number of countries in the Near East have authorized it; on Jan. 29, Hungary authorized BBIBp-CorV, making the country the first European nation to use a Chinese vaccine. The vaccine received approval for emergency use in children and adolescents in China on July 20. The U.A.E. approved the vaccine for use in those aged three and over on Aug. 2. VARIANTSIn February 2021, as concerns grew about new mutations in the coronavirus, Chinese researchers tested BBIBP-CorV against a variant called Beta.1.351, which was first found in South Africa. They reported that the antibody response created by the vaccine was only modestly weaker against Beta. B.1.351. The study has not yet been published in a medical journal. Another study from Sri Lanka, released in July, found that BBIBP-CorV produced antibody responses to the Delta variant that were as strong as those produced by natural infection. BOOSTERSOn May 18, amid concerns over the vaccine’s effectiveness, the U.A.E. announced that it would provide booster shots to those who have received two doses of BBIBP-CorV. Bahrain followed with a similar announcement on June 3. On Aug. 29, the U.A.E. mandated booster shots for all residents who received BBIBP-CorV. For more details, see How the Sinopharm Vaccine Works. APPROVED FOR USE IN: Bahrain, China, United Arab Emirates. EMERGENCY USE IN: Angola, Argentina, Bangladesh, Belarus, Belize, Bolivia, Brunei, Cambodia, Cameroon, Comoros, Egypt, Gabon, Gambia, Guyana, Hungary, Indonesia, Iran, Iraq, Jordan, Kenya NEW, Kyrgyzstan, Laos, Lebanon, Malawi NEW, Malaysia, Maldives, Moldova, Mongolia, Montenegro, Morocco, Mozambique, Namibia, Nepal, Niger, Nigeria NEW, North Macedonia, Pakistan, Peru, Philippines, Republic of the Congo, Saudi Arabia NEW, Senegal, Sierra Leone, Solomon Islands, Somalia, Sri Lanka, Thailand, Trinidad and Tobago NEW, Tunisia, Vietnam, Venezuela, Zimbabwe. Emergency use validation from the World Health Organization. Updated Sept. 3 Sinopharm and Beijing Institute vaccine NIGER CHINA IRAN EGYPT VENEZUELA PAKISTAN BAHRAIN GABON U.A.E. ZIMBABWE NAMIBIA INDONESIA PERU SEYCHELLES ARGENTINA Approved Early, limited or emergency use PHASE 3 APPROVED IN CHINA EMERGENCY USE IN OTHER COUNTRIES Sinovac logo VACCINE NAME: CoronaVac (formerly PiCoVacc) EFFICACY: 50.65% in Brazil trial, 83.5% in Turkey trial DOSE: 2 doses, 2 weeks apart TYPE: Muscle injection STORAGE: Refrigerated Coronavac, developed by the private Chinese company Sinovac, has emerged as one of China’s leading vaccines, with a billion doses distributed around the world as of August 2021. But concerns have arisen about how long its protection lasts. VACCINE DEVELOPMENTIn early 2020, Sinovac developed the Coronavac vaccine based on inactivated coronaviruses. They found in experiments on monkeys that the vaccine significantly lowered the amount of coronavirus that grew in the animals after an infection, and they recovered more quickly than unvaccinated monkeys. TRIAL RESULTSAfter creating their vaccine last spring, Sinovac ran a Phase 1/2 trial on 743 volunteers that revealed no severe adverse effects. Sinovac published the details of the trial in November in a medical journal, showing a comparatively modest production of antibodies. In July, Sinovac launched a Phase 3 trial in Brazil, followed by others in Indonesia and Turkey. The trials in Brazil and Turkey demonstrated that it could protect against Covid-19, but they delivered strikingly different results — in part because they designed the trials differently. In Brazil, the efficacy against Covid-19 with or without symptoms was 50 percent. Against severe disease, its efficacy was 100 percent. The Turkish trial found that the efficacy against Covid-19 with at least one symptom was 83.5 percent. After CoronaVac was taken up in other countries, some of them conducted studies to measure its effectiveness. In Chile, researchers reviewed 10.5 million people who were vaccinated and estimated that the vaccine had an effectiveness of 67 percent against symptomatic Covid-19, and 85 percent protection against hospitalization. Sinovac registered a Phase 2 trial of the vaccine in children and adolescents on May 13. They moved to Phase 3 on Aug. 5. AUTHORIZATIONChina began giving CoronaVac to some of its citizens as early as the summer of 2020, long before its formal authorization. In October, authorities in the eastern Chinese city of Jiaxing announced they were giving CoronaVac to people in relatively high-risk jobs, including medical workers, port inspectors and public service personnel. Indonesia gave the vaccine emergency authorization on Jan. 11, and two days later the president of Indonesia received an injection of CoronaVac on live television. Turkey authorized the vaccine on Jan. 13, and its president got vaccinated the next day. Brazil authorized CoronaVac on Jan. 17. On Feb. 6, 2021, Sinovac announced that China had given CoronaVac conditional approval. China expanded its authorization to include children and adolescents on June 4. Both authorizations came before Phase 3 data was made public. After reviewing clinical trial results, the World Health Organization gave emergency authorization to the vaccine on June 1, 2021. On May 4, the European Medicines Agency said it was launching a rolling review of CoronaVac, which will accelerate Sinovac’s marketing