NOTE: COVID-19 is an emerging, rapidly evolving situation[1] and this paper may be outdated by the time you are reading this.

Legal Barriers to an Equitable Distribution of a COVID-19 Vaccine

I. Overview of SARS-CoV-2

SARS-CoV-2 is a novel coronavirus that was discovered in Wuhan, China in December 2019.[2] Named COVID-19, it is an infectious disease that expresses mild symptoms for most individuals infected. For older individuals and those with pre-existing conditions like diabetes, cardiovascular disease, and cancer, the risk of developing a serious illness is more likely.[3] It also has a disproportionate effect on communities of color, with high rates of death in African American, Native American, and Latinx communities.[4] While the true mortality rate of the disease is difficult to calculate, the range is generally between 2-4%, with increases in the infection fatality rate when healthcare systems are overwhelmed.[5] The initial outbreak of COVID-19 occurred in China in early 2020 and was declared a pandemic when the virus spread across several countries and affected a pronounced number of people.[6] Currently, there are reported cases in 188 countries and territories, 46.8 million confirmed cases, and 1.2 million

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[1] National Center for Biotechnic Information (Nov. 20, 2020), https://www.ncbi.nlm.nih.gov
[2] Gianfranco Spiteri et al., *First cases of coronavirus disease 2019* (March 5, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7068164/
[3] World Health Organization, *Coronavirus* (Nov. 2, 2020), https://www.who.int/health-topics/coronavirus#tab=tab_1
[4] Don Bambino et al., *The Disproportionate Impact of COVID-19 on Racial and Ethnic Minorities in the United States* (June 20, 2020), https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa815/5860249
[5] Johns Hopkins University, *Mortality Analyses* (Nov. 20, 2020), https://coronavirus.jhu.edu/data/mortality
[6] Centers for Diseases Control and Prevention, *Coronavirus Disease 2019* (July 1, 2020), https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/about-epidemiology/identifying-source-outbreak.html#:~:text=The%20new%20virus%20was%20found,classified%20as%20a%20pandemic

deaths worldwide.[7] Because this a novel disease, it is assumed that we as a species do not have any immunity to it, and thus everyone is susceptible to being infected.[8]

The onset of the COVID-19 pandemic catalyzed global public health responses, with many countries issuing firm lockdowns to prevent the spread of the disease. Amidst the lockdowns, the global economy has faltered, and hospitals have been pushed to their limits.[9] Epidemiologists duly note that once a disease emerges, it is unlikely to go away.[10] Still, a vaccine is likely the only terminal solution for the pandemic, and its development is being pursued with unprecedented speed.[11] While a successful vaccine may not eradicate COVID-19, it will provide a much-needed pressure relief, potentially reducing the severity of symptoms and lowering the number of people that get infected. Indeed, vaccines have a dual public benefit in protecting the vaccinated person and building herd immunity by reducing the number of people who can transmit the virus.[12]

An effective vaccine could be available by mid-2021.[13] This is an extraordinary prospect; one that requires the United States to have a balanced vaccine distribution plan in place; one that

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[7] As of November 1, 2020. Johns Hopkins University, *Coronavirus Resource Center* (Nov. 1, 2020), https://coronavirus.jhu.edu.
[8] Centers for Diseases Control and Prevention, *Coronavirus Disease 2019* (Apr. 5, 2020), https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/#:~:text=Severe%20acute%20respiratory%20syndrome%20coronavirus,an%20individual%27s%20illness%20severity.
[9] *See* Miguel Marquez and Sonia Moghe, *Inside a Brooklyn hospital that is overwhelmed with Covid-19 patients* (March 31, 2020), https://www.cnn.com/2020/03/30/us/brooklyn-hospital-coronavirus-patients-deaths/index.html; Eliza Barclay and Dylan Scott, *Hospitals are Running out of staff, supplies, and beds* (July 16, 2020), https://www.vox.com/2020/7/15/21317776/covid-19-coronavirus-florida-arizona-texas-california-hospitals
[10] Nükhet Varlik, *When Will the Pandemic End?* (Oct. 15, 2020), https://www.sciencealert.com/history-tells-us-the-future-of-the-coronavirus-pandemic-has-no-end-date
[11] *Id.*
[12] Michael Liu et al, *March-In Rights and Compulsory Licensing* (May 6, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200501.798711/full/
[13] James Gallagher, *Coronavirus vaccine: When will we have one?* (Oct. 27, 2020), https://www.bbc.com/news/health-51665497

it is equitable *and* affordable. Indeed, "these are the times that try [our souls]", but an equitably distributed vaccine would kindle hope.[14]

In this paper, I seek to answer three legal issues that surround, and threaten, the equitable and total distribution of a COVID-19 vaccine:

1. What are (if any) the legal safeguards that can ensure an affordable vaccine?
2. Is allowing only the highest-risk groups to receive initial vaccine doses constitutional?
3. Assuming widespread vaccine availability, can the federal government mandate a national compulsory vaccination?

In section II, I will discuss the recent vaccine distribution effort for the H1N1 virus, comparing the disease and the response from public officials to COVID-19. In sections III-V, I conduct an analysis of the law and ethics governing each legal question presented to provide the possible outcomes to the questions. Finally, in section VI, I conclude with whether I think the law provides an adequate answer for these challenging issues.

II. Recent Vaccine Distributions Efforts in the United States: Influenza A (H1N1)[15]

The vaccine distribution framework that was utilized for a disease like H1N1 is a reminder of a basic premise: that for every widespread infectious disease, the targeted populations and methods of equitable vaccine distribution varies and is ultimately determined by who is most affected by the particular disease. Pregnant women and children younger than 5 years old were two of the most at risk for H1N1 complications.[16] For COVID-19, however, the most at risk

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[14] Thomas Paine, *American Crisis I* (1776)

[15] H1N1 was a novel Influenza A virus first detected causing disease in humans in 2009. The pandemic resulted in approximately 60.8 million cases and 12,469 deaths between April 2009 and April 2010, when the virus was contained.

[16] Centers for Disease Control and Prevention, *People at High Risk of Developing Flu-Related Complications* (Nov. 10, 2009), https://www.cdc.gov/h1n1flu/highrisk.htm

groups are the elderly and those with underlying conditions.[17] Because the high-risk groups are different, where these groups are concentrated differ. Thus, the methods of distribution may change. In addition, COVID-19 is much more severe; over 235,000 Americans have died thus far, compared to 12,469 from H1N1 in 2009 and 2010.[18]

Still, H1N1's vaccination campaigns in 2009 provides useful lessons. For example, H1N1 vaccine distribution faced a similar threshold challenge that a COVID-19 vaccine is likely to also grapple with: the initial supply of the vaccine dwarfed in comparison to the demand for it. Plagued with manufacturing shortages, only a total of forty-five million doses were distributed to the States in the initial vaccine shipment.[19] Those at higher risk for complications were targeted by distribution campaigns, but States opened up vaccination to anyone who wanted it.[20] However, the pandemic did not last long enough for the effects of the U.S. not instituting a legal bar against low-risk groups from receiving initial vaccine doses to be measured. Even without such mandate, the distribution campaign was successful at getting pregnant women, a high-risk group, vaccinated.[21] Rolling out a high initial dose count while preventing manufacturing troubles is a way to avoid having to consider a mandate.

