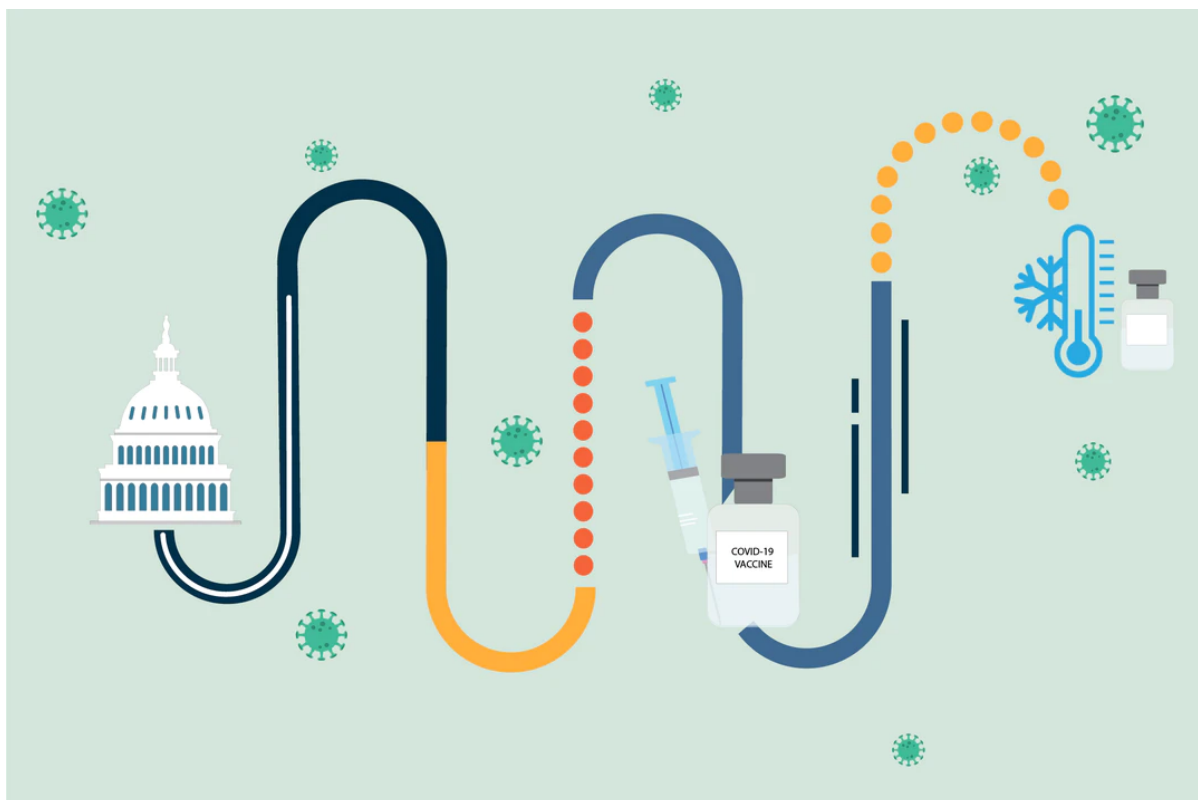


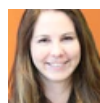
A COVID-19 Vaccine: Three Crucial Steps



David Kendall

Senior Fellow for Health and Fiscal Policy

[@DavidBKendall](https://twitter.com/DavidBKendall)



Kaitlin Hunter

Health Policy Advisor, Economic Program

Takeaways

A COVID-19 vaccine would save tens of thousands of lives in the United States and help rescue the economy. The Trump Administration has advertised its Operation Warp Speed as the answer, but the effort is underfunded and inadequate. Instead, Congress should act quickly to ensure the safe, effective, and rapid development of a vaccine by taking three crucial steps: 1) provide \$26 billion for the advanced purchase of up to ten prospective vaccines; 2) purchase a year supply of existing vaccines now to increase the production capacity for a COVID-19 vaccine; and 3) prevent supply chain shortages by covering 100% of manufacturers' retooling costs for products like glass vials, stoppers, and refrigeration needed for vaccine distribution. We must match this unprecedented pandemic with an equally unprecedented response.