authorization if the company decides to apply for one. DISTRIBUTIONSinovac has struck deals with at least 11 countries and regions to supply them with SinoVac. Sinovac reached an agreement announced on July 12 to supply up to 550 million doses to COVAX, the initiative to distribute vaccines to low- and middle-income countries. BOOSTERSIn the spring of 2021, more than 350 doctors and health care workers in Indonesia came down with Covid-19 despite being fully vaccinated with Sinovac. These alarming reports stirred concerns that CoronaVac’s protection was waning. In its June 2021 authorization of the vaccine, the World Health Organization noted that they observed possible signs of waning immunity in the first three months of the clinical trial in Brazil. A study released on July 25 found that six months after receiving two doses, healthy adults experienced a large drop in antibody levels. That same study showed that a booster of CoronaVac could restore high antibody levels. In another study released on Aug. 8, researchers found that a booster shot of the vaccine will be necessary in older adults, since immunity also dropped substantially after six months of receiving two doses. Sinovac is now running a Phase 4 trial to evaluate how well such a booster can protect against Covid-19 in healthy adults. But some countries are making other plans. In August, Chilean researchers registered a Phase 2 trial to assess the effectiveness of giving a different vaccine as a booster to those who received the Sinovac shot. CoronaVac is also part of a mixed-vaccine trial with Inovio’s vaccine. Results from a Chinese study, released on Sept. 7, suggested that getting a CanSino booster shot after the Sinovac vaccine produced a stronger antibody response compared to a third shot of the Sinovac vaccine. For more details, see How the Sinovac Vaccine Works. APPROVED FOR USE IN: China. STOPPED USE IN: Malaysia. EMERGENCY USE IN: Albania, Armenia, Azerbaijan, Bangladesh, Benin, Bolivia, Botswana, Brazil, Cambodia, Chile, Colombia, Dominican Republic, Ecuador, El Salvador, Egypt, Hong Kong, Indonesia, Laos, Malawi NEW, Malaysia, Mexico, Moldova, Nepal, Oman, Pakistan, Panama, Paraguay, Philippines, South Africa, Sri Lanka, Thailand, Timor-Leste, Tunisia, Turkey, Ukraine, Uruguay, Venezuela, Zimbabwe. Emergency use validation from the World Health Organization. Updated Sept. 17 Sinovac vaccine UKRAINE TUNISIA TURKEY CHINA PAKISTAN MEXICO MALAYSIA BRAZIL COLOMBIA BOTSWANA INDONESIA URUGUAY SOUTH AFRICA CHILE Stopped use in favor of other vaccines Approved Early, limited or emergency use PHASE 3 APPROVED IN CHINA LIMITED USE IN U.A.E. Sinopharm logoWuhan logo EFFICACY: 72.8% Along with their Beijing Institute vaccine, Sinopharm also tested an inactivated virus vaccine developed by the Wuhan Institute of Biological Products. The Phase 1/2 trial showed that the vaccine produced antibodies in volunteers, some of whom experienced fevers and other side effects. Sinopharm then launched a global Phase 3 trial of the Wuhan vaccine. In December, Peru briefly paused their trial to investigate neurological problems that one volunteer experienced, but determined that it had nothing to do with the vaccines. On Feb. 25, China announced the approval of the Wuhan vaccine for general use. In May, the vaccine researchers published the results of the Phase 3 trial, demonstrating that the vaccine has an efficacy of 72.8 percent. APPROVED FOR USE IN: China. LIMITED USE IN: United Arab Emirates. Updated May 29 Sinopharm and Wuhan Institute vaccine CHINA U.A.E. Approved Early, limited or emergency use PHASE 3 EMERGENCY USE IN INDIA, ELSEWHERE Bharat Biotech logoIndian Council of Medical Research logoNational Institute of Virology logo VACCINE NAME: Covaxin (also known as BBV152 A, B, C) EFFICACY: 77.8% DOSE: 2 doses, 4 weeks apart STORAGE: At least a week at room temperature Covaxin, produced by Bharat Biotech, was the first vaccine for Covid-19 developed in India to gain emergency use authorization. India approved it in April 2021. VACCINE DEVELOPMENTResearchers at the Indian Council of Medical Research and the National Institute of Virology, designed Covaxin from inactivated coronaviruses. Studies carried out in the spring of 2021 on monkeys and hamsters demonstrated that the vaccine provided the animals with protection against infection. TRIAL RESULTSBharat Biotech launched clinical trials in June 2020. The phase 1/2 trial showed that the vaccine didn’t cause any serious side effects while producing antibodies to the coronavirus. A follow-up study confirmed these results. On Oct. 23, the company announced they were initiating a Phase 3 trial, eventually recruiting over 25,800 volunteers. Bharat Biotech only began releasing results from the trial in March 2021, two months after the vaccine gained emergency authorization. The final results were posted online on July 2. The vaccine had an efficacy of 77.8 percent against symptomatic Covid-19, and its efficacy against severe Covid-19 was 93.4 percent. For asymptomatic disease, the vaccine had an efficacy of 63.6 percent, indicating that it can also slow transmission. In June, Bharat Biotech registered a trial on children as young as 2. Indian authorities announced on Aug. 11 that they will allow Bharat to perform a trial that mixes Covaxin with BBV154, the