Congress appropriated $6.15B to respond to the H1N1 pandemic.[22] The federal government used the funds to purchase the H1N1 vaccine supply and ancillary materials (syringes, needles,

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[17] Mayo Clinic Staff, *COVID-19: Who's at higher risk of serious symptoms?* (Nov. 5, 2020), https://www.mayoclinic.org/coronavirus-who-is-at-risk/art-20483301
[18] Centers for Disease Control and Prevention, *2009 H1N1 Pandemic* (June 11, 2019), https://www.cdc.gov/flu/pandemic-resources/2009-h1n1-pandemic.html
[19] Lisa Schnirring, *H1N1 Lessons Learned* (Apr. 30, 2010), https://www.cidrap.umn.edu/news-perspective/2010/04/h1n1-lessons-learned-vaccination-campaign-weathered-rough-road-paid
[20] Centers for Disease Control and Prevention, *Vaccine against 2009 H1N1 Virus* (Nov. 6, 2020), https://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm
[21] Lisa Schnirring, *H1N1 Lessons Learned* (Apr. 30, 2010), https://www.cidrap.umn.edu/news-perspective/2010/04/h1n1-lessons-learned-vaccination-campaign-weathered-rough-road-paid
[22] Robert Roos, *GAO details spending on, lessons from 2009, pandemic* (Jun. 28, 2011), https://www.cidrap.umn.edu/news-perspective/2011/06/gao-details-spending-lessons-2009-pandemic

alcohol swabs, etc.). [23] State and local health departments were responsible for distribution; many partnered with private parties to aid in distribution.[24] All providers were provided the necessary materials for vaccine distribution for free. Therefore, all Americans could receive the vaccine itself free of charge.[25] Even though some providers could still charge for vaccine administration, receiving the vaccine was either free or cheap for all Americans.[26] With this in mind, it is essential that the federal government ensure that a COVID-19 vaccine is affordable for all Americans. However, patent rights on a COVID-19 vaccine might jeopardize this possibility.

While the federal government did not issue national mandatory vaccination for H1N1, several states did. New York State issued a mandate requiring all health care workers with direct patient contact to get the H1N1 vaccine or risk losing their jobs.[27] That mandate was quickly challenged in court, and a temporary restraining order against the mandate was granted.[28] Governor Paterson later yielded to legal pressure and suspended the mandatory vaccination.[29] We could see similar challenges if mandatory vaccination laws are passed for coronavirus vaccine(s).

III. Barriers to the Availability of an Affordable COVID-19 vaccine

A requisite requirement for equitable distribution is affordability. Without an affordable vaccine, equitable distribution is impossible. Fortunately, however, during public health

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[23] John G. Bartlett, MD, *2009 H1N1 Influenza: Vaccine Essentials* (Nov. 23, 2009), https://www.medscape.com/viewarticle/709468_5
[24] *Id*.
[25] Centers for Disease Control and Prevention, *2009 H1N1 Vaccine Financing* (Nov. 30, 2009), https://www.cdc.gov/h1n1flu/vaccination/statelocal/vaccine_financing.htm
[26] Doug Kamerow, *Debate over H1N1 Vaccine? There Shouldn't Be One* (Oct. 13, 2009), https://www.npr.org/templates/story/story.php?storyId=113746160
[27] Kelly Lowenberg, *Mandatory H1N1 Vaccinations* (Oct. 13, 2009), https://lawandbiosciences.wordpress.com/2009/10/13/mandatory-h1n1-vaccinations/
[28] Kelly, Lowenberg, *Update of New York Mandatory H1N1 Vaccinations* (Oct. 22, 2009), https://law.stanford.edu/2009/10/22/update-on-new-york-mandatory-h1n1-vaccinations/
[29] Sewell Chan, *Paterson Suspends Flu Vaccination Rule* (Oct. 22, 2009), https://cityroom.blogs.nytimes.com/2009/10/22/paterson-rescinds-flu-vaccination-rule/

emergencies the federal government can pull legal levers to ensure an affordable vaccine for all Americans. Monetary barriers preventing low-income groups—who predominantly make up high-risk groups for COVID-19 complications—from receiving a vaccine, would have two troubling results. The first is, of course, that those who need the vaccine most would be in a disadvantaged position to become vaccinated and vaccinations would skew toward higher-income individuals. The second, as a result of the first, is more high-risk individuals would unnecessarily die while low-risk persons would be unnecessarily protected. It is thus absolutely necessary that the price of vaccination is not a consideration for individuals thinking about getting a COVID-19 vaccination.

Under the Coronavirus Aid, Relief, and Economic Security Act (CARES) Act, a COVID-19 vaccine is covered by most private insurance plans. However, the statute does not address the potential cost to the health care industry, persons without health insurance, or the federal government.[30] Thus, an authorized COVID-19 vaccine does not guarantee that the vaccine will be widely available or affordable.[31]

Additionally, Patent rights could affect the affordability of, and thus access to, a vaccine. Patents are a form of intellectual property that bestow upon inventors a 20-year temporary monopoly over the creation—in this case a vaccine.[32] That is, patent holders maintain exclusive rights to make, use, sell, and import the patented vaccine in the US.[33] Patent holders also have discretionary power to give permission to other to practice the invention.[34]

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[30] Kevin Hickey and Erin Ward, *Legal Issues in COVID-19 Vaccine Development* (June 8, 2020), https://crsreports.congress.gov/product/pdf/R/R46399
[31] *Id*. at 14
[32] Aarshi Tirkey, *Patenting the Cure: At what cost?* (Jun. 7, 2020), https://www.orfonline.org/expert-speak/patenting-cure-at-what-cost-67444/
[33] United States Patent and Trademark Office, *General information concerning patents* (Oct. 2015), https://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-2
[34] Kevin Hickey and Erin Ward, *Legal Issues in COVID-19 Vaccine Development* (June 8, 2020), https://crsreports.congress.gov/product/pdf/R/R46399

If regular patent rights apply to a company that develops a safe and effective COVID-19 vaccine, it could encourage profiteering because that company will have almost unfettered discretion to set a price point for the vaccine. Setting a high price point to increase profit would result restrict access to the vaccine for low-income Americans, many of whom are at high-risk for COVID-19 complications.

The federal government can prevent artificially high vaccine prices by offering federal assistance to companies to develop a COVID-19 Vaccine. Seven companies—including Pfizer and Moderna—are currently being funded by more than $9B from the federal government to develop a vaccine.[35] The controlling statute for intellectual property that arises from federal government-funded research is the Bayh-Dole Act of 1980.[36] Under the Act, when a private company relies on federal assistance to develop an invention, the resulting patent rights will generally be owned by the U.S. government itself.[37] The contractor may retain the patent rights in exchange for a government-use license, allowing the U.S. to practice the invention. In either scenario, the outcome is the same: avoidance of a temporary monopoly by the company or contractor by allowing the federal government to also practice the invention. For a safe and effective COVID-19 vaccine then, the federal government could "practice the invention" by producing its own supply and opting to subsidize the cost for all Americans.

