

Science May Be the Easy Part

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COVID-19 Vaccine
Is Used

By Joel M. Zinberg, M.D., J.D.

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Executive Summary

The COVID-19 pandemic has already infected more than 7 million Americans, claiming over 200,000 lives in the U.S. Since the disease is caused by a new virus, SARS-CoV-2, to which people lack immunity, the pandemic will not end until a new vaccine is developed to elicit an immune response and antibodies that protect against infection.

One or more vaccines will likely be approved in the coming months, but having a vaccine available does not ensure that people will use it. Evidence from vaccination for other diseases and public opinion surveys suggest that many will refuse to be vaccinated for COVID-19. Without widespread vaccination, it will be difficult to reach herd immunity and end the pandemic.

This paper examines whether mandatory vaccination programs will be needed, if mandatory vaccination is supported by the law, and if and how such a program could be targeted in a way that maximizes public health while respecting individual rights, including religious objections.

When, and if, a COVID-19 vaccine is finally approved or authorized by the Food and Drug Administration, it likely will be in limited supply. Vaccination should be targeted toward those who are most vulnerable to COVID-19—the elderly, people with concurrent medical conditions known as co-morbidities, minority groups (especially African Americans), and residents of long-term care facilities—and those who are most likely to transmit the disease. Health care workers in the acute and long-term care settings should also get priority, since they are exposed on a daily basis to infection and may expose their patients, many of whom are in vulnerable groups, to transmission. As supply increases, vaccination can be offered to the general population.

In both Europe and the United States, almost all the COVID-19 deaths have been in people 60 and older. Nearly all of those who died had at least one co-morbid condition. The severity of disease as represented by COVID-19 hospitalization rates per 100,000 population rises sharply with age. The hospitalization rate for those 65 and older is nearly twice that of those ages 50-64, four times that of people ages 18-49, and 42 times the rate for those aged 0-17. The coincidence of older age and co-morbidities as risk factors for COVID-19 death is not surprising. The incidence of diseases associated with COVID mortality, like hypertension, diabetes, and heart disease, increases with increasing age.

Both advanced age and multiple co-morbidities converge in residents of long-term care facilities like nursing homes and residential care communities, who account for 45 percent of total COVID deaths. Studies show that SARS-CoV-2 infection spreads rapidly and efficiently in nursing facilities and can spread from people who are symptomatic or asymptomatic. This suggests that all residents and staff of long-term care facilities are vulnerable to infection and are potential sources of spread to others, regardless of symptoms.

Members of racial and ethnic minority groups also appear to be at increased risk of contracting COVID-19 or experiencing severe illness and death. Black and Hispanic workers are far less likely to be able to work from home than whites, which makes them more susceptible to being infected in the first place. And they have much higher age-adjusted rates of hospitalization than whites.

Yet, when populations are weighted to reflect where COVID-19 outbreaks have been occurring, non-Hispanic blacks, but not Hispanics, are at disproportionate risk of death from COVID-19

compared to whites. Their higher COVID-19 death rate is due to higher rates of co-morbidities, the types of jobs they have, where they live, and other factors that deserve further study.

Despite the highly publicized pandemic having affected every aspect of our daily lives, there are indications that many Americans, including those in vulnerable groups, will not agree to be vaccinated. Only 45 percent of Americans have been vaccinated against another easily transmitted respiratory virus disease—influenza—in recent flu seasons, the two reasons cited for skipping flu shots are safety concerns and doubts about the effectiveness of and need for vaccination.

There appear to be similar concerns about prospective COVID-19 vaccines. Multiple opinion surveys in May 2020, at the height of the pandemic, show that while a majority Americans said they will likely be vaccinated against COVID-19, fewer were a definite yes and many worried about vaccine safety and expressed doubts about the need for vaccination and effectiveness of the vaccine. While the vulnerable elderly were more likely to say they would get vaccinated than younger Americans, only 25 percent of non-Hispanic black Americans definitely plan on getting vaccinated, less than whites (56 percent) and Hispanics (37 percent). Forty percent of blacks were a definite no.

The lack of enthusiasm for vaccination, especially among some vulnerable groups, is both surprising and concerning. Normally, demand for vaccinations is high when infectious disease prevalence is high. If less than half of people said they would definitely be vaccinated at the height of the pandemic, demand for vaccination may be far lower when a vaccine is finally approved and prevalence of the disease may be lower.

If voluntary consent to vaccination were to prove inadequate, it may be necessary to mandate vaccination, especially for groups that are most vulnerable to the illness or are in a position to transmit illness to others. In a series of cases dating back to a 1905 Supreme Court decision, *Jacobson v. Massachusetts*, courts have upheld vaccine mandates as a valid exercise of states' police powers necessary to protect the health of the community that does not violate the Fourteenth Amendment's due process guarantees or the First Amendment's Free Exercise of

Religion Clause. Yet this power is not unlimited. Vaccination mandates cannot be arbitrary or oppressive and should, if possible, accommodate genuine religious objections and medical contraindications.

Many state statutes already exist to mandate specific vaccinations, including, for example, staff in medical facilities or for school-age children. Since COVID-19 is a new disease, no statutes require vaccination against it yet, but that could change with vaccine approval.

Increasingly, private employers, especially in health care, are requiring their staff to be vaccinated against infectious diseases. Private employers have strong financial and reputational incentives to protect their workers and customers. Given that many of those most vulnerable to COVID-19 live and work in medical and long-term care facilities, employers in these settings are in a good position to require and provide vaccines. Any private mandates must conform to anti-discrimination statutes, workplace safety laws, government health guidance, and common law duties to maintain safe workplaces and public accommodations.

Since consent is always preferable to coercion, no-cost vaccines and other incentives should be provided to encourage voluntary vaccination, along with outreach to minority communities to promote vaccination and allay fears about safety. But if that does not elicit an adequate response, it may be necessary to mandate that personnel at medical and long-term care facilities should receive COVID-19 vaccination as a condition of their employment in order to protect patients and residents from transmission. Mandatory vaccination of residents of long-term care facilities should also be considered, since there has been rapid transmission of disease through the vulnerable resident populations in these settings. Requirements by private employers and health facility operators could suffice without the need for government action. Regardless of whether it is imposed privately or by the government, any mandatory vaccination program must recognize exemptions for medical reasons or genuine religious objections and should, if possible, find ways to accommodate persons who object to vaccination, while ensuring the safety of those around them.

Introduction

The COVID-19 pandemic is the result of community spread of a new virus to which people lack immunity. As with most viral diseases, Hepatitis C being a notable exception, there are no cures. Hence, the development of a vaccine that elicits an immune response that protects against infection will be the most effective means of curtailing the COVID-19 pandemic.

If and when a vaccine is developed, it can only be effective if people agree to use it. Despite the highly publicized pandemic having affected every aspect of our daily lives, there are indications that many Americans will not agree to be vaccinated. This paper will examine whether mandatory vaccination programs will be needed, if mandatory vaccination is supported by the law, and if and how such a program could be targeted in a way that maximizes public health while respecting individual rights, including religious objections. Vaccination should be targeted toward those who are most vulnerable and those who are most likely to transmit the disease, with voluntary uptake encouraged for others.

The first part of the paper will provide a brief background of how the pandemic has evolved. The following part examines which populations are most vulnerable to COVID-19, namely the elderly, people with concurrent medical conditions known as co-morbidities, minority groups

(especially African Americans), and residents, and to some extent, staff of long-term care facilities.

The next section examines evidence from vaccines available for other diseases and public opinion surveys to determine the likelihood that a COVID-19 vaccine will be voluntarily used. Much of the evidence indicates that vaccine uptake will fall far short of universal and will be inadequate, especially among some vulnerable groups.

The final section will discuss what can be done to ensure that vulnerable populations in particular, and public health in general, are protected when a vaccine becomes available. If no-cost provisions and other incentives are inadequate to elicit voluntary consent, it may be necessary to mandate vaccination for particular groups who are especially vulnerable to the illness or are in a position to transmit illness to others.

Some state statutes already exist to mandate certain vaccinations. Increasingly, private employers, especially in health care, are requiring their staff to be vaccinated against infectious diseases. Since COVID-19 is a new disease, no statutes require vaccination against it yet. Private employers have strong incentives to protect their workers and customers. Given that many of those most vulnerable to COVID-19 live and

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work in medical and long-term care facilities, employers in these settings are in a good position to require and provide vaccines.

This section will explore the constitutional and statutory limits on these mandates, as well as the cost barrier and particular problems in minority communities. While courts generally view mandatory vaccination to protect the public health and safety as constitutional, that power is not unlimited. Vaccination mandates cannot be arbitrary or oppressive and should, if possible, accommodate genuine religious objections and medical contraindications.

The COVID-19 Pandemic

On December 31, 2019 the Chinese government reported a cluster of pneumonia cases of unknown cause linked to a live animal market in Wuhan, China.¹ The cause was a new coronavirus, SARS-CoV-2, that causes a disease called COVID-19.²

The first reported case of infection with SARS-CoV-2 in the U.S. was on January 20, 2020, in Snohomish County, Washington, in a person who had recently traveled to Wuhan.³ Since then, it has become clear that the virus can spread easily from person to person.⁴ The earliest major U.S. outbreak was centered in New York City and the surrounding areas and is believed to have resulted from transmission from a traveler from Europe. The number of U.S. COVID-19 cases has ballooned to nearly 7 million; over 200,000 Americans have died from the disease.⁵

SARS-CoV-2 represents a particular threat because it is a novel virus to which humans have not been previously exposed. People have limited, if any, immunity to the virus. Thus far, treatment consists largely of supportive care, including provision of oxygen with or without ventilator support. While some new (remdesivir⁶)

1 Na Zhu, Dingyou Zhang, Wenling Wang, et al, “A Novel Coronavirus from Patients with Pneumonia in China, 2019,” *New England Journal of Medicine*, Vol. 382, No. 8 (January 24, 2020), pp. 727-733, <https://www.nejm.org/doi/full/10.1056/nejmoa2001017>.

2 SARS-CoV-2 is a novel RNA virus that is very similar to the SARS virus. Both are types of coronaviruses. SARS stands for severe acute respiratory syndrome. SARS-CoV-2 means severe acute respiratory syndrome coronavirus 2.