The development, production, and distribution of a COVID-19 vaccine is the nation's biggest challenge right now. It could save at least tens of thousands of lives in the United States alone and restore a portion of the \$2 trillion of the GDP lost to the coronavirus.¹ While President Trump has acknowledged the importance of a vaccine, he has not put the full weight of the nation behind the effort. His plan, called Operation Warp Speed, leaves out key steps the nation must take to make way for a COVID-19 vaccine without risking the outbreak of other diseases.² It also underplays the massive effort needed to produce a wide range of ancillary products needed for the distribution of the vaccine. The Administration should not cause the delay of vaccines as it did with personal protective gear and testing kits due to supply chain mismanagement.

Congress has begun to take the right measures with the House-passed Heroes Act which provides an additional \$9 billion for vaccine and treatment development.³ Yet, much more needs to be done. This memo explains where our current capacity to produce and distribute a vaccine falls short and recommends three crucial steps Congress must take for a massive and to-scale response:

1. Provide \$26 billion for the advanced purchase of up to ten prospective vaccines.
2. Purchase a year supply of existing vaccines now to increase the production capacity for a COVID-19 vaccine when it's ready.
3. Prevent supply chain shortages by covering 100% of manufacturers' retooling costs for products like glass vials, stoppers, and refrigeration needed for vaccine distribution.

Key Challenges for Vaccine Production

As our scientific and medical communities focus on COVID-19, several challenges stand in the way of rapid production of a safe and effective vaccine. Specifically:

1. **The current infrastructure to make enough vaccines is almost at capacity.** The United States has finite vaccine capacity to make 330 million COVID-19 vaccines for multiple potential candidates *in addition to* the other vaccines we already need. Each vaccine facility is highly specialized to make one specific type of vaccine, from Hepatitis to measles. For example, some vaccines require vats in which a virus is cultured in a broth of cells and later inactivated and purified.⁴ The limited number of existing vaccine production facilities are currently booked to make other necessary vaccines. According to one specialist, some facilities are booked until 2022.⁵ That means if we repurpose existing facilities to focus only on COVID-19, we could put the supply of other critical vaccines at risk.⁶

2. **Building new infrastructure is expensive.** Specialized facilities normally take years to

2. **Building new infrastructure is expensive.** Specialized facilities normally take years to build and cost around three times more than conventional pharmaceutical factories. Further, the kind of facility can vary dramatically depending on which of the 95 potential COVID-19 vaccines prove successful. For example, one production facility could require a 2000-liter bioreactor for growing a biological organism, filtration and centrifugation technology, and a single pass air system.⁷ Each of these technologies is incredibly expensive. Thankfully, the Gates Foundation is facilitating the construction of seven new facilities, knowing only one or two will be used to manufacture a COVID-19 vaccine.⁸ But that important effort is not enough to guarantee enough vaccine production for the whole country let alone the world.

3. **Supply chains are already strained, and more workers will be needed.** To manufacture and deliver a vaccine to every American, we must avoid the supply shortages we've seen with testing. For example, Dr. Rick Bright, former head of the Biomedical Advanced Research and Development Authority, warned in a whistleblower complaint of a "critical shortage" of syringes and glass vials that could take two years to produce. His complaint was valid: there are only 200 million vials left in the world right now because they have all been purchased by companies anticipating a vaccine.⁹

The supply chain can't handle making 330 million doses of multiple vaccines without a serious investment in supplies now. It's doable, but there is a challenge— given we don't know the type of vaccine, we could need a variety of supplies. So, every part of the vaccine supply chain, from large bioreactors to vials and stoppers, to a chain of temperature-controlled facilities and refrigerated trucks, needs to be secured and scaled. For example, to store and deliver 10 different vaccines, we will need more than a billion vials and stoppers.¹⁰ And that's assuming each vaccine requires just one dose.

To successfully secure the vaccine supply chain and ensure that we can make both our current vaccines and COVID-19 vaccines, the country needs thousands of people working around the clock. We need a massive investment to put people to work manufacturing vaccine administration and distribution supplies and a COVID-19 vaccine.