If a vaccine is developed as a result of a funding agreement between a private company and the U.S. government, in addition to receiving a government-use license, the government can also pull its second Bayh-Dole lever by exercising its "March-In Rights." Under Bayh-Dole, the

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[35] Karen Weintraub and Elizabeth Weise, *Federal Spending on COVID-19 vaccine candidates* (Aug. 8, 2020), https://www.usatoday.com/story/news/health/2020/08/08/feds-spending-more-than-9-billion-covid-19-vaccine-candidates/5575206002/

[36] *See generally* 35 U.S.C. § 18

[37] *See* 37 C.F.R. § 501.6(a)

government can "march-in" and grant compulsory licenses to third parties in some circumstances, where any person who wants to practice the invention need not get permission from the patent holder as long as the government sanctions the license.[38] In essence, the federal government forces the government funded party to grant the intellectual property to another entity. [39] Increasing the amount of vaccines suppliers would result in market saturation, which often leads to competitive pricing, which would lower the cost of the vaccine.[40] The federal government could still subsidize the vaccine in this case.

There are four scenarios that trigger the federal government marching in, the most likely of which is to "alleviate health or safety needs which are not reasonably satisfied by the contractor."[41] It must be noted that the government marching-in is still theoretical because it has never been able to exercise these rights.[42] The National Institute of Health (NIH) rejected petitions in 1997 and 2004 to exercise march-in rights under Bayh-Dole, maintaining that pricing concerns alone do not justify a march-in under Bayh-Dole.[43] Therefore, based on past NIH decisions, the federal government would need to use "health and safety needs" as a basis to march-in, not affordability concerns. To hedge against price gouging, this could be the route the federal government takes. Suppose a vaccine manufacturer, relying on federal funding, produced a small supply of a COVID-19 vaccine and sold doses at a generally unaffordable price.[44] In

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[38] *See generally* John R. Thomas, *March-In Rights Under the Bayh-Dole Act* (Aug. 22, 2016), https://fas.org/sgp/crs/misc/R44597.pdf

[39] Ron Lanton III, Esq., *Setting the Record Straight on March-In Rights and Drug Prices* (Oct. 29, 2020), https://www.pharmacytimes.com/publications/specialty-pharmacy-times/2019/october-2019/setting-the-record-straight-on-march-in-rights-and-drug-prices

[40] Marshall Hargrave, *Market Saturation* (July 17, 2019), https://www.investopedia.com/terms/m/marketsaturation.asp

[41] 35 U.S.C. §203(a)(2)

[42] *Id.*

[43] *See* Harold Varmus, Director, NIH, Determination in the Case of Petition of CellPro,Inc., August 1, 1997 and Elias A. Zerhouni, Director, NIH, In the Case of Norvir Manufactured by Abbott Laboratories, Inc., July 29, 2004.

[44] The market will determine what is unaffordable, and the price at which the vaccine will be "generally unaffordable" will not be predicted in this paper.

response, the federal government could theoretically march in on the basis the party contracted with is not reasonably satisfying health or safety needs. Those needs primarily being widespread immunization to prevent the spread of COVID-19 and to achieve "herd immunity."[45] If a petition is granted, it would open a pathway for supplying most Americans with an affordable vaccine.

However, if a private company with no federal assistance develops a safe and effective vaccine, the company could elect to charge a higher price for the vaccine with reasonable certainty that many Americans would still buy it, given the level of severity of the virus and general fear of the pandemic. In this scenario, a higher-priced vaccine might exclude many individuals from low-income communities, who are generally those most at risk for adverse health outcomes with COVID-19, and who are less likely to have health insurance.[46] [47] Communities of color, who also are at a higher-risk of adverse health outcomes with COVID-19, are less likely to have health insurance, and therefore more likely to be excluded from receiving a privately manufactured vaccine if it is charged at higher price.[48] Indeed, even in a pandemic, private manufacturers face pressure from their shareholders to extract as much profit as possible.[49] Thus, a dreadful situation lurks around the corner: the people who need protection most are unable to get it from the vaccine because they cannot afford it, while people who can

[45] The scientific community does not all agree that heard immunity is possible, but experts that do believe in it suggest that herd immunity can be achieved when approximately 80% of the population is immunized.
[46] Wyatt Koma et al, *Low Income and Communities of Color at Higher Risk of Serious Illness if Infected with Coronavirus* (May 7, 2020), https://www.kff.org/coronavirus-covid-19/issue-brief/low-income-and-communities-of-color-at-higher-risk-of-serious-illness-if-infected-with-coronavirus/H
[47] Low-income individuals are more likely to be deemed essential workers, which means they cannot participate in a total quarantine and come in contact with others who might be infected. Moreover, many low-income individuals rely on public transport to get to their jobs, increasing the chance of exposure to COVID-19. Finally, low-income individuals are more likely to have underlying conditions and comorbidities like diabetes, asthma, hypertension, and obesity, which puts them at an increased risk of severe illness from the coronavirus.
[48] Institute of Medicine (US) Committee on the Consequences of Uninsurance, *Coverage Matters: Insurance and Health Care* (2001), https://www.ncbi.nlm.nih.gov/books/NBK223657/
[49] Michael Liu et al, *March-In Rights and Compulsory Licensing* (May 6, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200501.798711/full/

afford, but who are not high-risk, will get, or those people who can afford it will not get it because they are not in a high-risk population. It would be cruel irony.

If this scenario comes to pass, the government can pull its third lever: a compulsory patent license. Applicable to any patented invention, not just inventions made with federal funding, 28 U.S.C. § 1498 gives authority to the federal government to practice (and manufacture) any patented invention "without license."[50] The stipulation with 28 U.S.C §1498 is that the entity whose patent is forcibly extended to the federal government can recover in the Court of Federal Claims reasonable and entire compensation for the use and manufacture of the invention by the government.[51] Essentially, government use under §1498 is like the power of eminent domain within the patent realm.

Pfizer did not take federal funding to help develop of manufacture its vaccine but did strike a $1.95 billion deal with the U.S government in July to deliver 100 million doses.[52] Those 100 million vaccines may be affordable because a deal is already in place, but it does not guarantee that the next batch of doses will be. In the agreement, almost all intellectual property rights are excluded from the government, surrendering the most obvious leverage if Pfizer decides to engage in price gouging in the future.[53] With the pandemic worsening across the U.S., and where most people see a public health crisis of epic proportions, Pfizer might see a business opportunity to charge exorbitantly, or even marginally higher prices for its vaccine, betting that people will pay because of a combination of pandemic exhaustion and generalized fear of contracting the

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[50] Kevin Hickey and Erin Ward, *Legal Issues in COVID-19 Vaccine Development* (June 8, 2020), https://crsreports.congress.gov/product/pdf/R/R46399

[51] *See* 28 U.S.C. § 1498(a)

[52] The New York Times, *Was the Pfizer vaccine part of the government's Operation Warp Speed?* (Nov. 10, 2020), https://www.nytimes.com/2020/11/10/health/was-the-pfizer-vaccine-part-of-the-governments-operation-warp-speed.html

[53] Sydney Lupkin, *Pfizer's Coronavirus Vaccine Contract Excludes Many Taxpayer Protections* (Nov. 24, 2020), https://www.npr.org/sections/health-shots/2020/11/24/938591815/pfizers-coronavirus-vaccine-supply-contract-excludes-many-taxpayer-protections

illness and reaping the monetary paybacks. In this situation, the federal government could attempt to issue a compulsory patent license. And there is precedent for the government to successfully implement, or threaten to implement, §1498 in the context of pharmaceuticals.[54] Seeking to stockpile the antibiotic ciprofloxacin (Cipro) during the 2001 anthrax scare, the federal government threatened to invoke §1498 against Bayer, the company who made Cipro at the time. Bayer acquiesced to the threat and subsequently provided a 50 percent price discount and guaranteed an adequate supply.[55] Thus, if a company like Pfizer chooses to engage in price gouging down the road, the federal government may rely on §1498 as a safety net to ensure access to a COVID-19 vaccine.