company’s intranasal vaccine. Two days later, they announced that BBV154 received authorization to begin Phase 2/3 trials on its own.AUTHORIZATIONOn Jan. 3, 2021, the Indian government granted Covaxin emergency authorization. Other countries in Africa, Asia, and South America later authorized the vaccine. In Brazil, a controversy over corruption led the government to suspend its authorization of Covaxin in July 2021. Bharat Biotech formed a partnership with Pennsylvania-based Ocugen to develop Covaxin for the United States market. In June 2021, Ocugen announced it would seek a full license for the vaccine, rather than an emergency use authorization. On an August earnings call, the chief executive of Ocugen said that the company might need to run an additional trial for the F.D.A., which they were prepared to start in 2021. DISTRIBUTIONBharat expects to produce as many as one billion doses per year after expanding their manufacturing capacity. VARIANTSBharat ran its clinical trials in India just as the Delta variant was rising to dominance in the country. As a result, they were able to calculate the efficacy of Covaxin against Delta by looking at the relative risk volunteers had of contracting the variant. They estimated that its efficacy was 65.2 percent. Delta subsequently evolved into new lineages, including AY.1, sometimes known as Delta Plus. Researchers found that antibodies from people vaccinated with Covaxin were able to neutralize AY.1 coronaviruses. For more details, see How Bharat Biotech’s Vaccine Works. STOPPED USE IN: Brazil suspended import. EMERGENCY USE IN: Botswana, Guatemala, Guyana, India, Iran, Mauritius, Mexico, Nepal, Nicaragua, Paraguay, Philippines, Venezuela, Zimbabwe. Updated Aug. 20 Bharat Biotech’s Covaxin vaccine PHILIPPINES NEPAL IRAN INDIA MEXICO BRAZIL ZIMBABWE PARAGUAY Suspended import Approved Early, limited or emergency use PHASE 3 EARLY USE IN KAZAKHSTAN Kazakhstan’s Research Institute for Biological Safety Problems logo The central Asian nation of Kazakhstan began research on a vaccine made from inactivated coronaviruses over the summer. On August 28, 2020, their Research Institute for Biological Safety Problems registered a Phase 1 trial on the vaccine. On Dec. 19, Kazinform reported that researchers had completed the Phase 2 trial, finding that the vaccine was safe and produced a promising immune response. The researchers commenced a Phase 3 trial in March, 2021. Kazakhstan’s vice minister of education and science announced that the vaccine, known as QazVac, was expected to be authorized in April, despite the lack of published results from the Phase 3 trial. Kazakhstan began administering its vaccine to the public in late April. On July 29, government officials announced that they would deliver 25,000 doses of the vaccine to neighboring country Kyrgyzstan. EARLY USE IN: Kazakhstan. Updated Sept. 3 QazVac vaccine KAZAKHSTAN Approved Early, limited or emergency use PHASE 3 EMERGENCY USE IN CHINA Shenzhen Kangtai Biological Products logo Shenzhen Kangtai Biological Products is a Chinese company that makes vaccines for diseases such as hepatitis B and measles. In August, AstraZeneca reached an agreement with Shenzhen to supply China with their adenovirus vaccine, despite the reports of corruption and scandals that have plagued the company. In October Shenzhen Kangtai launched a Phase 1 trial on 180 volunteers of its own vaccine, based on inactivated coronaviruses. In February 2021 the company ran a Phase 2 trial, followed by a Phase 3 trial launched in May. In that same month, the company announced that the Chinese government had given it emergency use approval. The first volunteers received injections on June 21 in Malaysia. EMERGENCY USE IN: China. Updated June 21 Shenzhen Kangtai vaccine CHINA Approved Early, limited or emergency use PHASE 3 EMERGENCY USE IN IRAN Shafa Pharmed Pars logo Shafa Pharmed Pars, an Iranian pharmaceutical company, developed a vaccine made of inactivated coronaviruses. Results from preclinical trials showed that the vaccine was safe and effective in animals. Known as COVIran Barekat, it entered a Phase 1 trial at the end of December, becoming the first vaccine developed in Iran to go into clinical testing. COVIran Barekat began a Phase 3 trial on April 25, 2021, and on June 14, the Iranian government announced it had authorized the vaccine, despite the fact that many volunteers in the Phase 3 trial had not yet received their second dose. On June 25, Ayatollah Khamenei received the COVIran Barekat vaccine on television. EMERGENCY USE IN: Iran. Updated June 30 Shafa Pharmed Pars vaccine IRAN Approved Early, limited or emergency use PHASE 3 Institute of Medical Biology at the Chinese Academy of Medical Sciences logo Researchers at the Institute of Medical Biology at the Chinese Academy of Medical Sciences, which has invented vaccines for polio and hepatitis A, created an inactivated coronavirus vaccine. In May 2020, they launched a Phase 1 trial on 192 volunteers which indicated the vaccine was safe and produced an immune response. A Phase 2 trial followed on 750 volunteers, which led the researchers to select a two-week spacing between the two doses of the vaccine. In December the researchers launched a Phase 3 trial on up to 34,020 volunteers in Brazil and Malaysia. On June 9, Chinese government