Solution: Three Key Steps for a Rapid COVID-19 Vaccine

We must match this unprecedented pandemic with an equally unprecedented response. Congress should act quickly to ensure the safe, effective, and rapid development of a vaccine by taking three crucial steps.

Step #1: Provide \$26 billion for the advanced purchase of up to 10 potential vaccines.

The nation can't wait for the normal vaccine development process, which can take up to 10

THE NATION CAN'T WAIT FOR THE NORMAL VACCINE DEVELOPMENT PROCESS, WHICH CAN TAKE UP TO 10 years before a new vaccine is given to a single person. Instead, the United States can start producing the most promising vaccines now. Essentially the clinical trials and the manufacturing of these vaccines would happen simultaneously. That way, the federal government can immediately distribute vaccines that work as soon as clinical trials show which ones are safe and effective. The unused vaccines would be safely discarded.

The House-passed HEROES Act provides \$9 billion for vaccine and treatments. This amount is a good start, but Congress should appropriate \$26 billion specifically for the advanced purchase of up to ten of the most promising vaccines for the country.¹¹ The Administration has committed to producing three to five potential vaccines, but that could be inadequate. Given that only one of ten new drugs make it to market on average, Congress should provide a contingency fund for up to ten total vaccines.¹² The criteria for choosing the leads should include a variety of new and fast vaccine production methods as well as established, but slower methods.

In very rough terms, the cost to produce each promising vaccine is \$2.6 billion. That amount assumes the vaccine costs \$10 per person and that 80% of the population will end up taking the vaccine.¹³ The cost could be much less in light of a recent deal with the federal government at \$4 per dose.¹⁴ The Secretary of Health and Human Services would negotiate a final price with the original vaccine producer and a license to extend production to other manufacturers. Advanced purchasing of a set number of vaccine doses will keep the price down.¹⁵ Under the Bayh-Dole Act, the federal government can ensure massive production and wide distribution of any vaccine developed with federal funding for “health and safety needs” like a pandemic.¹⁶ Many promising vaccine candidates are receiving federal funding to produce and test their products.¹⁷ The Trump Administration has announced the advanced purchase of at least two potential vaccines.¹⁸ That’s a start but far from sufficient.

As Congress provides funding, it should also provide \$700 million to step up safety and distribution monitoring once the vaccine is released. The current safety monitoring and reporting processes only take limited advantage of electronic health records.¹⁹ The Department of Health and Human Services would use the new resources to expand safety monitoring with tools like artificial intelligence to detect, contextualize, and report problems with drugs and vaccines as well as voluntary data uploads from new data sources like smartphones.²⁰ It would also bolster state immunization registers through expanded and streamlined immunization information systems that can draw vaccine data from providers’ electronic health records and other sources.²¹ Those processes need a significant upgrade, one that would dovetail with the need for widespread and rapid COVID-19 vaccine safety and distribution monitoring.²²

This approach will not only ensure rapid vaccine production but also ensure the robustness of

THIS APPROACH WILL NOT ONLY ENSURE RAPID VACCINE PRODUCTION BUT ALSO ENSURE THE ROBUSTNESS OF the usual safety and effectiveness standards. The National Institutes of Health is streamlining and coordinating multiple clinical trials to test multiple potential vaccines and share data.²³ The FDA will give final vaccine approval while also overseeing the production of potential vaccines purchased in advance.

Step # 2: Purchase a year supply of existing vaccines now to increase production capacity for a COVID-19 vaccine.

Congress should appropriate another \$6 billion for the purchase and rapid production of a year supply of current vaccines to open all possible production and distribution capacity for a future COVID-19 vaccine.²⁴ It should also direct the Administration to assemble a task force for the sole purpose of projecting non-COVID-19 and COVID-19 vaccine needs over the next several years and coordinating the production and storage of the vaccines with current vaccine needs. The task force will also need to handle the complex interactions and potential conflicts between vaccines, which vary by the types of production facilities, personnel needs, supply chain requirements, and distribution capacity.