IV. Barriers to the Equitable Distribution of a COVID-19

If vaccine dosages are scarce, equitable distribution becomes legally riskier, as some groups are prioritized over others. As seen with H1N1, Pregnant women, people who lived with or cared for infants younger than 6 months, healthcare workers, people 6 months to 24 years old, and people ages 25 to 64 with underlying health conditions that increased their risk of complications were targeted with the initial vaccine.[56] There was no legal bar to non-high-risk individuals receiving initial vaccine doses, but given the disparity in severity of health outcomes between high risk and low risk groups, there could be with COVID-19. So, while equal protection claims were not brought during the H1N1 distribution, they are certainly still a possibility for COVID-19 because (1) of the disproportionate impact that COVID-19 is having in communities of color (2) laws could be passed to prioritize individuals from those communities first.

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[54] Michael Liu et al., *March-In Rights And Compulsory Licensing—Safety Nets For Access to A COVID-19 Vaccine* (May 6, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200501.798711/full/.
[55] *Id*.
[56] Shawn Radcliffe, *Here's What Happened the Last Time We Had a Vaccine During a Pandemic* (Nov. 5, 2020), https://www.healthline.com/health-news/what-happened-the-last-time-we-had-a-vaccine-during-a-pandemic#Applying-lessons-to-COVID-19-vaccine-rollout

When a COVID-19 vaccine becomes available, and assuming that it is affordable, it is still unlikely that enough doses will be initially available to cover large portions of the American population.[57] This requires that guidelines be established to determine who should receive a vaccine first, second, third, and so on. It is firmly established that communities of color, including Black, Hispanic or Latinx, American Indian and Alaska Native, and Native Hawaiian and Pacific Islanders, disproportionately bear the burden of COVID-19.[58] Thus, when establishing an equitable distribution framework for a COVID-19 vaccine, it is imperative that these populations are prioritized to decrease transmission, illness, and deaths within these populations and among the U.S. population as a whole.

To be sure, existing frameworks for the distribution of a vaccine for COVID-19 recognize the disparate impact of the disease on communities of color and incorporate further prioritization of those communities.[59] For instance, the U.S. National Academy of Medicine (NAM) proposed an equitable framework in response to the novel coronavirus, guided by three principles: (1) benefiting people and limiting harm; (2) prioritizing disadvantaged populations; and (3) equal concern.[60] Logistically, this framework conceives of vaccine distribution rolling out in phases, with high risk workers and first responders receiving the vaccine first ("Phase 1a"), people with comorbid and underlying conditions and elderly persons living in crowded settings receiving the vaccine next ("Phase 1b"), and so on, with the guidance that for each phase's target population,

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[57] Katie Thomas and Jesse Drucker, *When Will You Be Able to Get a Coronavirus Vaccine?* (Sep. 17, 2020), https://www.nytimes.com/2020/09/17/health/covid-vaccine-when-available.html

[58] The National Academy of Medicine, *Framework for Equitable Allocation of COVID-19 Vaccine* (Oct. 2020), https://www.nap.edu/resource/25917/Framework%20for%20Equitable%20Allocation%20of%20COVID-19%20Vaccine_Highlights.pdf

[59] *Id.*

[60] Govind Persad et al., *Fairly Prioritizing Groups for Access to COVID-19 Vaccines* (Sep. 10, 2020), https://jamanetwork.com/journals/jama/fullarticle/2770684?guestAccessKey=0f8fea67-d3ea-4b1d-96fe-c7eaa7f5089e&utm_source=silverchair&utm_medium=email&utm_campaign=article_alert-jama&utm_content=olf&utm_term=091020

priority should be given to vaccinating racial and ethnic minorities within that phase's population.[61]

While these guidelines are useful, passing legislation is the best way to protect communities of color and ensure that they *are* prioritized. COVID-19 may be novel in its discovery, but the disproportionate adverse effect it is having on communities of color is consistent with previous infectious diseases.[62] While communities of color have always been at-risk populations for infectious diseases, the effects from COVID-19 on communities of color has been highlighted by concurrent social justice movements in the United States.[63] The precedent for passing targeted legislation is obvious and the convergence of the two situations creates an opportunity to address systemic racism. It is paramount that advantage of the opportunity is taken. To that end, the question becomes whether Congress can pass constitutional legislation that, in receiving a COVID-19 vaccine, communities of color are further prioritized in each phase of vaccine distribution.

Targeted COVID vaccine legislation prioritizing communities of color could result in challenges under the 14th Amendment Equal Protection Clause. Legislation that targets vaccine distribution toward communities of color would be an express race-based classification, as opposed to a facially neutral distinction. That is, the text of the legislation treats communities of different compared to all other communities; the classifications being "individuals from communities of color" and "individuals from all other communities." Where a race-based

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[61] *Id*. Also note also that "phase 1a" is approximately 5% of the US population and "phase 1b" is approximately 10% of the US population.
[62] Centers for Disease Control and Prevention, *TB in Specific Populations* (Nov. 29, 2020), https://www.cdc.gov/tb/topic/populations/tbinafricanamericans/default.htm
[63] Reza Nahkaie and F.S Nahkaie, *Black Lives Matter movement finds new urgency and allies because of COVID-19* (Nov. 25, 2020), https://theconversation.com/black-lives-matter-movement-finds-new-urgency-and-allies-because-of-covid-19-141500

classification exists, strict scrutiny applies.[64] To survive strict scrutiny, the government must provide a "compelling interest" for creating the classification and the means chosen must be "narrowly tailored" to achieve that interest. Contained in the general rule are stipulations that the means chosen cannot be overinclusive nor underinclusive, and race-neutral alternative means must have been meaningfully considered first.[65]

Courts will likely evaluate the constitutionality of a vaccine distribution program that contains explicit race-based classifications using affirmative action (AA) jurisprudence. The AA analysis has been applied in the context of education—primary, secondary, and higher education—and construction contracts.[66] Affirmative actions generally are deliberate decisions by a community to remedy racial discrimination—where no identified de jure discrimination exists—based on the acknowledgement of the continued effects of past segregation and white supremacy on modern society. In this way, the nature of the legislation is distinct from the usual equal protection claims brought to challenge the negative effects of classification-based legislation on a protected class. Regardless of ill-will or good intent, the legislation may target a group and thus strict scrutiny applies. While the controversy of affirmative action is duly noted here, it is still the case that affirmative action is doctrinally active, and thus informative, as it offers parallels to future targeted vaccine legislation for COVID-19. That is, the underlying history and reasoning that is proffered as justification for affirmative action is similar to the justification for targeting coronavirus vaccination legislation at communities of color.