newspaper Science and Technology Daily reported that the vaccine received emergency use authorization. Updated June 10 PHASE 3 Valneva logoDynavax logo The French vaccine maker Valneva created a vaccine from chemically inactivated coronaviruses, using an adjuvant from Dynavax. The vaccine, called VLA2001, is currently the only inactivated-virus vaccine being developed in Europe. On Dec. 16, Valneva launched a Phase 1/2 trial in the United Kingdom, and in April the company announced that the trial had delivered positive results. On April 22, Valneva launched a Phase 3 trial on 4,000 volunteers in the United Kingdom. The trial was different from the first wave of studies on Covid-19 vaccines, in which some volunteers got a vaccine and the others received a placebo. With a growing number of vaccines authorized for use in Britain, such randomized clinical trials were no longer ethical. Instead, Valneva gave VLA2001 to half of their volunteers, while the others received Vaxzevria, the vaccine made by AstraZeneca. Researchers then observed whether VLA2001 produced similar levels of antibodies to Vaxzevria. In June, the company announced the trial was complete and that they expected to release their results by September. Valneva said on Aug. 23 that it has begun applying for authorization in the United Kingdom for its vaccine. On Aug. 11, Valneva announced that it will begin another Phase 3 trial to assess the vaccine’s effectiveness in people 56 years or older and its effectiveness compared to a variant-specific vaccine called VLA2101. The British government has already reached an agreement to purchase 100 million doses of the vaccine should it prove safe and effective, with an option to acquire a further 90 million. Updated Aug. 24 PHASE 3 Erciyes University logo VACCINE NAME: Turkovac On Nov. 5, Turkey’s Erciyes University announced they had begun injecting volunteers with an inactivated coronavirus vaccine called ERUCOV-VAC. It was the first clinical trial of a coronavirus vaccine developed in Turkey. On Dec. 14, 2020, the president of the university said that the Phase 1 trial was complete. Sabah Today reported the following month that Phase 2 trials had begun. On June 23, 2021, Turkish president Recep Tayyip Erdoğan announced that the vaccine, renamed Turkovac, has entered a Phase 3 trial. In July, the researchers registered a Phase 2 trial to evaluate the vaccine as a booster shot. Updated Aug. 2 PHASE 2 Iran’s Ministry of Defence logo On March 16, 2021, Iran’s Ministry of Defence announced another vaccine made of inactivated coronaviruses. Known as Fakhravac, the vaccine is named after Mohsen Fakhrizadeh, Iran’s top nuclear scientist who was killed in November. After the completion of a Phase 1 trial, Fakhravac entered a Phase 2 trial in June. Updated May 6 PHASE 1 PHASE 2 COMBINED PHASES EARLY USE IN RUSSIA The Chumakov Center at the Russian Academy of Sciences logo The Chumakov Center at the Russian Academy of Sciences developed an inactivated coronavirus vaccine called CoviVac. On Oct. 14, 2020, Tass reported that clinical trials of the vaccine would begin in Kirov and St. Petersburg on Oct. 19. On Feb. 20, 2021, Russia approved the vaccine for domestic use, despite the fact that the Chumakov Center only later began a Phase 3 trial. On June 3, the director of the Chumakov Center said the trial was still underway and it was not yet possible to speak of the vaccine’s efficacy. The director said on Aug. 24 that the Chumakov Center is working on a modified version of the vaccine tailored for new variants, and that they plan to double the production capacity for CoviVac to 2.5 million doses per month. EARLY USE IN: Russia. Updated Aug. 26 Chumakov Center vaccine RUSSIA Approved Early, limited or emergency use PHASE 1 PHASE 2 COMBINED PHASES KM Biologics logo On March 22, 2021, Japan’s KM Biologics announced that it had begun a Phase 1/2 trial of its inactivated vaccine candidate, called KD-414. The company has also played a part in manufacturing AstraZeneca’s vaccine. Updated May 7 PHASE 1 Codagenix logo New York-based Codagenix develops vaccines based on live attenuated viruses, but with a twist: they create the viruses from scratch. Researchers rewrite the genome of viruses, introducing hundreds of mutations. Then they manufacture RNA molecules encoding the rewritten genes. In special host cells, the molecules can give rise to full-blown viruses. But thanks to their numerous mutations, they are too weak to cause Covid-19 when they’re delivered in a vaccine. After successful experiments in animals, a Phase 1 trial was launched in the United Kingdom in January 2021. The results of the trial are anticipated in the third quarter of 2021. Updated July 1 PHASE 1 Koçak Farma logo Turkish researchers at Koçak Farma have developed a vaccine made of inactivated coronaviruses. They began a Phase 1 trial on April 8, 2021. Updated April 9 PHASE 1 In addition to its protein vaccine, the Scientific and Technological Research Council of Turkey has also developed a vaccine that uses inactivated coronaviruses. On April 29, 2021, they registered a Phase 1 trial in Turkey. Updated April 30 PRECLINICAL Other inactivated or attenuated coronavirus vaccines in active preclinical development include vaccines from: Indian Immunologicals and Griffith University; Osaka University.