From March 13 to April 19, there was a 2.5 million-dose decline in orders of regular childhood vaccines—not counting influenza vaccines. For example, there was a 250,000-dose decline in vaccines containing measles protection.²⁵ This is detrimental to children's health and jeopardizes the vaccine supply chain, as an onslaught of these missed orders could come when stay-at-home orders are lifted across the country. Furthermore, childhood vaccines save nearly \$300 billion in direct costs and \$1.3 trillion in social costs. Efforts to address COVID-19 must allow children to get their vaccines and COVID-19 vaccine production does not displace other necessary vaccines, including influenza and vital childhood vaccines.

Currently, the federal government purchases vaccines for half of the children in the country.²⁶ To ensure every child has access to the vaccines they need, the government should double this budget by adding \$5 billion and purchase vaccines for every child. The other \$1 billion could purchase a large supply of adult vaccines. This purchasing agreement would give companies the financial stability to produce those vaccines in an accelerated manner, knowing there is a buyer, and to clear the production line for future COVID-19 vaccine production. Additionally, Congress should increase Medicaid and Medicare reimbursement rates for vaccine administration and fund a comprehensive educational campaign to ensure that Americans, especially children, are caught up on their vaccines before a different outbreak occurs.

Step # 3: Prevent supply chain shortages by providing up to 100% of all manufacturing retooling costs for products like glass vials, stoppers, and refrigeration

products like glass vials, stoppers, and refrigeration needed for vaccine distribution.

The federal government should cover domestic manufacturers' retooling costs as they change their current processes to mass-produce supplies ranging from glass vials and stoppers to refrigeration and syringes. This would allow existing manufacturers to scale-up their current production, build new capacity, or allow other companies to retool their facility. Retooling costs should include funding for all the needed wage, benefits, and additional shifts added to existing or new facilities that are working to produce the stockpile of current vaccines, preparing the new COVID-19 vaccine, or manufacturing critical vaccine supplies. At a minimum, the labor wage and benefit standards should be as good as they are for similar jobs in the federal workforce.

Congress should also require the President to appoint a supply chain czar to anticipate worldwide demand and supplies needed for the COVID-19 vaccine on top of existing vaccines as proposed in the Heroes Act.²⁷ While the Administration has made key appointments for Operation Warp Speed's leadership, it is critical to have a role specifically accountable for the supply chain since the Administration has failed so far to purchase supplies at the scale needed. For example, the Administration spent \$111.5 million on 320 million syringes.²⁸ We would need double that if the COVID-19 vaccine a two-dose vaccine. Further, the White House director of trade and manufacturing policy Peter Navarro estimated the country would need 850 million needles and syringes, meaning the White House is \$296 million short of their own estimates.²⁹

The Trump Administration has acknowledged the need to anticipate certain supplies, but it hasn't publicly mapped out *all* the needed supplies or shown how it will prevent supply chain issues.³⁰ Vaccines are incredibly complex—their production can require hundreds of components from all over the world. One potential COVID-19 vaccine requires oil produced in one South American tree, another requires its own device to administer, while another requires a lipid complexing agent.³¹ Without adequate preparation for each of these supplies, the effort to produce a vaccine could be significantly delayed. For that reason, Congress should appropriate \$5 billion to immediately respond to supply chain shortages.³²

A full vaccine effort will involve producing and storing over 2 billion doses of vaccines and distributing one or more across the nation, not to mention the doses needed for the 7.6 billion people in the rest of the world. The logistics are challenging to say the least—from warehouses and refrigeration or freezing to getting shipments of vaccines from production facilities to states to cities to providers and ultimately to every single American. Given its track record with personal protective equipment and diagnostic tests, Congress should insist on a full, public accounting of the Administration's planning, as the bipartisan leadership of the House Energy and Commerce Committee has already begun to do.³³

Conclusion

CONCLUSION

The nation needs a robust, coordinated national push to develop and release a vaccine. This is going to involve a significant ramp-up in manufacturing, coordination of dozens of critical services and supplies, and a substantial federal investment. But that's not all. Once there's a vaccine, policymakers need to ensure that every American has equitable access. The United States is only as safe as its sickest neighbor; we will need to coordinate and work with other countries to ensure every single person in the world can get a vaccine. As a vaccine becomes available, the nation will need a plan for how to get it to every corner of the country and who gets access to it first. This is a once-in-a-decade crisis and we need to respond accordingly.