Explicitly considering race to remedy the continued effects of past segregation has been upheld in university admissions processes when race is used only as one factor among many in

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[64] Loving v. Virginia, 388 U.S. 1, 87 S. Ct. 1817 (1967).

[65] *See* 1 Modern Constitutional Law § 10:13 (3rd ed.)

[66] *See generally* Grutter v. Bollinger, 539 U.S. 306 (2003); Gratz v. Bollinger, 539 U.S. 244 (2003); Richmond v. J.A. Croson Co., 488 U.S. 469 (1989); and Adarand Constructors v. Peña, 515 U.S. 200 (1995).

the admissions process. In *Grutter v. Bollinger*, the University of Michigan's Law School admissions maintained a policy of looking beyond applicant grades at "soft" variables to achieve a level of student body diversity with the potential to enrich every student's education. [67] The policy included an express commitment to racial and ethnic diversity, especially to those groups who have been historically discriminated against. Because the policy considered race as a factor in admissions, and even though it was well-intentioned, the policy created an express race-based classification and thus was subject to strict scrutiny by the Court. First examining the government's offered interest, the Court then analyzed their "true interest", intending to "smoke out"[68] any invidious purposes, but found none here. Thus, the Court accepted "achieving the benefits that flow from diversity" as a compelling interest, while the means chosen—the University's admissions policy—was determined to be narrowly tailored to achieve that diversity because it was simply a race conscious measure (as opposed to a racial quota or racial balancing[69]) and the University extensively considered race-neutral alternatives. Using race was necessary to achieve the benefits that flow from diversity because to know what race or ethnicity an applicant is, it's necessary to consider their race or ethnicity.[70]

However, where a university's admissions process does not provide enough "individualized consideration" of applicants deemed necessary in *Grutter*, the Court ruled that such a policy does not pass strict scrutiny.[71] Decided on the same day as *Grutter*, in *Gratz v. Bollinger*, the University of Michigan's undergraduate admissions program used a "selection index", where an applicant could score up to 150 points based on a wide array of factors. If an

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[67] Grutter v. Bollinger, 539 U.S. 306 (2003).
[68] *See Croson, 488 U.S.* at 493.
[69] *See* Gratz v. Bollinger, 539 U.S. 244 (2003).
[70] *Id*.
[71] University of Rhode Island, *Affirmative Action History* (Nov. 21, 2020), https://web.uri.edu/affirmativeaction/affirmative-action-history/

applicant was a member of an underrepresented racial or ethnic minority, they were given an automatic 20 points in the selection index. The Court struck down the University's admissions program because it automatically gave preference to an applicant solely because of their race without additional individualized consideration.[72] Without a more individualized, holistic approach, the University's policy was more like a racial quota rather than a race conscious measure. Moreover, alternative race-neutral measures were not considered because the undergraduate admissions program decided that it was not administratively feasible to engage in a more individualized review that the law school did because of the sheer number of applicants the undergraduate program received. The Court rejected this argument, asserting that administrative challenges are not an excuse for not considering race-neutral alternatives.[73] Therefore, for an affirmative action program to be upheld, the degree of individualized consideration within a program must be proportional to the stated government interest sought to be achieved.

Vaccine mandates ensuring that communities of color are the first to receive a vaccine is similar to affirmative action because it would be a deliberate decision, by lawmakers as representatives of their communities, to remedy the continued effects of racial discrimination and white supremacy on the health vulnerabilities in communities of color. Just as *Grutter* held that race can be considered a factor in the admissions process, the same can be said for a vaccine mandate that prioritizes individuals from communities of color. While race *is* emphasized, it is also considered alongside other criteria, like whether an individual is an essential worker or has comorbidities or underlying conditions. Consideration of non-racial risk factors of either contracting or suffering a serious illness are the only other factors necessary to prevent the

[72] Bollinger, 539 U.S. 244
[73] *Id.*

spread of COVID-19. Whereas achieving "benefits that flow from diversity" requires a more extensive suite of factors to be considered because diversity is a far more subjective standard than is "preventing the spread of" an infectious disease. Thus, further prioritization of communities of color is proportionally considering race only as a factor among others; a secondary consideration to the primary at-risk population being targeted in each phase. In other words, a primary at-risk population group would be targeted with the vaccine, like healthcare workers, but within that group, communities of color would be legally prioritized. This type of consideration of race as a factor is dissimilar to the undergraduate program in *Gratz* because individuals from communities of color are not automatically prioritized but are prioritized only when there is a convergence of race and another health vulnerability, like having an underlying condition. In other words, just because a individual is from a community of color does not mean that they will be automatically prioritized to receive the vaccine.

The compelling government interest in the pandemic context distinguishes this type of affirmative action from affirmative action in the context of education, where the Court grappled with whether racial balancing was the true government interest. If we apply to the affirmative action framework to legislation aimed at protecting communities of color from the coronavirus, the compelling government interest is preventing the spread of COVID-19 within communities of color, individuals within which, on aggregate, have a documented increased risk of adverse health outcomes if infected with coronavirus. While perhaps not a self-evident proposition, preventing the spread of a deadly infectious disease—saving people from unnecessary premature deaths—is intuitively more compelling a state interest than is promoting diversity in a student body.

The means chosen is the Congressional enacted mandate that for each distribution population phase (phase 1a, 1b, etc.), individuals from communities of color will be prioritized in receiving the vaccine over individuals not from communities of color. One race-neutral alternative is the NAD's phased distribution framework, where the phases are based on (1) risk of acquiring infection, (2) risk of severe morbidity and mortality, (3) risk of negative societal impact, and (4) risk of transmitting infection to others.[74] Even if these principles theoretically would result in prioritizing distribution on the basis of race, they do not necessarily mean that individuals from communities of color will be prioritized within each phase in practice. For example, if there are not enough doses of a vaccine to cover all of the "phase 1a" population—high risk health workers and first responders—deciding who receives the limited vaccine supply will not necessarily be by prioritizing individuals from communities of color. Therefore, the government interest would be frustrated.

With any race-neutral alternative, communities of color cannot be prioritized without race being explicitly considered. Moreover, the mandate would be neither underinclusive nor overinclusive, because it restricts prioritization to each phase population. An individual from a community of color must be a high-risk health worker or first responder to be prioritized for phase 1a. In other words, occupational and other health requisites act as safeguards to under and over inclusivity. Thus, if legislation is passed mandating that individuals from communities of color be prioritized over individuals not from communities of color, the further prioritization of communities of color within the NAD's phased population framework is one route that an express race-based classification could pass strict scrutiny. While it may be the case that

[74] The National Academy of Medicine, *Framework for Equitable Allocation of COVID-19 Vaccine* (Oct. 2020), https://www.nap.edu/resource/25917/Framework%20for%20Equitable%20Allocation%20of%20COVID-19%20Vaccine_Highlights.pdf

individuals from communities of color would be prioritized without a mandate, targeted race conscious legislation ensures that they will be, and if in passing such legislation even one more vulnerable individual from a community of color is prioritized over someone who is less at-risk, it conforms to the NAD's first principle of utilitarianism: benefiting people and limiting harm.