3 Michelle L. Holsue, Cad DeBolt, Scott Lindquist, et al, “First Case of 2019 Novel Coronavirus in the United States,” *New England Journal of Medicine*, Vol. 382, No. 10 (March 5, 2020), pp. 929-936, <https://www.nejm.org/doi/full/10.1056/NEJMoa2001191>.

4 U.S. Centers for Disease Control and Prevention, “How COVID-19 Spreads,” updated June 16, 2020, https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fprepare%2Ftransmission.html.

5 Johns Hopkins University, COVID-19 Dashboard, accessed September 23, 2020, <https://coronavirus.jhu.edu/map.html>.

6 John H. Beigel, Kay M. Tomashek, Lori E. Dodd, et al. “Remdesivir for the Treatment of Covid-19—Preliminary Report,” *New England Journal of Medicine*, May 22, 2020, <https://www.nejm.org/doi/full/10.1056/NEJMoa2007764>.

and old (dexamethasone⁷) medications are showing promise, these treatments mitigate the disease but do not cure it. The best hope for controlling the pandemic is development of a vaccine that elicits an immune response that protects against infection.

There are now multiple promising vaccine candidates in late stage trials, accelerated by the public-private partnerships in Operation Warp Speed.⁸ Unfortunately, demonstration of safety and efficacy resulting in Food and Drug Administration (FDA) approval or authorization for one or more vaccines is likely many months away.

Populations Most Vulnerable to COVID-19

A. The Elderly and Sick

It has been clear from early in the pandemic that COVID-19 is most severe and most likely to result in

death in the elderly and in people with other, concurrent medical conditions known as co-morbidities. Unlike seasonal influenza, which primarily kills the very old and very young, or the catastrophic 1918 influenza pandemic, which was especially lethal among young adults—half of deaths were in the 20-40 age group—and where the absolute risk of death was higher in people younger than 65 than in those who were older,⁹ COVID-19 is generally not a severe disease in children or healthy adults under age 40.

In Europe, 95 percent of COVID-19 deaths occurred in patients older than 60, and 80 percent of deaths were in people with at least one co-morbidity.¹⁰ In New York state, the early U.S. epicenter, 84 percent of the COVID-19 dead were 60 or older, just 6 percent were under 50, and deaths below age 20 were exceedingly rare. About 89 percent of New Yorkers who died had a least one medical co-morbidity.¹¹

There are now multiple promising vaccine candidates in late stage trials.

7 Paul E. Sax, “Dexamethasone Improves Survival in COVID-19—Why this Should Be Practice Changing Even Before the Paper is Published,” *NEJM Journal Watch*, HIV and ID Observations Blog, June 27, 2020, https://blogs.jwatch.org/hiv-id-observations/index.php/dexamethasone-improves-survival-in-covid-19-why-this-should-be-practice-changing-even-before-the-paper-is-published/2020/06/21/?query=C19&cid=DM94477_NEJM_Registered_Users_and_InActive&bid=220333907.

8 U.S. Department of Health and Human Services, “Fact Sheet: Explaining Operation Warp Speed,” June 16, 2020, <https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html>.

9 Jeffrey K. Taubenberger and David M. Morens, “1918 Influenza: the Mother of All Pandemics,” *Emerging Infectious Diseases*, Vol. 12, No. 1 (January 2006), pp. 15–22, https://wwwnc.cdc.gov/eid/article/12/1/05-0979_article.

10 Alexa Lardieri, “WHO: Nearly All Coronavirus Deaths in Europe Are People Aged 60 and Older,” *U.S. News & World Report*, April 2, 2020, <https://www.usnews.com/news/world-report/articles/2020-04-02/who-nearly-all-coronavirus-deaths-in-europe-are-people-aged-60-and-older>.

11 New York State Department of Health, COVID Tracker, Fatalities, accessed September 6, 2020, <https://covid19tracker.health.ny.gov/views/NYS-COVID19-Tracker/NYSDOHCOVID-19Tracker-Fatalities?%3Aembed=yes&%3Atoolbar=no&%3Atabs=n>.

In Sweden, which did not undertake the stringent lockdown measures that other countries did, the preponderance of death among the elderly is even more striking.

As of early September 2020, data from the U.S. Centers for Disease Control and Prevention (CDC) show that nearly 80 percent of U.S. COVID-19 deaths were in people 65 and older. Ninety-two percent of deaths were in people 55 and older. There were only 360 COVID deaths in the 0 to 24 age range (0.2 percent of total COVID-19 deaths) and 1,318 deaths in the 25- to 34-year-old age group (0.8 percent of the total). The average number of co-morbidities among all who died was 2.5.¹²

In Sweden, which did not undertake the stringent lockdown measures that other countries did, the preponderance of death among the elderly is even more striking. Eighty-nine percent of Swedish COVID deaths were in people 70 or older. Only 4 percent of the deaths were in people under 60. Many attribute the high death toll to high numbers of Swedes in nursing homes and on home care and to Swedish health guidelines that

denied hospital and intensive care to the elderly.¹³

The severity of disease as represented by COVID-19 hospitalization rates per 100,000 population are 137.6 for the country as a whole, but, like deaths, are strongly correlated with increasing age. For people 65 and older, there are 378.8 COVID-19 hospitalizations per 100,000 population. The rate is just over one half of that (207/100,000) for people 50 to 64. It falls by more than half again for ages 18 to 49 (96.3) and is less than 9/100,000 for ages 0 to 17.¹⁴

In addition to having a miniscule risk of death from COVID-19, children under 10 also have lower rates of infection and fewer and less severe symptoms than adults.¹⁵ A possible explanation for this is that children make less of the cell surface receptor that binds the viral protein and allows virus entry into the cells in their nasal passages than adults do.¹⁶

12 CDC Weekly Updates by Select Demographic and Geographic Characteristics: Provisional Death Counts for Coronavirus Disease 2019 (COVID-19), Table 1 (Provisional COVID-19 Death Counts by Sex, Age, and State) updated September 2, 2020, https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm.

13 Bojan Pancevski, "Coronavirus Is Taking a High Toll on Sweden's Elderly. Families Blame the Government," *Wall Street Journal*, June 18, 2020, <https://www.wsj.com/articles/coronavirus-is-taking-a-high-toll-on-swedens-elderly-families-blame-the-government-11592479430>.

14 CDC, Coronavirus Disease 2019, Hospitalizations, accessed August 9, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html#hospitalizations>.

15 Ankit B. Patel and Ashish Verma, "Nasal ACE2 Levels and COVID-19 in Children," *JAMA*, Vol. 323, No. 23 (May 20, 2020), pp. 2386–2387, <https://jamanetwork.com/journals/jama/fullarticle/2766522>.

16 Supinda Bunyavanich, Anh Do, and Alfin Vicencio, "Nasal Gene Expression of Angiotensin-Converting Enzyme 2 in Children and Adults," *JAMA*, Vol. 323, No. 23 (May 20, 2020), pp. 2427–2429, https://jamanetwork.com/journals/jama/fullarticle/2766524?guestAccessKey=0fc08c03-aba6-43b4-9f2b-b4350904cf18&utm_source=silverchair&utm_medium=email&utm_campaign=article_alert-jama&utm_content=etoc&utm_term=061620.

B. Residents of Long-Term Care Facilities

The coincidence of older age and co-morbidities as risk factors for COVID-19 death is not surprising. The incidence of diseases associated with COVID mortality, like hypertension, diabetes, and heart disease, increases with increasing age. Both advanced age and multiple co-morbidities are frequently found in residents of long-term care facilities like nursing homes and residential care communities.¹⁷

CDC data indicate there are 15,600 nursing homes and 28,900 residential care community providers, with 1,347,600 and 811,000 patient users, respectively. The patient populations are overwhelmingly elderly with 83.5 percent of nursing home residents and 93.4 percent of residential care resident 65 and older; about half of this group are 85 and over. They suffer from a variety of chronic medical conditions—nearly half have Alzheimer’s disease or other dementias and more than half have hypertension.¹⁸

Early outbreaks in Washington state indicated that SARS-CoV-2 infection

spreads rapidly in skilled nursing facilities and can spread from people who are symptomatic or asymptomatic. In one Washington facility where nearly all of the residents were tested, two thirds tested positive in just over three weeks from when the first positive resident became symptomatic.¹⁹ More than half of those who tested positive were asymptomatic at the time of testing. Most who were asymptomatic at the time of a positive test went on to subsequently develop symptoms (they were “pre-symptomatic”). Viral loads were similarly high in residents who were symptomatic, pre-symptomatic, and those who stayed asymptomatic, indicating that asymptomatic people play a role in transmitting the virus. In addition, 26 symptomatic staff (19 percent of the staff) tested positive. These staff undoubtedly contributed to intra-facility transmission, since 65 percent of them continued to work while symptomatic. Transmission also likely occurred from infected, but asymptomatic staff who were not tested. This pattern of a resident population vulnerable to infection, serious illness, and death because of

The coincidence of older age and co-morbidities as risk factors for COVID-19 death is not surprising.

17 Hospice care is excluded from this discussion since hospice patients are expected to die within a prescribed time period and will not receive long-term care.

18 U.S. Department of Health and Human Services/National Center for Health Statistics, “Long-term Care Providers and Services Users in the United States, 2015–2016, Analytical and Epidemiological Studies,” Vital and Health Statistics, Series 3, Number 43 (February 2019), (Appendix II, Tables V & VIII), https://www.cdc.gov/nchs/nsltcp/nsltcp_reports.htm.

19 Melissa M. Arons, Kelly M. Hatfield, Susan C. Reddy, et al, “Presymptomatic SARS-CoV-2 infections and transmission in a skilled nursing facility,” *New England Journal of Medicine*, Vol. 382, No. 22 (May 28, 2020), pp. 2081-2090, <https://www.nejm.org/doi/full/10.1056/NEJMoa2008457>.

their advanced age and other medical conditions and transmission from other residents and staff was repeated around the country and the world.