ENDNOTES

1. \$2 trillion Is the reduction from CBO's original GDP of \$23.251 trillion In 2021 as of January 2020 before the coronavirus crisis to the current projection of \$21.3 trillion. United States, Congress, Congressional Budget Office. "Budget and Economic Data: 10-Year Budget Projections." Jan. 2020, www.cbo.gov/data/budget-economic-data#4. Accessed 28 May 2020. See also United States, Congress, Congressional Budget Office. "CBO's Current Projections of Output, Employment, and Interest Rates and a Preliminary Look at Federal Deficits for 2020 and 2021." 24 Apr. 2020, www.cbo.gov/publication/56335. Accessed 28 May 2020.
2. United States, Department of Health and Human Services. "Trump Administration Announces Framework and Leadership for 'Operation Warp Speed.'" Press release, 15 May 2020, www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html. Accessed 28 May 2020.
3. United States, Congress, House of Representatives, Committee on Appropriations. "H.R. 6800, The Heroes Act: Title-By-Title Summary." 15 May 2020, p. 6, <https://appropriations.house.gov/news/press-releases/house-passes-heroes-act>. Accessed 28 May 2020.
4. Thompson, Stuart A. "Long Will a Vaccine Really Take?" *The New York Times*, 30 Apr. 2020, www.nytimes.com/interactive/2020/04/30/opinion/coronavirus-covid-vaccine.html. Accessed 28 May 2020.
5. Goldhill, Olivia. "The US is spending hundreds of millions to make experimental coronavirus vaccines." *Quartz*, 22 Apr. 2020, <https://qz.com/1842490/us-invests-hundreds-of-millions-to-produce-covid-19-vaccines/>. Accessed 28 May 2020.
6. Ridley, David. "Don't count on getting a coronavirus vaccine in 2021. Testing and production take time." *USAToday*, 5 May 2020, <https://www.usatoday.com/story/opinion/2020/05/05/coronavirus-vaccine-limited-supply-likely-2021-column/3075349001/>. Accessed 29 May 2020.
7. Cohen, Jon. "The \$1 billion bet: Pharma giant and U.S. government team up in all-out