V. Ensuring an Efficacious COVID-19 Vaccination Campaign: Mandatory Vaccination

Low levels of trust in government and scientists could jeopardize a successful COVID-19 vaccination campaign. The coronavirus pandemic comes at a time of enormous social unrest and political polarization. Public trust in our government is near historic lows: in a Pew Research study, only 14% of Americans in 2019 said they trust the government to make the right decisions "most of the time."[75] And while public confidence in scientists to act in the public interest is not eroding (and has actually increased since 2016), it hovers about 30%.[76].

Moreover, there are widespread public concerns about the COVID-19 vaccine development process— that a vaccine will be approved in the U.S. before its safety and effectiveness are fully understood.[77] Indeed, only 51% of U.S. adults said they would get a vaccine if it were available to them today.[78] Assuming those numbers are accurate, the alarming scenario is this: if receiving a vaccination is done on a strictly voluntary basis, and only 50% of U.S. adults elect to receive it, termination of the pandemic through herd immunity[79] by vaccination would not be possible, and many more people would die unnecessarily reaching herd immunity through natural infection.[80]

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[75] Pew Research Center, *Public Trust in Government: 1958-2019* (Apr. 11, 2020), https://www.pewresearch.org/politics/2019/04/11/public-trust-in-government-1958-2019/
[76] Pew Research Center, *Key findings about Americans' confidence in science* (Feb. 12, 2020), https://www.pewresearch.org/fact-tank/2020/02/12/key-findings-about-americans-confidence-in-science-and-their-views-on-scientists-role-in-society/
[77] *Id.*
[78] Pew Research Center, *U.S. Public Now Divided Over Whether To Get COVID-19 Vaccine* (Sep. 17, 2020), https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/
[79] Herd immunity occurs when a large proportion of the population becomes immune to a disease.
[80] Serena McNiff, *What If Many Americans Say No to a COVID Vaccine?* (Aug. 25, 2020), https://www.webmd.com/lung/news/20200825/what-if-many-americans-say-no-to-a-coronavirus-vaccine#1

Experts estimate that 70% of the population must be immune to COVID-19 to terminate transmission.[81] If achieving herd immunity through vaccination is the path—with the least amount of COVID deaths— out of the virus battlefield, the issue is, then, whether the U.S. government can require vaccinations of everyone in the United States.[82] Indeed, it is not enough that individuals most in need are able to receive the vaccine, those individuals must also be willing to receive it.[83]

Although adjudicated in 1905 and perhaps outdated, *Jacobson v. Massachusetts* remains steadfast as the controlling authority in public health law on the issue of the constitutionality of mandating vaccines and other public health measure.[84] In the case, the Court upheld a mandatory vaccination law for smallpox under Massachusetts's police powers.[85] Justice John Harlan, guided by the notion that "the Constitution does not bestow unrestrained freedom upon a person," determined that Massachusetts's citizens' rights subjected to restraint was constitutional because the statute bore a real and substantial relation to the protection of public health and safety.[86] However, *Jacobson* is distinguished from the issue presented here because the holding applies only to States' police powers, not the enumerated powers that apply to the federal government. In other words, the federal government could not rely on *Jacobson* as precedent to enact a similar national mandatory vaccination because public health matters are left to the States. That being said, the government might be able to make use of the Taxing and Spending Clause and

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[81] Angela K. Shen et al., *Ensuring Equitable Access to COVID-19 Vaccines In The US* (Nov. 19, 2020), https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01554
[82] Of course, those for whom it is not medically advisable to be vaccinated would be exempted.
[83] *See* Sections III and IV.
[84] Anthony Sanders, *A Tale of Two Case and Two Pandemics* (Nov. 30, 2020), https://ij.org/cje-post/a-tale-of-two-cases-and-two-pandemics/.
[85] Jacobson v. Massachusetts, 197 U.S. 11 (1905).
[86] *Id*.

the Commerce Clause to encourage States to enact mandatory COVID-19 vaccination laws that would be tantamount to a national mandatory vaccination law.[87]

Underutilized, but obviously influential, the taxing and spending clause empowers the U.S. government to "collect taxes…and provide for the general welfare of the United States."[88] Alexander Hamilton conceived that, and the Court today generally agrees, the spending clause is a plenary power.[89] Through this power, Congress may condition a state's receipt of federal funds on the state's agreement to abide by certain federal directives, such as adopting federal policies or administering federal programs.[90] The boundaries of the spending power allow Congress much room to graze, and as Justice Rehnquist notes, "[t]he Government can, without violating the Constitution, selectively fund a program to encourage certain activities it believes to be in the public interest."[91]

South Dakota v. Dole remains the controlling authority for Congress's spending power. The Court upheld a federal statute that withheld a portion of federal highway funds from states that did not prohibit the purchase of alcohol by people under 21 because it was a relatively mild encouragement for States to enact higher minimum drinking ages than they otherwise would. The Court in *Dole* presents a framework that Congress must operate within. For conditional spending to be constitutional, the conditions attached to the receipt of federal funds must: (1) be in pursuit of the general welfare; (2) be unambiguously stated so that recipients can knowingly accept or reject them (the clear statement rule)[92]; (3) be related to the federal interest in particular

[87] If Congress uses an enumerated power to encourage States to enact a mandatory vaccination law that they would not have otherwise enacted, logically it can be said that the national government mandated those laws, and if every state enacts one, then the national government essentially enacted a national COVID-19 vaccination law.
[88] U.S. Const. art. I, § 8, cl. 1.
[89] *See generally* David E. Engdahl, *The Spending* Power, 44 Duke L.J. 1 (1994).
[90] 483 U.S. 203 (1987)
[91] Rust v. Sullivan, 500 U.S. 173, 193 (1991).
[92] If a clear statement rule is present, the conditions in the statute offer only one interpretation of the terms, much like the terms of a contract.

national projects or programs; and (4) not violate a separate constitutional provision.[93] In general, courts defer substantially to the judgment of Congress for any expenditure in pursuit of the general welfare.[94] Thus, if Congress abides by these principles, and does not cross the boundary into coercion, the spending power is a viable pathway to incentivize states to vaccinate all their citizens.

Yet, there is a nuance in the doctrine that carves out at least one judicial restraint on Congress's power to spend "for the general welfare." In *National Federation of Independent Business v. Sebelius*, the Court severed the Medicaid expansion program under the Affordable Care Act (ACA), because Congress threatened to withhold States' existing Medicaid funds if they did not implement the expansion program.[95] To the Court, the conditions breached the wall that separates inducement from coercion. Whereas the inducement in dole was "relatively mild encouragement", to Chief Justice Roberts, the Medicaid expansion program was "a gun to the head."[96] The conditions attached to the Medicaid expansion program undermined state sovereignty such that States could not voluntarily accept the terms but were compelled to. After *Sebelius*, we know that a boundary *does* exist, where the Court determines that Congress' conditional spending meant to induce action instead compels action, akin to undue influence.[97] But that boundary, to say the least, is unclear. But, both in *Dole* and *Sebellius*, the Court refused to articulate a rule describing the boundary, and instead proceeded on a "we'll know it when we see it" basis. What is certain is that *Sebelius* adds a layer of risk— because of the ill-defined rule

[93] *Id*. at 206.
[94] *Id*. at 207.
[95] *See* National Federation of Independent Business v. Sebelius, 567 U.S. 519 (2012).
[96] *Id*. at 51.
[97] *Id*. at 47.

for when inducement becomes coercion— if Congress utilizes its spending power to marshal nationwide mandatory vaccination laws.