A subsequent review of multiple episodes of SARS-CoV-2 spread indicates that nearly half of infected persons stay asymptomatic.²⁰ A more recent study in a Korean community treatment center confirmed that a high percentage of positive patients (36 percent) were asymptomatic at the time of testing and most of them (81 percent) remained asymptomatic. As in the earlier study, viral load was similar in both asymptomatic and symptomatic patients, which indicates both patient groups represent a risk of transmission. It also suggests that all residents and staff of long-term care facilities are potential sources of spread to others, regardless of symptoms.²¹

In the U.S., long-term care facilities account for 45 percent of total COVID deaths.²² This is probably an

underestimate. New York State, the nation's first pandemic epicenter, reported long-term facility deaths as 21 percent of statewide COVID deaths, but did not count persons who contracted COVID at a facility and later died in hospital as deaths related to those facilities.

In Sweden, where 96 percent of deaths were in people over 60, more than 70 percent of deaths were in the elderly care system, including nursing homes and home care facilities with roving staff from nursing homes.²³ In the rest of Europe, about half of COVID-19 deaths were in nursing homes and long-term care facilities.²⁴ World Health Organization (WHO) data show that for the European Union as a whole, there are an average of 753 nursing and elderly home beds per 100,000 population. Nordic countries' numbers are higher, with an average of 1,053 nursing and elderly home beds per 100,000 population. But Sweden (1,276 beds/100,000) is a clear

20 Daniel P. Oran and Eric J. Topol, "Prevalence of Asymptomatic SARS-CoV-2 Infection: A Narrative Review," *Annals of Internal Medicine*, Vol. 173, Issue 5 (September 1, 2020), <https://www.acpjournals.org/doi/10.7326/M20-3012>.

21 Seungjae Lee, Tark Kim, Eunjung Lee, et al, "Clinical Course and Molecular Viral Shedding among Asymptomatic and Symptomatic Patients with SARS-CoV-2 Infection in a Community Treatment Center in the Republic of Korea," *JAMA Internal Medicine*, August 6, 2020, <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2769235>.

22 KFF, State Data and Policy Actions to Address Coronavirus. Table: State Reports of Long-Term Care Facility Cases and Deaths Related to COVID-19, https://www.kff.org/health-costs/issue-brief/state-data-and-policy-actions-to-address-coronavirus/?utm_source=web&utm_medium=trending&utm_campaign=covid-19#long-term-care-cases-deaths.

23 Carlotta Stern and Daniel B. Stein, "Stockholm City's Elderly Care and Covid19: Interview with Barbro Karlsson," *Society*, Vol. 57 (July 19, 2020), pp. 434-445, <https://link.springer.com/content/pdf/10.1007/s12115-020-00508-0.pdf>.

24 Haven Orecchio-Egresitz, "As many as half of Europe's COVID-19 deaths were people in long-term care facilities," *Business Insider*, April 26, 2020, <https://www.businessinsider.com/half-europes-covid-19-deaths-in-long-term-care-facilities-2020-4>.

outlier compared with Denmark (817 beds/100,000) and Norway (802 beds/100,000). Only Finland (1,152 beds/100,000) comes close. Italy, in contrast, has only 389 beds per 100,000 population.²⁵

These differences in capacity persist when we take account of countries' elderly populations. The number of beds in long-term care residential facilities per 1,000 population aged 65 and older in 2016 were 18.3, 33.4, and 65, respectively, for Italy, the United States, and Sweden.²⁶ Italy's high numbers of deaths early in the pandemic are explained by its elderly population and high numbers of multigenerational households, rather than large numbers of long-term care facility beds.

C. Minority Groups

Members of racial and ethnic minority groups appear to be at increased risk of getting COVID-19 or experiencing

severe illness and death. Different employment patterns make minorities more susceptible to being infected in the first place. According to the Bureau of Labor Statistics, black workers are only two thirds as likely as white workers to be able to work from home. Hispanic workers were half as likely as non-Hispanic workers to be able to work from home.²⁷

The age-adjusted rates of hospitalization from COVID-19 are five times higher for non-Hispanic blacks and four times higher for Hispanics than for non-Hispanic whites.²⁸ While non-Hispanic blacks only account for 12.5 percent of the U.S. population, they account for 20.9 percent of all COVID-19 deaths.²⁹ This is partly explained by the higher incidence of medical co-morbidities in the black population—27 percent of non-elderly (ages 18-64) black adults are at increased risk of serious illness due to underlying medical conditions

Different employment patterns make minorities more susceptible to being infected in the first place.

25 World Health Organization, "Nursing and elderly home beds per 100,000," accessed September 2, 2020, https://gateway.euro.who.int/en/indicators/hfa_490-5100-nursing-and-elderly-home-beds-per-100-000/visualizations/#id=19554&tab=table.

26 Organisation for Economic Co-operation and Development, "Long-Term Care Resources and Utilisation: Beds in residential long-term care facilities," OECD.Stat, accessed September 2, 2020, <https://stats.oecd.org/Index.aspx?QueryId=30142>.

27 U.S. Bureau of Labor Statistics, "Table 1. Workers who could work at home, did work at home, and were paid for work at home, by selected characteristics, averages for the period 2017-2018," Economic News Release, September 24, 2019, <https://www.bls.gov/news.release/flex2.t01.htm>.

28 Centers for Disease Control and Prevention, "COVID-19 in Racial and Ethnic Minority Groups," updated July 24, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html>.

29 Centers for Disease Control and Prevention, "Provisional Death Counts for Coronavirus Disease (COVID-19): Weekly State-Specific Data Updates," data as of September 23, 2020, <https://data.cdc.gov/NCHS/Provisional-Death-Counts-for-Coronavirus-Disease-C/pj7m-y5uh>.

compared to 21 percent of non-Hispanic whites.³⁰

It is also partly explained by where black people live—they form a higher percentage of the population in areas where the illness has hit thus far.

Nationwide there were 454.1 COVID-19 deaths per million population (as of July 29, 2020) but these were heavily concentrated in a few states:

- New York (1,678.5/million);
- New Jersey (1,781.7/million);
- Connecticut (1,240.6/million);
- Massachusetts (1,166.5/million);
- Rhode Island (948.7/million);
- District of Columbia (827.5/million);
- Louisiana (820.0/million);
- Michigan (642.9/million);
- Illinois (602.8/million).³¹

These states have large urban areas with large minority populations. In fact, the majority of COVID-19 deaths have occurred in New York City and other urban areas with large minority

populations. When weighted to reflect where COVID-19 outbreaks have been occurring, non-Hispanic blacks represent 15.4 percent of the population.³²

Finally, innate biological factors may play a role in making blacks more susceptible to infection. A recent report found significantly higher levels of a protein (TMPRSS2) that facilitates entry of the SARS-CoV-2 virus into the body in the nasal cells of in black individuals compared with Asian, Latino, mixed race/ethnicity, and white individuals.³³

Interestingly, the sizable disparity between percentages of deaths and population observed for blacks is not observed in the Hispanic population. Hispanics account for 21.2 percent of COVID-19 deaths, 18.5 percent of the unweighted population, and 32.2 percent of the weighted population distribution. When population weightings are accounted for, Hispanics appear to do as well or better than whites, who represent

30 Wyatt Koma, Samantha Artiga, Tricai Neuman, et al, “Low-Income and Communities of Color at Higher Risk of Serious Illness if Infected with Coronavirus, Figure 1,” KFF, 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/>.

31 KFF, “State Data and Policy Actions to Address Coronavirus. Table: Confirmed Cases, Deaths and Testing Data,” https://www.kff.org/health-costs/issue-brief/state-data-and-policy-actions-to-address-coronavirus/?utm_source=web&utm_medium=trending&utm_campaign=covid-19#long-term-care-cases-deaths.

32 CDC, “Provisional Death Counts” *supra note 29*.

33 Supinda Bunyavanich, Chantal Grant, Alfin Vincencio, “Racial/Ethnic Variation in Nasal Gene Expression of Transmembrane Serine Protease 2 (TMPRSS2),” *JAMA*, published online September 10, 2020, https://jamanetwork.com/journals/jama/fullarticle/2770682?utm_source=silverchair&utm_campaign=jama_network&utm_content=covid_weekly_highlights&utm_medium=email.

51.1 percent of deaths and 60.1 percent of the unweighted population, but just 40.2 percent of the weighted population.³⁴ This is due in part to the fact that, unlike blacks, who have higher rates of co-morbidities, the percentage of non-elderly (ages 18-64) Hispanic adults at increased risk of serious illness due to underlying medical conditions, 20 percent, is comparable to the 21 percent of non-Hispanic whites.³⁵

Hispanics' seemingly lower likelihood of dying is likely explained by the fact that, unlike the figures for hospitalization, the mortality figures are not age-adjusted. Hispanics are a notably young group, with a median age of 30—the median age for the U.S. population as a whole is 38, for non-Hispanic whites 44, and for non-Hispanic blacks 34.³⁶ Hence, while within specific age ranges Hispanics are more likely to be hospitalized than whites, as a group they are less likely to die than whites, for whom an older population makes them more likely overall to be hospitalized and die. One early study suggested that when the

Hispanic population's younger age distribution is taken into account, they have an 88 percent increased risk of death as compared to non-Hispanic whites.³⁷ However, this study relied on early data, as of April 21, 2020, from only 28 states and New York City, with large amounts of missing race and ethnicity data, and therefore needs confirmation from a larger study with more mature and reliable data.

The median age of non-Hispanic blacks (34) is also substantially lower than the median ages for the nation as a whole (38) and for non-Hispanic whites (44), and is only four years higher than the median age of Hispanics (30). This suggests that the higher COVID-19 death rate of African-Americans is due to higher rates of co-morbidities, the types of jobs they have, where they live, and other factors that deserve further study.

Will a Vaccine Be Widely Used?

A vaccine can only work if people agree to be vaccinated.³⁸ In recent flu seasons only 45 percent of the U.S.

34 CDC, "Provisional Death Counts" *supra* note 29.

35 Koma, Artiga, Neuman, *supra* note 30.

36 Katherine Shaeffer, "The most common age among whites in U.S. is 58—more than double that of racial and ethnic minorities," Fact Tank, Pew Research Center, July 30, 2019, <https://www.pewresearch.org/fact-tank/2019/07/30/most-common-age-among-us-racial-ethnic-groups/>.