7. Cohen, John. "The \$10-billion bet: Pharma giant and US government team up for coronavirus vaccine push." *Science*, 31 Mar. 2020, www.sciencemag.org/news/2020/03/1-billion-bet-pharma-giant-and-us-government-team-all-out-coronavirus-vaccine-push. Accessed 28 May 2020.
8. Guzman, Joseph. "Bill Gates is spending billions to produce 7 potential coronavirus vaccines." *The Hill*, 3 Apr. 2020, <https://thehill.com/changing-america/well-being/prevention-cures/491006-bill-gates-is-funding-factories-for-7-potential>. Accessed 28 May 2020.
9. Bostock, Bill. "Even if a successful coronavirus vaccine is developed, billions could struggle to access it because of a global shortage of glass vials." *Business Insider*, 8 May 2020, www.businessinsider.com/coronavirus-vaccine-glass-vial-shortage-could-delay-global-rollout-2020-5. Accessed 28 May 2020.
10. Serebrov, Mari. "Shortage of needles, syringes looms in race to develop COVID-19 vaccine." *BioWorld*, 8 May 2020, www.bioworld.com/articles/434969-shortage-of-needles-syringes-looms-in-race-to-develop-covid-19-vaccine. Accessed 28 May 2020.
11. The cost to purchase 264 million doses, or 80% of the US population, would be \$2.64 billion for each vaccine if each vaccine (regardless of dosage) cost \$10. This would be approximately \$26.4 billion for 10 vaccines. Congress appropriated \$3 billion for vaccines in the first supplemental bill, with \$300 million for the direct purchasing of vaccines, and \$11 billion for vaccines, therapeutics and diagnostics, with at least \$3.5 billion more for BARDA to manufacture and purchase vaccines, therapeutics, and diagnostics and \$1 billion for the NIH under CARES. Based on BARDA's reported appropriations of funds, \$5 billion has been used to support vaccine development and \$1 billion has been allocated to pharmaceutical companies to support their COVID-19 efforts. Leftover money could be used to purchase the vaccine and House Democrats have appropriated \$9 billion for these efforts. See McGrail, Samantha. "BARDA Director Rick Bright Leaves Agency Amid COVID-19 Pandemic." *Pharma News Intelligence*, 22 Apr. 2020, <https://pharmanewsintel.com/news/barda-director-rick-bright-leaves-agency-amid-covid-19-pandemic>; See also Hughes IV, Richard, Kelly Cappio, and Alessandra Fix. "Ensuring COVID-19 Vaccine Affordability: Existing Mechanisms Should Not Be Overlooked." *Health Affairs*, 30 Mar. 2020, www.healthaffairs.org/doi/10.1377/hblog20200327.868172/full/. Accessed 28 May 2020. See also McConaghie, Andrew. "COVID-19 Vaccine Could Cost as Little As \$10 A Dose, Says Janssen." *Scrip*, 2 Apr. 2020, <https://scrip.pharmaintelligence.informa.com/SC141970/COVID19-Vaccine-Could-Cost-As-Little-As-10-A-Dose-Says-Janssen>. Accessed 28 May 2020. See also "\$340 Billion Surge in Emergency Funding to Combat Coronavirus Outbreak." United States Senate, Senate Appropriations Committee, 25 March 2020, https://www.appropriations.senate.gov/imo/media/doc/Coronavirus%20Supplemental%20Appropriations%20Summary_FINAL.pdf. Accessed 29 May 2020.
12. Thompson, Stuart A. "Long Will a Vaccine Really Take?" *The New York Times*, 30 Apr. 2020, www.nytimes.com/interactive/2020/04/30/opinion/coronavirus-covid-vaccine.html. Accessed 28 May 2020.
13. Surveys show that about 75% of Americans would take a COVID-19 vaccine. Purchasing enough

13. Survey shows that about 75% of Americans would take a COVID-19 vaccine if funding enough for 80% initially allows for some vaccine wastage. The Department of Health and Human Services should also guarantee the option to purchase more vaccine if needed. See DeRoo, Sarah Schaffer, Natalie J. Pudalov, and Linda Y. Fu. *JAMA*, 18 May 2020, <https://jamanetwork.com/journals/jama/fullarticle/2766370>. Accessed 28 May 2020.
14. "AstraZeneca Wins \$1.2B from BARDA to Develop, Manufacture COVID-19 Vaccine." *Genetic Engineering & Biotechnology News*, 26 May 2020, <https://www.genengnews.com/news/astrazeneca-wins-1-2b-from-barda-to-develop-manufacture-covid-19-vaccine/>. Accessed 28 May 2020.
15. Bach, Peter B. and Mark Trusheim. "U.S. Should Buy Coronavirus Vaccines Before They're Invented." *Bloomberg*, 17 Mar. 2020, www.bloomberg.com/opinion/articles/2020-03-17/the-u-s-should-buy-covid-19-vaccines-before-they-re-invented. Accessed 28 May 2020.
16. March-in rights. USC 35 Sec. 203. United States Code, US Government Publishing Office, 3 Jan. 2012, www.govinfo.gov/app/details/USCODE-2011-title35/USCODE-2011-title35-partII-chap18-sec203. Accessed 28 May 2020.
17. Facher, Lev. "NIH partners with 16 drug companies in hopes of accelerating Covid-19 treatments and vaccines." *Stat*, 17 Apr. 2020, www.statnews.com/2020/04/17/nih-partners-with-16-drug-companies-in-hopes-of-accelerating-covid-19-treatments-and-vaccines/. Accessed 28 May 2020.
18. Steenhuisen, Julie. "J&J, Moderna sign deals with U.S. to produce huge quantity of possible coronavirus vaccines." *Reuters*, 30 Mar. 2020, <https://www.reuters.com/article/us-health-coronavirus-johnson-johnson/jj-moderna-sign-deals-with-us-to-produce-huge-quantity-of-possible-coronavirus-vaccines-idUSKBN21H10Y>. Accessed 28 May 2020. See also DeArment, Alaric. "AstraZeneca gets \$1B in BARDA funding to advance Covid-19 vaccine." *MedCity News*, 21 May 2020, <https://medcitynews.com/2020/05/astrazeneca-gets-1b-in-barda-funding-to-advance-covid-19-vaccine/>. Accessed 28 May 2020.
19. United States, Department of Health and Human Services, Centers for Disease Control. "Vaccine Safety Datalink." 17 Jun. 2019, <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html>. Accessed 4 Jun. 2020.
20. Tang, Huaxiu et al. "Leveraging Food and Drug Administration Adverse Event Reports for the Automated Monitoring of Electronic Health Records in a Pediatric Hospital." *Biomedical Informatic Insights*, 8 Jun. 2017, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5467704/>. Accessed 28 May 2020. See also Streefland, Mariette Boerstoel. "Why Are We Still Creating Individual Case Safety Reports?" *Clinical Therapeutics*, 9 Nov. 2018, [www.clinicaltherapeutics.com/article/S0149-2918\(18\)30507-1/fulltext](http://www.clinicaltherapeutics.com/article/S0149-2918(18)30507-1/fulltext). Accessed 28 May 2020.
21. "Preparing for a COVID-19 Vaccine One-Sheet." American Immunization Registry Association, 5 May 5, 2020, <https://repository.immregistries.org/resource/preparing-for-a-covid-19-vaccine-one-sheet/>. Accessed 4 Jun. 2020.
22. Taylor, Nick Paul. Researchers automate EHR analysis for postmarket safety surveillance "