In theory, Congress could incentivize States, under the Spending Clause, to enact mandatory vaccination laws that meet certain criteria by imposing it as a condition of receiving federal funds.[98] Applying the *Dole* framework and using the ACA as a template, let us consider what spending power legislation for a coronavirus vaccine might look like. There are obviously a lot of ways to encourage states but suppose Congress will subsidize a state's vaccination program—fronting all of the costs— on the condition that they enact a statewide mandatory vaccination law that meets basic criteria set forth by the federal government's newly created COVID-19 vaccination program. The major condition to receive funding is that the State must enact a mandatory vaccination law and that any individual able to receive one but does not will be taxed. Undoubtedly, Congress's action would be in pursuit of the general welfare. Preventing the spread of COVID-19 will, at the very least, lead to a healthier population and thus the first condition is satisfied. Satisfying the second condition is also quite simple: Congress, in laying out the basic criteria needed to be included in the state's vaccine mandate, uses language that make those criteria unambiguous. The third condition is satisfied because the condition here—imposition of a tax on individuals who do not get vaccinated—
is related to the federal interest in seeing out a successful COVID-19 vaccination program.

However, there is an argument that the 10th Amendment precludes Congress from enacting a national vaccine program because public health is a power designated to the states. Yet, the Court has found that, where a spending power act raises federalism concerns, "there is no violation of [the] state's sovereignty because the state could simply refuse the federal funds in

[98] Congressional Research Service, *Could the President or Congress Enact A Nationwide Mask Mandate?* (Aug. 6, 2020), https://crsreports.congress.gov/product/pdf/LSB/LSB10530

question."[99] To be sure, States could technically refuse the government subsidization for their vaccination program, but there is reason to think that because this scenario would similar to *Sebelius*, the Court could rule that the incentive from Congress does not leave any room for States to exercise their will. Essentially, they must take the government funding and enact a statewide mandatory vaccination law because it is so attractive an offer.

Refusal to accept federal funds in this scenario would have less of a ripple effect than the potential withholding of States' existing Medicaid funds in *Sebelius* would have had. For one, a state vaccination program would not be appropriated nearly the amount of funds that State Medicaid programs are (in some states, 15% of their overall budgets[100]). In addition, Congress would not be threatening to withhold any existing funding but instead extending an invitation of new funding. Refusing federal funding would mean that States would not lose any existing funding. Thus, the federal government's offer might not be "mild encouragement", but it certainly would not be a "gun to the head." It would lie somewhere between the two. Since the only reference point to when inducement becomes coercion is *Sebelius*, that also points in favor of constitutionality. Therefore, because of these differences between *Sebelius* and the conditional spending program hypothetical offered here, and in light of the deferential standard the Court applies to spending power legislation, there is reason to think that the preceding scenario would be found constitutional.[101]

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[99] *Id*. at 210.
[100] Medicaid and CHIP Payment and Access Commission, *Medicaid's share of total budget* (Nov. 24, 2020), https://www.macpac.gov/subtopic/medicaids-share-of-state-budgets/
[101] It must be reiterated that what a conditional spending statute for COVID-19 might look like could vary greatly and would be far more complex than the broad strokes brushed in this paper.

Congress might also be able to use its Commerce Clause powers—"the power to regulate Commerce with foreign nations and among the states"[102]—to effectuate the mandatory vaccination of every citizen in the United States. Indeed, Commerce Clause power can reach subject matter not intuitively anticipated, including public health.[103] During the New Deal Era, there were almost no bounds imposed for Congress's Commerce Power.[104] For the Commerce Power, the question is whether Congress could require proof of vaccination from anyone engaging in an activity considered interstate commerce.

Recently, however, the Supreme Court began defining the outer bounds of the Commerce Clause, limiting its scope in *Lopez* and *Morrison,* and then refunding some power back to Congress in *Raich.*[105] Asserting that there must be some discernible, *judicially enforceable* stopping point to Congress's commerce power, the Supreme Court in *Lopez* laid out the current test for determining whether a federal statute exceeds the scope of Congress's Commerce power.[106] Modern Commerce Clause doctrine permits Congress to regulate both economic and non-economic activity. Congress may regulate three broad categories of activity: (1) the channels of interstate commerce; (2) the instrumentalities of interstate commerce, or people or things in interstate commerce; (3) activities that substantially affect interstate commerce. If a regulated activity falls under the third category, the court applies the aggregation test and applies rational basis review.[107] Commerce Clause jurisprudence also recognizes four ways Congress can use its commerce power to regulate non-economic activities: (1) regulating the channels of interstate

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[102] U.S. Const. art. I, § 8, cl. 3.
[103] Lainie Rutkow and John S. Vernick, *The U.S. Constitution's Commerce Clause, the Supreme Court, and Public Health* (Sep. 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3151195/
[104] Andrew Nolan et al., *Federalism-Based Limitations on Congressional Power: An Overview* (Sep. 27, 2018), https://crsreports.congress.gov/product/pdf/R/R45323
[105] United States v. Lopez, 514 U.S. 549 (1995); United States v. Morrison, 529 U.S. 598 (2000); Gonzales v. Raich, 545 U.S 1 (2005)
[106] 514 U.S. 549 (1995).
[107] *See* Wickard v. Filburn, 317 U.S. 111 (1942)

commerce; (2) regulating and/or protecting the instrumentalities of interstate commerce, or people or things in interstate commerce; (3) if the statute has a "jurisdictional element"[108]; (4) if regulating the non-economic activity is an essential part of a broader regulation of economic activity.[109] However, the majority in *Sebelius* maintained that Congress cannot compel individuals to engage in commercial activity.[110] Underlying this test is the Court's attention to preserving federalism.

Say Congress were to enact a federal statute that required all U.S. adults to show proof of vaccination before engaging in all economic interstate commerce activities—such as traveling to another state or buying food at the grocery store—among many other activities. Essentially, Congress would be severely limiting an individual's ability to be a consumer and participate in the market. On its face, that would be an unprecedented move, but then again, so is a pandemic. The first step of the analysis is to place the regulated activity into one of the three broad categories. Quite obviously, being unable to participate in interstate commerce substantially affects interstate commerce. Under category three, we must also determine if the regulated activity is non-economic or economic; above, I described the statute as only requiring proof of vaccination before engaging in all *economic* interstate commerce activities.