37 Cary P. Gross, Utibe R. Essien, Saamir Pasha, et al, "Racial and Ethnic Disparities in Population Level Covid-19 Mortality," *Journal of General Internal Medicine*, August 4, 2020, <https://link.springer.com/article/10.1007%2Fs11606-020-06081-w>.

38 Council of Economic Advisers, "Mitigating the Impact of Pandemic Influenza through Vaccine Innovation," September 2019, <https://www.whitehouse.gov/wp-content/uploads/2019/09/Mitigating-the-Impact-of-Pandemic-Influenza-through-Vaccine-Innovation.pdf>.

There are two types of reasons Americans cite for skipping the influenza vaccine: safety concerns and doubts about the effectiveness and need for vaccination.

population was vaccinated. Within the past year, the figures were even worse. Only 33 percent of the total population received an influenza vaccine, although the more vulnerable population over 65 had a higher vaccination rate of 54 percent.³⁹ During the 2009 influenza pandemic, when a new and different influenza virus posed a risk to which, like the new coronavirus SARS-CoV-2, people would not have underlying immunity, only 27 percent of Americans chose to be vaccinated.⁴⁰

There are two types of reasons Americans cite for skipping the influenza vaccine: safety concerns (36 percent worry about side effects and 31 percent believe the vaccine causes the flu) and doubts about the effectiveness and need for vaccination (31 percent believe vaccines don't work very well; 30 percent say they never get the flu; and 27 percent believe they will not get seriously sick from the flu).⁴¹ These concerns and low vaccination

rates have persisted despite campaigns encouraging flu vaccination.

The situation may not be much different for COVID-19. A May 2020 Reuters poll reported that a majority of Americans would agree to vaccination against COVID-19, but 38 percent said they would wait until a vaccine had already been taken by much of the public and proven safe.⁴² A *Washington Post*–ABC News Poll, also from May 2020, reported that while 71 percent would likely get a vaccine, only 43 percent were a definite yes (an additional 28 percent said probably). Among those not likely to be vaccinated 50 percent said they don't trust the vaccine and 23 percent don't think it is necessary.⁴³

Another survey by the University of Chicago's NORC Center for Public Affairs Research, also from May, found that less than half of Americans (49 percent) say they will definitely be vaccinated when a COVID vaccine

39 KFF, "State Data and Policy Actions to Address Coronavirus. Table: Influenza and Pneumonia Deaths and Vaccinations, https://www.kff.org/health-costs/issue-brief/state-data-and-policy-actions-to-address-coronavirus/?utm_source=web&utm_medium=trending&utm_campaign=covid-19#long-term-care-cases-deaths.

40 Ibid.

41 NORC at the University of Chicago, "41 Percent of Americans Do Not Intend to Get a Flu Shot this Season," December 5, 2018, <https://www.norc.org/NewsEventsPublications/PressReleases/Pages/41-percent-of-americans-do-not-intend-to-get-a-flu-shot.aspx>.

42 Sharon Bernstein, "Most Americans would take coronavirus vaccine if deemed safe: Reuters/Ipsos poll," *Reuters*, May 5, 2020, <https://www.reuters.com/article/us-health-coronavirus-usa-poll/most-americans-would-take-coronavirus-vaccine-if-deemed-safe-reuters-ipsos-poll-idUSKBN22I019>.

43 "Washington Post—ABC News Poll, Questions 23 & 24," *Washington Post*, May 25-28, 2020, https://www.washingtonpost.com/context/may-25-28-2020-washington-post-abc-news-poll/bb30c35e-797e-4b5c-91fc-1a1cdfbe85cc/?itid=lk_inline_manual_2&itid=lk_inline_manual_2&itid=lk_inline_manual_2.

becomes available.⁴⁴ Thirty-one percent were unsure, and 20 percent were a definite no. As with the influenza vaccine, the major reason cited by those who will definitely decline a COVID-19 vaccine is safety (70 percent worry about side effects and 42 percent worry they will be infected with the virus). They also voice doubts about the effectiveness and need for vaccination (31 percent are not concerned about getting COVID-19; 30 percent don't think vaccines work; and 24 percent don't think the pandemic is as serious as some say it is).

Fortunately, in the NORC survey, the elderly were far more likely to say they would get vaccinated than younger Americans—67 percent for those 60 and older versus 40 percent for those under 60. Unfortunately, only 25 percent of non-Hispanic black Americans, who have higher rates of infections and death from COVID, definitely plan on getting vaccinated, less than whites (56 percent) and

Hispanics (37 percent). Forty percent of blacks were a definite no.⁴⁵

The low numbers of people who would definitely commit to vaccination during the height of a pandemic is striking. There is usually a high “prevalence-elasticity” of demand for vaccines for acute infectious diseases—as the prevalence of illness rises in a pandemic, the demand for a vaccine will also increase.⁴⁶ For the measles vaccine the prevalence elasticity has been estimated to be between 1.56 and 1.89, meaning that for every percentage point increase in the prevalence of the disease, there will be a greater than one percentage point (1.56-1.89) increase in the demand for the vaccine.⁴⁷ The corollary is that, “as the disease disappears, so too does the demand for vaccines, subsequently allowing the disease to return.”⁴⁸ A study of the determinants of demand for the influenza vaccine found that an individual's likelihood of being vaccinated was positively related to the number of weeks of widespread flu

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44 Associated Press-NORC Center for Public Affairs Research, “Expectations for a COVID-19 vaccine,” May 2020, <https://apnorc.org/projects/expectations-for-a-covid-19-vaccine/>.

45 Ibid.

46 Tomas Philipson, “Economic epidemiology and infectious diseases,” Chapter 33 in *Handbook of Health Economics*, Vol. 1 (2000), pp 1761-1799, <https://econpapers.repec.org/bookchap/eeeheachp/1-33.htm>.

47 Tomas Philipson, “Private Vaccination and Public Health: An Empirical Examination for U.S. Measles,” *Journal of Human Resources*, Vol. 31, No. 3 (Summer, 1996), pp. 611–630, <https://www.jstor.org/stable/146268>.

48 Pirre-Yves Geoffard and Tomas Philipson, “Disease eradication: private versus public vaccination,” *American Economic Review*, Vol. 87, No. 1 (March, 1997), pp. 222–230, http://static.stevereads.com/papers_to_read/disease_eradication_public_versus_private_vaccination.pdf.

If less than half of people would definitely be vaccinated at the height of a pandemic, when COVID-19 news was ubiquitous, demand for vaccination may be far lower by the time a vaccine is finally approved.

the previous year and the individual's perceived risk—people at greater risk from infection like the elderly or those with poor baseline health are more likely to get vaccinated.⁴⁹

If less than half of people would definitely be vaccinated at the height of a pandemic, when COVID-19 news was ubiquitous, demand for vaccination may be far lower by the time a vaccine is finally approved. One problem could be that despite all the publicity, the actual prevalence of COVID-19 is low, especially in the less hard-hit areas of the country. As of mid-August 2020, there were 13,225.7 cumulative cases per million population across the U.S. The hardest hit states early on were New York (21,224/million) and New Jersey (20,298/million) and then, because of a recent surge, Arizona (22,797/million) and Florida (21,018/million). But many states still had a prevalence far below the U.S. average (e.g., Ohio, – 7,400/million; Missouri – 7,430/million; Kentucky – 6,292; Oregon – 4,127/million; West Virginia – 3,415/million; Montana – 3,250/million; Maine – 2,876/million; Hawaii – 1,241/million). Even the

“hot spots” of Texas and California had cumulative cases of 14,141/million and 11,984/million, not much different than the national average.⁵⁰ It is difficult to know what COVID-19 prevalence will actually be if and when a vaccine is finally approved, but if it is lower, demand for vaccines would likely decline.

Maximizing the Benefits of a COVID-19 Vaccine

A. Protecting Vulnerable Groups with Vaccination

If and when a vaccine becomes available, it is unlikely there will be adequate doses available early on to vaccinate everyone. During the 2009 H1N1 Influenza pandemic, limited early supplies were directed toward people at highest risk for complications from the virus and toward health care personnel.⁵¹ A similar strategy should be followed for COVID-19.

COVID-19's most severe effects are concentrated in a few well-defined populations. The elderly and persons with co-morbid health conditions are

49 John Mullahy, “It’ll Only Hurt a Second? Microeconomic Determinants of Who Gets Flu Shots,” *Health Economics*, Vol. 8, No. 1 (1999), pp. 9-24, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=226244.

50 KFF, “State Data and Policy Actions to Address Coronavirus,” https://www.kff.org/health-costs/issue-brief/state-data-and-policy-actions-to-address-coronavirus/?utm_source=web&utm_medium=trending&utm_campaign=covid-19#long-term-care-cases-deaths.

51 Centers for Disease Control and Prevention, “H1N1 Flu; Questions & Answers: Vaccine Against H1N1 Influenza Virus,” accessed September 2, 2020, https://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm.

the most likely to have severe disease or die. Therefore, vaccination efforts should be directed toward those groups. The unique pattern of disease observed with COVID-19, which largely spares children and young adults from severe complications, means these groups can be vaccinated later, and may not even need vaccination, as long as vulnerable groups can be vaccinated and protected from spread from less vulnerable groups.

Despite the lack of a vaccine, the American Academy of Pediatrics has issued guidance advocating opening schools for the coming year with students physically present and mitigation measures like social distancing and masks when distancing is not possible, because “the preponderance of evidence indicates that children and adolescents are less likely to be symptomatic and less likely to have severe disease resulting from SARS-CoV-2 infection. In addition, children may be less likely to become infected and to spread infection.”⁵²

The high percentage of total COVID-19 deaths in long-term care facilities highlights the convergence of older age and medical co-morbidities in that

setting. Residents of these facilities and the people who care for them should be the highest priority for vaccination. Similarly, medical personnel, both in and outside of hospitals, should be vaccinated, since they care for and could transmit infection to vulnerable patients and will themselves be exposed to the virus while they do so. The fact that approximately half of infected people are asymptomatic but can still spread the virus makes it clear that screening patients, residents, and staff for symptoms is an inadequate way to safeguard hospitals and long-term care facilities. Vaccination is necessary.