### Adv 2

#### Norloff doesn’t apply to our specific scenario so reject it

#### Forsyth doesn’t make sense – it just says that there is a chance for complexity and potential miscalculation but that’s not a reaosn why the US and china would be drawn into war

#### Hegemony is unsustainable – pursuit causes extinction from nuke war, climate change, and global autocracy – decline solves

Pampinella 19 [Stephenis Assistant Professor of Political Science and International Relations at the State University of New York (SUNY) at New Paltz. 1/23. "The Internationalist Disposition and US Grand Strategy." https://thedisorderofthings.com/2019/01/23/the-internationalist-disposition-and-us-grand-strategy/]

Finally, attempts to revive US hegemony will doom transnational efforts to deal with existential non-state threats. Hegemonists like Thomas Wright argue that Russia and China are the greatest threat to the United States, and that Washington should never make concessions to either power as a means of ensuring cooperation on issues of global governance. However, “ring-fencing” global capitalism and climate change as separate issues will fail to achieve the necessary level of cooperation to cope with these threats. National security policymakers cannot recognize that the greatest dangers faced by US citizens are non-state economic and ecological global processes that shape domestic politics from the inside-out, and not rival sovereigns. Economic destitution to the point of embracing fascist dictators coupled with environmental collapse are near-certain non-state threats which transcend our boundaries – in fact, as a global power, the United States has been complicit in creating them.