Since the statute regulates an economic activity, the court then applies the *Wickard* aggregation test and reviews the regulation under rational basis scrutiny.[111] The aggregation test asks whether Congress could rationally conclude that the activity, when aggregated nationally, has a substantial effect on interstate commerce. The answer here is a resounding yes; if everyone

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[108] *See* 18 U.S.C § 922(q), as amended after *Lopez*.
[109] *See* 545 U.S 1 (2005).
[110] 567 U.S. 519 (2012).
[111] *See* Railway Express Agency, Inc. v. New York, 336 U.S. 106 (1949) (holding that economic and commercial matters are to receive rational basis review).

had to show proof of vaccination before engaging in economic interstate commerce activities, it would affect the national economy for all imported goods, travel from state to state, and large swaths of the employment sector, to name a few. Thus, rational basis review now applies. Under rational basis, the government must show a conceivable, legitimate interest and its means must be reasonably related to achieving that interest.[112]

Almost anything goes under rational basis review and the court will go to great lengths to come up with a legitimate interest. Public health is a compelling interest, so inserting as its interest "preventing the spread of COVID-19" would be an automatic legitimate government interest. The measure would not be arbitrary[113] because engaging in interstate commerce often requires being around other people and, where groups are gathered or people are in close proximity, disease can spread. Flying is a prime example of this concept: an indoor, relatively poorly ventilated area[114] with hundreds of people—breathing, talking, coughing— sitting inches from one another. Disease is less likely to spread if the individuals in those groups engaging in economic interstate commerce activities, like flying, are vaccinated and must prove it. Thus, requiring proof of vaccination to engage in all economic interstate commerce activities as encouragement for U.S. adults to get vaccinated is reasonably related to preventing the spread of COVID-19 under the highly deferential standard of rational basis review. Still, the Supreme Court's standard can be subjective, reducing the certainty of a prediction of legality for federal laws affecting public health.[115]

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[112] *See* San Antonio Independent School District v. Rodriguez, 411 U.S. 1 (1973).
[113] *See* Lochner v. New York, 198 U.S. 45 (1905) (holding that a labor law limiting the number of hours an employee can work in a day is arbitrary).
[114] Michael Laris, *Scientists know ways to help stop viruses from spreading on planes* (Apr. 29, 2020), https://www.washingtonpost.com/local/trafficandcommuting/scientists-think-they-know-ways-to-combat-viruses-on-airplanes-theyre-too-late-for-this-pandemic/2020/04/20/83279318-76ab-11ea-87da-77a8136c1a6d_story.html
[115] Lainie Rutkow and John S. Vernick, *The U.S. Constitution's Commerce Clause, the Supreme Court, and Public Health* (Sep. 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3151195/

Thus, the federal government, while likely unable to directly mandate a national vaccination law because it would infringe on States' police powers, may effectively be able to mandate that all citizens (or at least all adults) in the U.S. be vaccinated through the use of the Spending Clause or the Commerce Clause.

VI. Conclusion

The content that I've posed in this paper—the potential legal avenues and hypothetical situations—with one caveat, are unlikely to occur.

The caveat—Concerning the affordability of the COVID-19 vaccine: Given the neo-liberal version of capitalism that dominates our economy, and really, every aspect of our society, it is rather easy to envision a scenario where a company like Pfizer, who did not accept federal funding upfront, might try to increase prices of a COVID-19 vaccine to maximize profitability and by doing so, restricts access of the vaccine to low-income individuals. Yet, with how quickly Bayer yielded in 2001 to the federal government's threat of invoking §1498, the government could preempt or quash any price gouging of a COVID-19 vaccine through another threat of invocation. Because if government use under §1498 is issued, the price of the vaccine would drop below what the company it is issued against could have charged if they acquiesced to the government's threat. To maximize profits, a company manufacturing a COVID-19 vaccine would give into lowering their prices and agreeing to produce an adequate supply. Therefore, I do not think that affordability will be an issue with a COVID-19 vaccine.

Though we have seen a rise in awareness of and activism to combat structural racism and white supremacy within the past year through the Black Lives Matter movement (BLM) and related grassroots campaigns, it is unlikely that targeted COVID-19 vaccine legislation prioritizing communities of color will be passed. I do think it would be legal (based on the

discussion above) but I do not think it is politically viable. Substantive legislative progression that combats structural racism has not yet reached the white-washed halls of the Capitol building.

However, the COVID-19 pandemic is the ultimate opportunity to jump start a series of targeted legislation that seeks to repair the hundreds of years of discrimination and generational wealth inequality that has left Black and brown communities to fend for themselves with little to no tangible resources or recourse for justice. To be sure, BLM is gaining more traction than any racially motivated social movement since the 1960s, but it has not yet reached the critical mass of political buy-in to be truly successful as a component in COVID-19 vaccine legislation. That being said, the impact of BLM on municipal legislation suggests that national reparative legislation for communities of color is coming, but the coronavirus pandemic is not the stage where it will make its enduring debut.

The rise in States' rights doctrine since the Rehnquist Court is predictive of whether a federal government mandate of a national COVID-19 vaccination would be held constitutional: it wouldn't.[116] Amy Coney Barrett's recent appointment to the Supreme Court solidified a conservative majority, there has been no national response to the pandemic, only piecemeal, state-by-state response that has resulted in a staggering gap in public health measures, and pandemic exhaustion is seemingly taking its toll on lawmakers who cannot pass a relief bill and who seem to have resigned to letting the virus take its course. These three factors are sufficient to predict that (1) a national vaccine mandate will not be passed and even if passed (2) it would be instantaneously challenged as unconstitutional for invading on States' police powers and soon thereafter struck down by the newly minted conservative majority on the Supreme Court.

[116] This outcome was alluded to at the beginning of section V.

Use of Spending Power or the Commerce Clause to ensure widespread national vaccination is more likely to come to pass, but still unlikely to occur. Public attitude towards lockdowns, social distancing, and wearing face coverings suggests that Americans are reaching the end of their rope in adhering to public health measures that prevent the spread of COVID-19. The "pandemic exhaustion" is reaching its apex. Moderna recently announced that its vaccine is 94% effective and will be available as early as December 2020. The convergence of public dissolution toward preventing COVID-19 spread and Moderna's unprecedented effective vaccine suggests that Americans will readily receive the vaccine when it becomes widely available. The noisy minority that is the equivalent to anti-vaxxers is just that: noise. I do not think their boisterous rejection of being vaccinated reflects the reality of what Americans will do when they have the option of possibly returning to a normal life. In other words, use of the Spending Power or Commerce Clause to ensure widespread vaccination will be unnecessary because Americans so desperately want life to go back to "normal."

Finally, if the Spending Power or Commerce Clause is used to ensure total national vaccination, this legislation will have a better chance of being passed in Congress and upheld as constitutional in court because the legislation would be economic in nature and Congress has enjoyed an almost unfettered discretion in exercising these two powers. The Spending Clause is the most workable option. Since the only two data points we have for whether Congress oversteps its Spending power are *Dole* and *Sebelius*, and any conditional spending program implemented would not be nearly as large as or deep-rooted as States' Medicaid programs, if the program is more like *Dole*, then States may seriously consider adopting vaccine mandates to avoid economic hardship from both a conditional spending program and the continued prevalence of COVID-19 within their state.