The problem is that many people may refuse vaccination, as highlighted by a history of low rates of influenza vaccination and current surveys showing lukewarm willingness to receive COVID-19 vaccination. Lack of enthusiasm for COVID-19 vaccination is particularly common and worrisome in minority communities. Demand for vaccination could decrease still more if new COVID-19 cases, the surrounding publicity, and the community’s sense of health threat decline by the time a vaccine becomes widely available.

52 American Academy of Pediatrics, “COVID-19 Planning Considerations: Guidance for School Re-Entry,” August 19, 2020, <https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/covid-19-planning-considerations-return-to-in-person-education-in-schools/>.

Annual influenza vaccination has long been recommended to reduce influenza morbidity and mortality.

This could even be a problem in settings where we know vaccination is imperative. Annual influenza vaccination has long been recommended to reduce influenza morbidity and mortality. Yet, only 78.4 percent of health care workers—a group that is at great risk of contracting or spreading contagious diseases—reported being vaccinated for influenza during a recent flu season.⁵³ The percentage was highest among personnel in hospitals (91.9 percent), followed by those working in ambulatory care (75.1 percent), other clinical settings (74.9 percent), and lowest in long-term care settings (67.4 percent). Vaccination coverage was high among physicians (96.1 percent), pharmacists (92.2 percent), nurses (90.5 percent), and nurse practitioners and physicians’ assistants (87.8 percent), but low among assistants and aides (71.1 percent) and non-clinical personnel (72.8 percent).

Vaccination was highest (94.8 percent) among health care personnel working in settings where vaccination was required. Vaccination was most commonly required (68.3 percent) in hospitals and least commonly required

in long-term care settings (29.6 percent). Vaccination coverage was also higher among personnel at sites where the employer offered no cost, on-site vaccination or provided financial or other incentives for workers to get vaccinated.⁵⁴

The foregoing suggests that no-cost vaccines and incentives should be provided for personnel at medical and long-term care facilities, but if voluntary vaccination is inadequate, mandatory vaccination should be considered. It also suggests that the residents of long-term care facilities should be offered on-site COVID-19 vaccinations at no cost. It may be necessary to require demonstration of immunity, either by proof of vaccination or by documenting high antibody levels from previous exposure and recovery, for continued residence in or admission to such a facility.

1. Vaccination Requirements

Health care facilities across the country are increasingly requiring personnel to be vaccinated against vaccine-preventable diseases, including influenza. This trend was evident well

53 Carla L. Black, Xin Yue, Sarah W. Ball, et al. “Influenza Vaccination Coverage Among Health Care Personnel — United States, 2017–18 Influenza Season,” *Morbidity and Mortality Weekly Report*, Centers for Disease Control and Prevention, Vol. 67, No. 38 (September 28, 2018), pp. 1050–1054, https://www.cdc.gov/mmwr/volumes/67/wr/mm6738a2.htm#T1_down.
54 Ibid.

before COVID-19. Sometimes the facilities impose these requirements themselves and sometimes they are in response to state statutes and regulations.⁵⁵ These legal requirements are intended to limit infections from occurring during the course of health care delivery. The regulations can apply to health care workers, patients, or both.

Influenza, like COVID-19, is a respiratory viral illness that is transmitted person to person and studies have demonstrated that vaccinating health care providers can decrease infections, illness, and mortality in long-term care settings.⁵⁶ Therefore, state influenza vaccination laws provide a good place to start when discussing what can be done about COVID-19.

Eighteen states have established influenza vaccination requirements for

hospital health care workers and 16 states have requirements for hospital patients.⁵⁷ Similarly, 24 states have established influenza vaccination requirements for long-term care facility health care workers and 32 have established requirements for long-term care facility patients.⁵⁸ For both settings and for both providers and patients, the requirements fall into three categories:

- Required assessment of vaccination status;
- Requirement that vaccination be offered; and
- Requirement that facilities ensure their staff or patients have been vaccinated.

The last requirement for mandatory vaccination is a minority of the statutes. Only eight states require hospital providers, and 16 states require health care workers in long-term care facilities

State influenza vaccination laws provide a good place to start when discussing what can be done about COVID-19.

55 Centers for Disease Control and Prevention, Public Health Professionals Gateway: Public Health Law, accessed September 3, 2020, <https://www.cdc.gov/phlp/publications/topic/vaccinationlaws.html>.

56 Andrew C. Hayward, Richard Harling, Sally Wetten, et al, "Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial," *BMJ*, Vol. 333 (2006), p. 1241, <https://www.bmj.com/content/333/7581/1241>. R.E. Thomas, T.O. Jefferson, V. Demicheli, et al, "Influenza vaccination for health-care workers who work with elderly people in institutions: a systematic review," *The Lancet Infectious Diseases*, Vol. 6, Issue 5 (May 1, 2006), pp. 273-279, [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(06\)70462-5/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(06)70462-5/fulltext). Magali Lemaitre, Thierry Meret, Monique Rothan-Tondeur, et al, "Effect of Influenza Vaccination of Nursing Home Staff on Mortality of Residents: a Cluster-Randomized Trial," *Journal of the American Geriatrics Society*, Vol. 57, Issue 9 (September 2009), pp. 1580-1586, <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1532-5415.2009.02402.x>.

57 Centers for Disease Control and Prevention, Public Health Professionals' Gateway: Public Health Law, Menu of State Hospital Influenza Vaccination Laws, accessed September 6, 2020, <https://www.cdc.gov/phlp/docs/menu-shfluvacclaws.pdf>.

58 Centers for Disease Control and Prevention, Public Health Professionals' Gateway: Public Health Law, Menu of State Long-Term Care Facility Influenza Vaccination Laws, accessed September 6, 2020, <https://www.cdc.gov/phlp/publications/topic/menus/lcinflluza/index.html>.

to be vaccinated. Only one state, New Hampshire, requires hospitals to “immunize all consenting patients for influenza.”⁵⁹ In contrast, 23 states require long-term care facilities to ensure that patients are vaccinated for influenza—a policy that is consistent with the fact that most of the residents are vulnerable to infection because of advanced age or co-morbid medical conditions. All of the statutes requiring facilities to ensure vaccination provide for exemptions for medical reasons or religious or philosophical objections. Many states specify that health care workers who cannot or will not be vaccinated must wear a surgical mask during patient contact.

Outside of influenza, all states require children over five years old to be vaccinated against childhood diseases prior to enrollment in school.⁶⁰ All states grant exemptions for medical contraindications, such as allergic reactions or immunodeficiency, all but

two grant religious exemptions, and 20 grant philosophical exemptions for “personal,” “moral,” or “other” beliefs.

2. Limitations on Government’s Power to Mandate Vaccination

States’ police⁶¹ and *parens patriae*⁶² powers give them the authority to protect the public health, safety, and welfare by taking a variety of actions, including requiring vaccinations in specified settings.⁶³ While states may require vaccination to protect public health, are there any federal constitutional or statutory bars to such a policy?

In the late 19th and early 20th centuries a minority of states had laws requiring adults and children to undergo smallpox vaccination or face a fine or exclusion from school. None of the statutes required physically restraining and forcibly vaccinating unwilling individuals. Several state supreme courts upheld these requirements.⁶⁴

59 C N.H. Code Admin. R. He-P 802.21(h).

60 Laurence O. Gostin, “Law, Ethics, and Public Health in the Vaccination Debates: Politics of the Measles Outbreak,” *JAMA*, February 12, 2015, <https://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=2472&context=facpub>.

61 *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (The police power is the authority reserved to the states by the Constitution and includes “such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety”, 197 U.S. at 25), <https://supreme.justia.com/cases/federal/us/197/11/>.

62 “Parens patriae, literally ‘parent of the country,’ is the government’s power and responsibility, beyond its police power over all citizens, to protect, care for, and control citizens who cannot take care of themselves.” Natalie Loder Clark, “Parens Patriae and a Modest Proposal for the Twenty-first Century: Legal Philosophy and a New Look at Children’s Welfare,” *Michigan Journal of Gender and Law*, Vol. 6, Issue 2, (2000), pp. 382-447, <https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1147&context=mjgl#:~:text=Parens%20patriae%2C%20literally%20%22parent%20of,other%20protector.%22%20The%20doctrine>.

63 Laurence O. Gostin, *Public Health Law: Power, Duty, and Restraint*, 92-98 (Oakland, CA: University of California Press 2008).

64 Mary Holland, “Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children,” *Yale Journal of Health Policy, Law, and Ethics*, Vol 12, Issue 1 (2012), pp. 39-85, at 43-44, <https://digitalcommons.law.yale.edu/yjhple/vol12/iss1/2/>.

In 1905, the U.S. Supreme Court, in *Jacobson v. Massachusetts*, upheld a Massachusetts state statute requiring the entire population to undergo smallpox vaccination or pay a fine during a smallpox epidemic as a valid exercise of a state's police powers that did not violate the U.S. Constitution's Fourteenth Amendment's Due Process Clause, because the vaccinations were necessary to protect the health of the community.⁶⁵ Yet, the Court cautioned:

[T]hat an acknowledged power of a local community to protect itself against an epidemic threatening the safety of all, might be exercised in particular circumstances and in reference to particular persons in such an arbitrary, unreasonable manner, or might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons.⁶⁶

While state and local authorities have the power under the Constitution to restrict individuals' liberty to protect the health and safety of their communities,

[T]he police power of a State, whether exercised by the legislature or by a local body acting under its authority, may be exerted in such circumstances or by regulations so arbitrary and oppressive in particular cases as to justify the interference of the courts to prevent wrong and oppression.⁶⁷

Interestingly, two months later, the Supreme Court, in its landmark *Lochner* decision, relied on the doctrine of substantive due process to strike down a New York statute that purported to protect the public health by limiting bakers' working hours.⁶⁸ The *Lochner* court explicitly distinguished the case from *Jacobson*, which upheld state police powers requiring vaccination to safeguard public health by saying that the New York work hours statute could not be viewed as protecting the health of the public in general or the health of bakers in particular, but instead was an unconstitutional infringement on personal liberty and the right of contract.⁶⁹ *Lochner* has since been largely repudiated by scholars and the

65 *Jacobson v. Massachusetts*, 197 U.S. 11 (1905). The *Jacobson* holding that a parent "has no constitutional right to an exemption" from vaccination requirements remains accepted law. *Nikolao v. Lyon*, 875 F.3d 310, 316 (Sixth Circuit 2017), <https://www.leagle.com/decision/infco20171107141>.