21. Taylor, Merrick. "Researchers automate EHR analysis for postmarket safety surveillance." *MedTech Dive*, 2 Oct. 2019, www.medtechdive.com/news/researchers-automate-ehr-analysis-for-postmarket-safety-surveillance/564164/. Accessed 28 May 2020.
23. Facher, Lev. "NIH partners with 16 drug companies in hopes of accelerating Covid-19 treatments and vaccines." *Stat*, 17 Apr. 2020, www.statnews.com/2020/04/17/nih-partners-with-16-drug-companies-in-hopes-of-accelerating-covid-19-treatments-and-vaccines/. Accessed 28 May 2020. See also United States, Department of Health and Human Services, National Institutes of Health. "NIH to launch public-private partnership to speed COVID-19 vaccine and treatment options." Press release, 17 Apr. 2020, www.nih.gov/news-events/news-releases/nih-launch-public-private-partnership-speed-covid-19-vaccine-treatment-options. Accessed 28 May 2020.
24. \$5 billion would go towards purchasing vaccines for every single child, essentially doubling the Vaccines for Children program (which cost \$4.7 billion in 2019). \$1 billion would go towards purchasing adult vaccines. There are fewer adult vaccines and a lot lower take-up, so this purchasing would be on a much smaller scale. For example, to purchase the pneumococcal vaccine (\$125/dose for pneumococcal 13-valent) for every senior aged 65 (1.7 million seniors were 65 in 2018) it would cost \$212.5 million, as less than half of adults typically get their vaccines, the US government could purchase all adult vaccines for \$1 billion. See "Immunization Policy Issues Overview." National Conference of State Legislatures, 14 May 2020, <https://www.ncsl.org/research/health/immunizations-policy-issues-overview.aspx>. Accessed 29 May 2020. See also The National Vaccine Program Office. "National Adult Immunization Plan." Department of Health and Human Services, <https://www.hhs.gov/sites/default/files/nvpo/national-adult-immunization-plan/naip.pdf>. Accessed 29 May 2020. See also "CDC Vaccine Price List." Centers for Disease Control and Prevention, 1 May 2020, <https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html>. Accessed 29 May 2020. See also "Total Medicare Enrollment: Part A and/or Part B Total, Aged, and Disabled Enrollees, Calendar Years 2013-2018." Centers for Medicare and Medicaid Services, Office of Enterprise Data and Analytics, CMS Chronic Conditions Data Warehouse, 2018, <https://www.cms.gov/research-statistics-data-systems/cms-program-statistics/2018-medicare-enrollment-section#Total>. Accessed 29 May 2020.
25. Branswell, Helen. "Routine vaccinations for U.S. children have plummeted during the Covid-19 pandemic." *Stat*, 8 May 2020, www.statnews.com/2020/05/08/childhood-vaccinations-decline-coronavirus-pandemic/. Accessed 28 May 2020.
26. Branswell, Helen. "Routine vaccinations for U.S. children have plummeted during the Covid-19 pandemic." *Stat*, 8 May 2020, www.statnews.com/2020/05/08/childhood-vaccinations-decline-coronavirus-pandemic/. Accessed 28 May 2020.
27. United States, Congress, House of Representatives, Committee on Appropriations. "H.R. 6800, The Heroes Act: Title-By-Title Summary." 15 May 2020, p. 22, <https://appropriations.house.gov/news/press-releases/house-passes-heroes-act>. Accessed 28 May 2020.
28. Stein, Shira. "Pandemic's Next Medical Shortage? Vaccine Needles, Syringes." *Bloomberg Law*.