The internationalist disposition would suggest that the priorities of US foreign policy must change. Regulating global processes should be the primary objective, and it requires that the United States pursue intense macro-levels of cooperation with all other states, including its rivals, to achieve them. Yet it will be unlikely to do so if it remains wedded to liberal hegemony and consumed by great power competition. Short-term incentives to accumulate resources and power will override the long-term need for global governance. The result will be a world whose people live in precarity, ravaged by climate change, and constantly on the verge of great power war.

#### Unipolarity causes prolif – states will try to balance against the U.S.

**Fettweis 19** [Christopher J. Fettweis is associate professor of political science at Tulane University, “Pessimism and Nostalgia in the Second Nuclear Age”, Strategic Studies Quarterly , Vol. 13, No. 1 (SPRING 2019), pp. 12-41, JSTOR]

First and most obviously, the SNA would likely be marked by a great deal more proliferation than the first. According to Bracken, the “overarching theme” of the age will be the “breakdown of the major power monopoly over the bomb.”7 Unipolarity provides strong incentives for smaller states, who have no hope of balancing the United States, to pursue nuclear weapons. No matter how much effort the United States puts into non- and counterproliferation, “nuclear weapons will nevertheless spread, with a new member occasionally joining the club,” predicted Kenneth Waltz. 8 “The most likely scenario in the wake of the Cold War,” argued John Mearsheimer, “is further nuclear proliferation in Europe,” and “it is not likely the proliferation will be well managed.”9 Instability and insecurity would spread, as would nuclear weapons, throughout the Global South.10 Since new nuclear states were almost inevitable, both Waltz and Mearsheimer felt that it was in the interest of the West to attempt to manage, and indeed even to encourage, gradual proliferation to help stabilize the system.

#### Hegemony causes overextension and conflict spirals that trigger great power war

**Forsyth 19** [Jim Forsyth currently serves as dean of Air Command and Staff College, Maxwell AFB, Alabama. He earned his PhD from the University of Denver, Josef Korbel School of International Studies. He has written and published extensively on great power war, intervention, and nuclear issues. “Through the Glass—Darker”, Strategic Studies Quarterly , Vol. 13, No. 4 (WINTER 2019), pp. 18-36, JSTOR] \* we do not endorse ableist language

Finally, US forays into countering globalization’s unforeseen effects are apt to generate security risks similar to those Britain assumed before WWI. US efforts to shore up waning hegemony by (re)building and exercising its vast power-projection capabilities, reminiscent of Britain’s imperial overextension of the early 1900s, could ultimately undermine stability.54 The United States is still coming to grips with the need to curb China’s aims in the Pacific. While the US Navy is “shrunken and overworked,” the PLA navy is now the largest (in raw numbers of warships and submarines, though not in tonnage) and fastest growing in the world.55 Xi Jinping identifies the PLA’s naval buildup and modernization as crucial to China’s strength, prompting some to draw parallels between Xi and Kaiser Wilhelm.56 Though China’s fleet is far less advanced, it has nonetheless allowed for the expansion of Chinese dominance in the South China, East China, and Yellow Seas. Indeed, the Pentagon’s attempt to compensate for two decades of underinvestment during China’s military modernization and A2/AD advancements may herald the next phase of a spiral toward conflict. The Pentagon has reportedly assembled war plans to account for a possible confrontation with China. It is also expanding and refurbishing the US fleet and fast-tracking weapons development and acquisition efforts (most notably, for longer-range missiles).57 Meanwhile, US partners and allies are prodding the United States to play a greater role in the Indo-Pacific region, offset Iran’s ambitions in the Middle East, and deter Russian incursions into the Baltics . . . at the same time the US is trying to back away from its role as the global policeman.58 In other words, the need for US architectural planning—particularly with respect to China—may be disrupted by calls for firefighting. The push to fight fires rather than craft and execute measured plans is problematic; it not only derails the US ability to best prepare for great power competition but also generates the additional risk of stumbling ~~blindly~~ into great power war.