66 *Jacobson supra*, 197 U.S. at 28.

67 *Ibid.* at 38.

68 *Lochner v. New York*, 198 U.S. 45 (1905).

A statute that contemplated physically restraining and forcibly vaccinating unwilling individuals would undoubtedly attract stricter judicial scrutiny.

Supreme Court, which now gives far more deference to the decisions of state legislatures.⁷⁰

Regardless of the cautionary language in *Jacobson* about arbitrary, unreasonable, or oppressive regulation, by 1922 the Supreme Court, in upholding a Texas law that excluded children from school who could not produce a certificate of vaccination, held that, “*Jacobson* ... settled that it is within the police power of a state to provide for compulsory vaccination.”⁷¹ *Jacobson* and other cases “had settled that ... [state and local] officials [have] broad discretion in matters affecting

the application and enforcement of a health law.”⁷² It is worth noting, however, that these statutes penalized non-compliance with vaccination requirements by either a fine or exclusion from activities that placed others at risk, such as school attendance. A statute that contemplated physically restraining and forcibly vaccinating unwilling individuals would undoubtedly attract stricter judicial scrutiny under the Supreme Court’s subsequent personal autonomy jurisprudence.⁷³

School vaccination requirements have also been found to not violate the Free

69 Ibid. at 55-56, 58

“We think the limit of the police power has been reached and passed in this case. There is, in our judgment, no reasonable foundation for holding this to be necessary or appropriate as a health law to safeguard the public health or the health of the individuals who are following the trade of a baker.” Ibid. at 58.

70 *West Coast Hotel Co. v. Parrish*, 300 U.S. 379 (1937) is generally regarded as having ended the “*Lochner* era,” in which the court applied substantive due process to invalidate many economic regulations.

71 *Zucht v. King*, 260 U.S. 174, 176 (1922), <https://supreme.justia.com/cases/federal/us/260/174/>.

72 Ibid.

73 When a law does not burden a fundamental right or interest, the Court generally applies a rational basis test that will uphold a law “so long as it bears a rational relation to some legitimate end.” (*Romer v. Evans*, 517 U.S. 620, 631 (1996)). This is essentially the standard applied in *Jacobson*. Since *Jacobson*, the Supreme Court has decided several cases dealing with liberty interests in personal autonomy and the level of scrutiny a court should apply to statutes restricting them. The Court has recognized a fundamental liberty interest in marriage and procreation and applied “strict scrutiny” to strike down statutes that penalized or limited those interests: *Skinner v. Oklahoma*, 316 U.S. 535 (1942) (striking down a state criminal statute that specified forced sterilization for certain crimes); *Griswold v. Connecticut*, 381 U.S. 479 (1965) (limiting state restrictions of contraceptives to protect personal autonomy in making decisions about procreation); *Roe v. Wade*, 410 U.S. 113 (1973) (striking down a statute regulating abortion). To be constitutional under a strict scrutiny standard the law must address a compelling governmental interest and must be narrowly tailored to achieve its end.

In the 1990s the Supreme Court recognized strong liberty interests in bodily integrity and the right to make decisions about medical treatment, but did not consider these interests fundamental, and therefore applied an intermediate level of scrutiny that balances the state’s interest against the individual’s liberty interest: *Washington v. Harper*, 494 U.S. 210 (1990) (interest in avoiding unwanted injection of antipsychotic drugs); *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990) (recognizing right to refuse unwanted, lifesaving medical treatment); *Glucksberg v. Washington*, 521 U.S. 702 (1997) (recognizing the right to refuse lifesaving treatment that requires heightened protection against government interference but unanimously holding that it did not extend to assisted suicide).

If a statute required forcible vaccination it seems likely the Supreme Court would at least apply intermediate scrutiny, if not strict scrutiny.

Exercise of Religion Clause of the First Amendment.⁷⁴ In an employment case, *Employment Division, Department of Human Resources of Oregon v. Smith*,⁷⁵ the Supreme Court held that the free exercise clause only protects against government regulation of religious beliefs⁷⁶ and that “the right of free exercise does not relieve an individual of the obligation to comply with a ‘valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion proscribes (or proscribes).’”⁷⁷ While *Smith* has been widely criticized, it remains “binding precedent.”⁷⁸

In a direct response to the holding in *Smith*, Congress enacted the Religious Freedom Restoration Act (RFRA) in 1993 to provide greater protection for religious freedom than is available

under the First Amendment by applying a strict scrutiny standard to federal legislation and policies that burden the exercise of religion, even if the burden results from a rule of general applicability.⁷⁹

After the Supreme Court held that the RFRA does not apply to the states (although it still governs federal statutes and regulations),⁸⁰ 21 states enacted their own RFRA-type statutes, which are substantially similar to the federal law.⁸¹ Both the federal RFRA and the state statutes apply strict scrutiny to statutes and regulations that burden the free exercise of religion and require lawmakers to demonstrate a) a compelling government interest justifying a mandate and b) that the mandate is the least restrictive means of furthering that interest.⁸²

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Amendment.*

74 U.S. Constitution Amendment I (prohibiting federal laws “respecting an establishment of religion, or prohibiting the free exercise thereof.”). *Prince v. Massachusetts*, 321 U.S. 158, 167 (1944) (“The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death.”), <https://supreme.justia.com/cases/federal/us/321/158/>. *Phillips v. City of New York*, 775 F.3d 538, 543 (Second Circuit 2015) (New York State statute requiring vaccination for admission to school does not violate the establishment clause or due process), <https://casetext.com/case/phillips-ex-rel-bp-v-city-of-ny-2>.

75 494 U.S. 872 (1990).

76 *Ibid.* at 877.

77 *Ibid.* at 879.

78 *Horvath v. City of Leander*, 946 F.3d 787, 794-795 (Ho CJ, concurring in judgment in part and dissenting in part) (Fifth Circuit 2020), <https://law.justia.com/cases/federal/appellate-courts/cafc/17-1801/17-1801-2018-07-20.html>.

79 42 U.S.C. § 2000bb-1 (1993) (“Government shall not substantially burden a person’s exercise of religion even if the burden results from a rule of general applicability. ...”).

80 *City of Boerne v. Flores*, 521 U.S. 507, 536 (1997) (striking down RFRA to the extent that it applied to state and local governments because “RFRA contradicts vital principles necessary to maintain separation of powers and the federal balance”), <https://supreme.justia.com/cases/federal/us/521/507/>.

81 National Conference of State Legislatures, State Religious Freedom Restoration Acts, May 4, 2017, <https://www.ncsl.org/research/civil-and-criminal-justice/state-rfra-statutes.aspx>.

Mandating vaccination would likely garner even stricter scrutiny than mandating insurance coverage for vaccination, since it involves requiring a medical treatment.

In *Burwell v. Hobby Lobby Stores*⁸³ the Supreme Court held that the RFRA protections apply to both individuals and to not-for-profit and for-profit corporations. The Court found that enforcing the Affordable Care Act's (ACA) mandate to provide insurance coverage for contraception against closely held corporations whose owners had sincere religious opposition to abortion would not meet the strict scrutiny standards of the RFRA. The Court made clear that its decision dealt solely with the contraceptive mandate. The Court's statement that, "Other coverage requirements, such as immunizations, may be supported by different interests (for example, the need to combat the spread of infectious diseases) and may involve different arguments about the least restrictive means of providing them" suggests the Court might find the government's interest in protecting the public from infectious disease more compelling than its interest in protecting it from the cost of contraceptives.⁸⁴

Mandating vaccination would likely garner even stricter scrutiny than

mandating insurance coverage for vaccination, since it involves requiring a medical treatment. However, the RFRA would only apply in a case of a federal vaccine mandate, not a state mandate, since the RFRA does not apply to the states. State statutes requiring COVID-19 vaccination are far more likely than a federal one. Hence, strict scrutiny in a claim that a vaccine mandate burdens the free exercise of religion would only apply in the 21 states that have their own version of the RFRA.

In the health care setting, vaccination is necessary to protect vulnerable patients, but might not be necessary to apply to employees who have no patient contact. Outside of health care, it might be harder to identify a compelling government interest and it may be necessary to exempt or provide accommodations for employees with genuine religious objections. Nearly all vaccination statutes provide an exemption for genuine religious beliefs that satisfy this standard.

It is worth noting that many religious

82 See, e.g., Connecticut General Statutes § 52-571b (2012): "The state or any political subdivision of the state may burden a person's exercise of religion only if it demonstrates that application of the burden to the person (1) is in furtherance of a compelling governmental interest, and (2) is the least restrictive means of furthering that compelling governmental interest."

83 *Burwell v. Hobby Lobby Stores*, 573 U.S. 682 (2014), <https://www.law.cornell.edu/supremecourt/text/13-354>.

84 *Ibid.* at 733.

denominations, including the Catholic Church⁸⁵ and the Church of Jesus Christ of Latter-day Saints, have endorsed vaccinations.⁸⁶ Every major religion, including those that lack a centralized source of guidance, has had prominent figures opine that vaccination is consistent with the religion’s teachings.⁸⁷ With few exceptions, like Christian Science, none actively oppose it.

3. Can Employers Require Vaccination?

Employers in general, not just at health care facilities, have incentives to require their employees to be vaccinated against COVID-19. Vaccinated employees are less likely to become ill themselves or infect their co-workers, thus reducing absenteeism. A healthier workforce will incur lower health care costs, which could ultimately be reflected in lower premiums for employer-provided health insurance. They are also less likely to infect their

customers and patrons, leading to an enhanced business reputation for safety. If vaccination is the norm, then both employees and customers will have confidence that the business is a safe place and will be less likely to stay away out of fear of being infected.

An employer could theoretically face liability for failing to maintain safety by instituting a mandatory vaccination policy.⁸⁸ Employees can transmit disease to other employees or to customers and, in the health care setting, to patients, residents, or visitors at hospitals and long-term care facilities. An infected employee, patient, or patron could argue that the employer’s failure to mandate vaccination was negligent or violated a statutory duty.