28. Stein, Shira. "Pandemic's Next Medical Shortage? Vaccine Needles, Syringes." Bloomberg Law, 7 May 2020, <https://news.bloomberglaw.com/health-law-and-business/pandemics-next-medical-shortage-vaccine-needles-syringes>. Accessed 28 May 2020.
29. Stein, Shira. "Pandemic's Next Medical Shortage? Vaccine Needles, Syringes." Bloomberg Law, 7 May 2020, <https://news.bloomberglaw.com/health-law-and-business/pandemics-next-medical-shortage-vaccine-needles-syringes>. Accessed 28 May 2020.
30. United States, Department of Health and Human Services. "Trump Administration Announces Framework and Leadership for 'Operation Warp Speed.'" Press release, 15 May 2020, www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html. Accessed 28 May 2020.
31. Koerth, Maggie. "How COVID-19 Is Wreaking Havoc on Our Ability to Make Things — Including Vaccines." 15 Apr. 2020, <https://fivethirtyeight.com/features/how-covid-19-is-wreaking-havoc-on-our-ability-to-make-things-including-vaccines/>. Accessed 28 May 2020.
32. Based on our calculations, supply costs could come from a lot of places and add up quickly. Building 5 new vaccine production sites could cost \$275 million each (average of the range given in the Plotkin study) or 1.38 billion total, each new refrigeration device would cost thousands of dollars, and 264 million vials (estimated at \$0.40/vial) would cost \$105.6 million (Cost of Kimble Serum Vials was \$0.42/vial and study estimated \$0.40/dose vial). See Plotkin, Stanley et al. "The complexity and cost of vaccine manufacturing – An overview." *Vaccine*, Vol. 35, Issue 33, Pgs. 4064-4071, 24 Jul. 2017, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5518734/>. Accessed 29 May 2020. See also "Cost Comparison of TempArmour™ vs Other Refrigerators." Temparmour Refrigeration, <https://www.temparmour.com/total-cost-comparison-vaccine-refrigerators>. Accessed 29 May 2020. See also "Kimble Serum Vials." Daigger Scientific, <https://www.daigger.com/kimble-serum-vials-15989-group>. Accessed 29 May 2020. See also Sedita, Jeff et al. "Cost of goods sold and total cost of delivery for oral and parenteral vaccine packaging formats." *Vaccine*, Vol. 36, Iss. 12, Pgs. 1700-1709, 14 Mar. 2018, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5844852/>. Accessed 29 May 2020.
33. United States, Congress, House of Representatives, Committee on Energy and Commerce. "Bipartisan Energy and Commerce Leaders Urge Trump Administration to Develop a National COVID-19 Vaccine Plan." Press release, 22 May 2020, <https://energycommerce.house.gov/newsroom/press-releases/bipartisan-energy-and-commerce-leaders-urge-trump-administration-to-develop>. Accessed 28 May 2020.