The Occupational Safety and Health Administration (OSHA)—the agency within the U.S. Department of Labor charged with ensuring safe and healthy workplaces—and the CDC have issued guidance for employers to keep employees safe during the

Many religious denominations, including the Catholic Church and the Church of Jesus Christ of Latter-day Saints, have endorsed vaccinations.

85 National Catholic Bioethics Center, *New Charter for Health Care Workers*, Articles 69-70 (2017), April 14, 2020, <https://www.nbccenter.org/free-scribd-texts/new-charter-for-health-care-workers?rq=health%20care%20workers>.

86 Geoffrey S. Nelson, *Mormons and Compulsory Vaccination*, Mormon Press, March 30, 2015, http://www.mormonpress.com/mormon_vaccination.

87 John D. Graberstein, “What the World’s Religions Teach, Applied to Vaccines and Immune Globulins,” *Vaccine*, Vol. 31, No. 16 (2013), https://www.researchgate.net/publication/236053964_What_the_World%27s_religions_teach_applied_to_vaccines_and_immune_globulins.

88 Teri Dobbins Baxter, “Employer-Mandated Vaccination Policies: Different Employers, New Vaccines, and Hidden Risks,” *Utah Law Review*, Vol. 2017, No. 5, pp. 885-938, <https://dc.law.utah.edu/cgi/viewcontent.cgi?article=1125&context=ulr>.

An employer who did not require workers to be vaccinated, or at least provide vaccines and testing of employees, could face tort liability for negligently failing to protect customers and other workers from infection.

pandemic. This guidance does not have the effect of law, but general OSHA requirements do. An infected employee could claim a violation of the general duty clause of the Occupational Safety and Health Act, which obligates employers to provide workers “employment and a place of employment, which are free from recognized hazards that are causing or are likely to cause death or serious physical harm.”⁸⁹ To prove a general duty clause violation, OSHA must prove four elements:

- The employer failed to keep the workplace free of a hazard to which workers were exposed; The hazard was recognized;
- The hazard causes or was likely to cause death or physical harm; and
- There was a feasible method available to correct or abate the hazard.⁹⁰

Responses could include providing adequate social distancing for workers who interact with other workers, customers, and the general public and possibly testing to remove the hazard of an infected worker. OSHA guidance⁹¹

covers personal protective equipment (PPE) worn to minimize exposure to hazards that cause workplace injuries and illness.⁹² But, arguably, vaccination could be considered an available method to abate the hazard of COVID-19.

There are also common law duties to provide a safe workplace and safe setting for patrons. An employer who did not require workers to be vaccinated, or at least provide vaccines and testing of employees, could face tort liability for negligently failing to protect customers and other workers from infection.

In health care settings, vaccinated employees are less likely to infect or be infected by patients, many of whom are in vulnerable populations. As described above, many states’ statutes encourage health care facilities to adopt immunization policies or require employers to make certain vaccines available to health care professionals. Only a small number of states specifically mandate the vaccination of health care employees and the mandates vary considerably from state to state in terms of which vaccines are

89 Occupational Safety and Health Act of 1970, §5(a)(1), 29 U.S.C. 654(a)(1).

90 Jim Stanley, “OSHA’s ‘general duty’ clause—often used and frequently misunderstood,” FDR Safety, May 6, 2011, <https://www.fdrsafety.com/oshas-general-duty-clause-often-used-and-frequently-misunderstood/>.

91 United States Department of Labor/Occupational Safety and Health Administration, Personal Protective Equipment, accessed September 3, 2020, <https://www.osha.gov/personal-protective-equipment>.

92 29 CFR 1910.132.

required and which health care workers and health care settings are affected.⁹³ Moreover, even in states with specific vaccination requirements, private mandates can be more stringent than state mandates, although they are limited by employment or collective bargaining agreements.⁹⁴

Since COVID-19 is a new disease for which a vaccine does not yet exist, no state has a statute requiring vaccination for the disease. This could change after initial vaccine approvals, but most employers, especially health care employers, will face the issue of requiring COVID-19 vaccination without the cover of state law. Indeed, a unique Oregon statute requires employers of health care workers at risk of contracting an infectious disease in the course of employment to provide available preventative immunizations to employees free of charge but provides that: “A worker shall not be required as a condition of

work to be immunized under this section, unless such immunization is otherwise required by federal or state law, rule or regulation.”⁹⁵ [Emphasis added]

While there are no federal vaccination mandates for health care workers, various agencies have issued vaccination guidance. The CDC recommends vaccines for workers in contact with patients or materials that could transmit diseases.⁹⁶ OSHA requires all employers to offer, at no cost, the vaccine for Hepatitis B to any employee who might be occupationally exposed to blood.⁹⁷ The Joint Commission—a private non-profit that is the nation’s largest accrediting organization for hospitals and health care organizations whose accreditation is required by most states as a condition of licensure for receipt of Medicare and Medicaid reimbursement—requires hospitals to offer influenza vaccination to their staff.⁹⁸

While there are no federal vaccination mandates for health care workers, various agencies have issued vaccination guidance.

93 Brian Dean Abramson, “Vaccine Law in the Health Care Workplace,” *Journal of Health & Life Sciences Law*, Vol. 12, No. 3 (June 2019), pp 24-37,

http://www.healthlawyersjournal.com/healthlawyers/june_2019/MobilePagedReplica.action?pm=2&folio=22#pg26.

94 *Virginia Mason Hospital v. Washington State Nurses Association*, 511 F.3d 908 (9th Cir. 2007) (invalidating hospital’s imposition of an influenza vaccination mandate as a condition of employment since it violated the collective bargaining requirement to bargain over terms of employment), <https://cite.case.law/f3d/511/908/>.

95 Oregon Statute § 433.416(3).

96 Centers for Disease Control and Prevention, Recommended Vaccines for Healthcare Workers, accessed September 6, 2020, <https://www.cdc.gov/vaccines/adults/rec-vac/hew.html>.

97 Occupational Safety and Health Administration, Fact Sheet: Hepatitis B Vaccination Protection, accessed September 3, 2020, https://www.osha.gov/OshDoc/data_BloodborneFacts/bbfact05.pdf.

98 Joint Commission, Standard IC.02.04.01 Influenza Vaccination for Licensed Independent Practitioners and Staff, November 18, 2011, https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/influenza_bhc_2011-11-18pdf.pdf?db=web&hash=7906F9A54B265A101D46C9922A38C235.

Ideally, employers could convince most, if not all, of their employees to be vaccinated by providing on-site, no-cost vaccines, time off to be vaccinated, and various incentives.

Ideally, employers could convince most, if not all, of their employees to be vaccinated by providing on-site, no-cost vaccines, time off to be vaccinated, and various incentives like extra time off, monetary incentives, or some sort of workplace recognition for those who are vaccinated. But if many employees do not voluntarily avail themselves of the opportunity for vaccination, employers will have to consider requiring vaccination as a condition of employment.

These employers will have to navigate federal statutes that would limit their ability to require vaccination. The Americans with Disabilities Act of 1990 (ADA)⁹⁹ prohibits discrimination on the basis of disability in employment by private employers with 15 or more employees, state and local government employers, employment agencies, and labor unions. An individual is disabled under the ADA if that individual:

- Has a physical or mental impairment that substantially limits one or more major life activities; or
- Has a record of such an impairment; or
- Is regarded as having such an impairment.¹⁰⁰

Employers are prohibited from discriminating against “qualified” applicants and employees with disabilities and are required to provide reasonable accommodations for such individuals, unless doing so would cause an “undue hardship” on the business. Individuals with disabilities are qualified under the ADA if, absent their disability or with a reasonable accommodation, they could perform the essential functions of the job.

In *Ruggiero v. Mount Nittany Medical Center*, the Third Circuit Court of Appeals reversed the dismissal of an action by a nurse with an anxiety disorder and esophagitis who claimed she was discharged for refusing to adhere to hospital policy requiring vaccination for tetanus, diphtheria, and pertussis in violation of the ADA.¹⁰¹ While the court did not rule on the merits and remanded the case to the district court, it found that the nurse stated a cause of action for violating the ADA when she provided a letter from her physician stating she should be exempted from vaccination because of her medical history—even though her conditions were not listed as vaccine contraindications by the vaccine manufacturer or the CDC—and that the employer had failed to

99 42 U.S.C. §§12101 et Seq.

100 42 U.S.C. § 12102 (2012).

101 736 Federal Appeals 35 (Court of Appeals Third Circuit 2018).

consider her proposal that she be allowed to wear a mask instead of vaccination as a reasonable accommodation. Of note, the U.S. Equal Employment Opportunity Commission appeared as *amicus curiae* in support of the nurse.

Shortly thereafter, however, the Eight Circuit, in *Hustvet v. Allina Health System*,¹⁰² held that a rehabilitation facility employee's purported history of allergies, chemical sensitivities, and seizures years before did not constitute a disability that was sufficiently related to the accommodation she sought—being excused from having a mumps immunization—to constitute an ADA violation.¹⁰³ The Court found that her employment brought her into daily contact with vulnerable clients and that her refusal to be vaccinated was a legitimate reason for her termination.¹⁰⁴

Given the lack of complete clarity on the matter, health care employers would be well advised to determine if employees who object to COVID-19 vaccination can be accommodated either with some other protective mechanism or by reassigning them to different work that does not involve

patient contact or contact with other people. Depending on the type of position and degree of patient contact, wearing PPE may, or may not, be an adequate substitute for vaccination. Transfer to a different position that does not involve patient contact is allowed as long as it does not constitute a demotion or could be viewed as retaliation. Another option, if available, would be for employers to allow employees to provide proof of immunity through, for example, serological tests that measure antibody levels. All these accommodations are subject to the limitation that they must not impose an undue burden on the employer.

Just as state vaccination statutes allow for religious exemptions, employers would be well advised to include religious exemptions in private COVID-19 vaccine requirements.

The Equal Employment Opportunity Commission, on multiple occasions, has pursued actions against health care employers over vaccination mandates that the agency believed failed to accommodate the employees' religious beliefs under Title VII of the 1964 Civil Rights Act.¹⁰⁵ Title VII makes it

Just as state vaccination statutes allow for religious exemptions, employers would be well advised to include religious exemptions in private COVID-19 vaccine requirements.

102 910 F.3d 399 (Eighth Circuit 2018).

103 *Ibid.* at 411.

104 *Ibid.* at 412.

105 42 U.S.C. § 2000e *et seq.*

Before resorting to mandatory vaccinations, we should ensure access to and affordability of a new COVID-19 vaccine to encourage voluntary uptake.

unlawful for employers to discriminate on the basis of various characteristics, including religion, and civil damages can be assessed.¹⁰⁶ Employers' religious exemptions must be neutral without a requirement for participation in a specific religious group, but an employee's objection must be based on religious rather than philosophical or medical grounds.¹⁰⁷

B. Ensuring that Vaccine Cost Is Not a Barrier

Before resorting to mandatory vaccinations, we should ensure access to and affordability of a new COVID-19 vaccine to encourage voluntary uptake. This would occur through two mechanisms: a) existing public and private insurance coverage or b) public-private partnerships to develop, produce, and distribute vaccines to respond to public health emergencies.¹⁰⁸

It is likely that some combination of approaches will be used. In addition, the federal government, through Operation Warp Speed, has made financial commitments to develop, produce, and deliver 300 million vaccine doses to be distributed, by an

as yet unspecified mechanism, to patients at no cost.¹⁰⁹

Cost should not be a significant barrier to vaccination for the most vulnerable group—the elderly and disabled—since they are covered by Medicare. Medicare Part B and Medicare Advantage cover some vaccines (such as influenza, pneumococcus, and hepatitis B) as preventive services without cost sharing (no deductible or coinsurance). Other vaccines have been covered under Medicare Part D, which was created in 2003 by the Medicare Modernization Act. Part D, though, often has cost sharing for medications, including vaccines. Section 3713 of the recently enacted Coronavirus Aid, Relief, and Economic Security, or CARES, Act provides no-cost coverage of a COVID-19 vaccine under Part B.

Medicaid, which provides insurance for the poor, covers all recommended vaccines for children and most vaccines for adults, although coverage and copays vary from state to state. Under the Medicaid Best Price policy, manufacturers must offer Medicaid

106 42 U.S.C. §1981a.

107 See generally Abramson *supra* note 95, at 31-34.

108 Richard Hughs IV, Kelly Cappio, and Alessandra Fix, "Ensuring COVID-19 Vaccine Affordability: Existing Mechanisms Should Not Be Overlooked," Health Affairs Blog, March 30, 2020, <https://www.healthaffairs.org/doi/10.1377/hblog20200327.868172/full/>.

109 Department of Health and Human Services, Fact Sheet: Explaining Operation Warp Speed, September 1, 2020, <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html>.

the best price given to any other purchaser, with a few exceptions, with a minimum discount of 23.1 percent off the list price. In return, Medicaid agrees to cover nearly all of the manufacturer's drugs.¹¹⁰

In addition, most private insurance plans, including individual and group plans, cover preventive services like vaccination without cost sharing. The Affordable Care Act requires that all vaccines recommended by the CDC's Advisory Committee on Immunization Practices (ACIP) be covered without cost sharing by non-grandfathered commercial health insurance plans and Medicaid expansion programs. Traditional Medicaid, though, continues to have some cost sharing requirements. Once a COVID-19 vaccine is available, ACIP should expeditiously include it on its recommended list.

Federally funded health centers, other federal programs, and many state public health services provide preventative services like vaccination for the uninsured.¹¹¹ The federal Vaccines for Children program (VFC) provides childhood vaccines for over

40 million children under 19 who are Medicaid eligible, uninsured, under-insured, or Native Americans or Alaskan Natives.¹¹² The CDC negotiates prices directly with vaccine manufacturers for VFC, usually at substantial discounts to list prices. Section 317 of the Public Health Service Act authorizes federal support of state and local vaccination programs for people who are otherwise uninsured and under-insured and for direct federal purchase of vaccines at discounted, CDC-negotiated rates for distribution to states.¹¹³

The federal government also runs the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to develop, procure, and stockpile medical countermeasures against chemical, radiological, and biological threats, including emerging infectious diseases. Guided by the PHEMCE, the National Institutes of Health and the Biomedical Advanced Research and Development Agency (BARDA) partner with biopharmaceutical companies to develop products through direct

Federally funded health centers, other federal programs, and many state public health services provide preventative services like vaccination for the uninsured.

110 Ramsey Baghdadi, "Medicaid Best Price," Health Affairs Health Policy Brief, August 10, 2017, <https://www.healthaffairs.org/doi/10.1377/hpb20171008.000173/full/>.

111 Department of Health and Human Services/Vaccines.gov, How to Pay, accessed September 3, 2020, <https://www.vaccines.gov/getting/pay>.

112 Centers for Disease Control and Prevention, Vaccines for Children Program (VFC), About VFC, accessed September 3, 2020, <https://www.cdc.gov/vaccines/programs/vfc/about/index.html>.

113 Centers for Disease Control and Prevention, Questions Answered on Vaccines Purchased with 317 Funds, accessed September 3, 2020, <https://www.cdc.gov/vaccines/imz-managers/guides-pubs/qa-317-funds.html>.

The heavy federal involvement in the direct purchase of vaccines either in the existing insurance markets or public-private partnerships means a COVID-19 vaccine would likely be accessible and affordable.

funding and technical assistance with development, testing, and manufacturing. BARDA and its partner companies are already committing funds through Operation Warp Speed to set up manufacturing in advance of vaccine approvals so that production can ramp up quickly once approval is granted. The federal government may directly purchase these products to place in the Strategic National Stockpile or, as was done for the vaccine in the 2009 H1N1 influenza pandemic, to directly distribute in a public health emergency.

The heavy federal involvement in the direct purchase of vaccines either in the existing insurance markets (e.g., the Medicaid best price, VFC, and Section 317 programs) or public-private partnerships means a COVID-19 vaccine would likely be accessible and affordable. The U.S. government announced it is committing to buying the first 100 million doses of Pfizer's proposed COVID-19 vaccine if it proves to be successful and will distribute those doses to Americans at no cost.¹¹⁴ The government has subsequently made similar

arrangements with other vaccine producers.

Even if a vaccine were only going to be provided through private markets, price gouging is unlikely to occur in the current environment. Drug manufacturers are not only concerned with profit maximization; they are also concerned with their public reputation for fairness.¹¹⁵ It is probably not an accident that no vaccine available in the U.S. market has a list price greater than \$230 per dose, and the actual market price for most medical products is well below the list price.¹¹⁶

C. Outreach to Minority Communities to Emphasize the Need for Vaccination and Allay Fears About Safety

While surveys indicate black Americans are less likely to be vaccinated for COVID-19, examining vaccination rates for other diseases indicates that there may not necessarily be a disparity along racial lines. While African Americans over 65 were about 10 percent less likely to receive the

114 Department of Health and Human Services, "U.S. Government Engages Pfizer to Produce Millions of Doses of COVID-19 Vaccine," news release, July 22, 2020, <https://www.hhs.gov/about/news/2020/07/22/us-government-engages-pfizer-produce-millions-doses-covid-19-vaccine.html>.
115 Joel Zinberg, "The Self-Correcting Drug Market," *City Journal*, January 26, 2017, <https://www.city-journal.org/html/self-correcting-drug-market-14985.html>.
116 Hughs, Cappio, and Fix. *supra*.

influenza vaccine than non-Hispanic white Americans, there was little difference in the percentage of children and adolescents vaccinated for childhood diseases (MMR and DTaP vaccines).¹¹⁷ Nonetheless, many claim there is less trust of the medical establishment and experimental vaccines and treatments within minority communities. Both private and government researchers are striving to ensure there is racial and ethnic diversity among subjects in COVID-19 vaccine trials to rule out differences in safety and efficacy between groups and to build up trust in communities that are hardest hit by the disease.¹¹⁸

Conclusion

When, and if, a COVID-19 vaccine is finally approved or authorized by the FDA, it likely will be in limited supply. Therefore, vaccines should be targeted toward the populations that are most vulnerable to the disease: the elderly, those with co-morbid medical conditions, long-term care facility residents, and, in some cases, minority communities. Health care workers in

the acute and long-term care settings should also get priority, since they are exposed on a daily basis to infection and may expose their patients, many of whom are in vulnerable groups, to transmission. As supply becomes more robust, vaccination can be offered to the general population.

But having a supply of vaccine does not ensure that people will use it. Evidence from vaccination for other diseases and public opinion surveys suggest that many will refuse to be vaccinated for COVID-19.

Since consent is always preferable to coercion, no-cost vaccines and other incentives should be provided to encourage voluntary vaccination. But if that does not elicit an adequate response, it may be necessary to mandate that personnel at medical and long-term care facilities receive COVID-19 vaccination as a condition of their employment in order to protect patients and residents from transmission. Preferably, this could be done by private employers in appropriate settings without the need for government action. It also suggests mandatory vaccination of residents of

*Vaccines should
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that are most
vulnerable.*

117 U.S. Department of Health and Human Services/Office of Minority Health, “Immunizations and African Americans,” accessed September 4, 2020, <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=22>.

118 Mary Chris Jaklevic, “Researchers Strive to Recruit Hard-Hit Minorities Into COVID-19 Vaccine Trials,” *JAMA*, published online August 13, 2020, https://jamanetwork.com/journals/jama/fullarticle/2769611?guestAccessKey=21455965-ff5d-4474-a38a-77f5e6f27815&utm_source=silverchair&utm_medium=email&utm_campaign=article_alert-jama&utm_content=olf&utm_term=081320.

long-term care facilities should be considered, since there has been rapid transmission of disease through the vulnerable resident populations in these settings. Reasonable governmental vaccination requirements to protect public health are consistent with constitutional safeguards, but do not yet exist for COVID-19. Private requirements could suffice if they

comply with antidiscrimination statutes and health guidance. Regardless, any mandatory vaccination program must recognize exemptions for medical reasons or genuine religious objections and should, if possible, find ways to accommodate persons who object to vaccination while ensuring the safety of those around them.

About the Author

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