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# Considerations in mandating a new Covid-19 vaccine in the USA for children and adults

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## CONSIDERATIONS IN MANDATING A NEW COVID-19 VACCINE IN THE USA

As cases of coronavirus disease 2019 (COVID-19) spread globally and across the USA, reaching over 140,000 US cases by March 30, 2020 (a number that is almost certainly an under estimate, given the lack of testing across states), scientists and companies throughout the world are searching for a response, a treatment or vaccine.<sup>1</sup> Multiple companies are currently working on developing vaccines for the disease.<sup>2</sup> A vaccine will, by the most optimistic estimates, not be available for at least 12–18 months; but while there is no certainty, there are good chances one or more of variable efficacy will,

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1 United States cases: Centers for Diseases Control and Prevention, *Coronavirus Disease 2019 (COVID-19): Cases in the U.S.*, <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html> (accessed Mar. 30, 2020). Search for a response: Andre C. Kalil, *Treating COVID-19—Off-Label Drug Use, Compassionate Use, and Randomized Clinical Trials During Pandemics*, JAMA, (2020), DOI: 10.1001/jama.2020.4742.

2 Damian Garde, *An Updated Guide to Coronavirus Drugs and Vaccines in Development*, STATNEWS, <https://www.statnews.com/2020/03/19/an-updated-guide-to-the-coronavirus-drugs-and-vaccines-in-development/> (accessed Mar. 19, 2020); Jaimy Lee, *These 16 Companies are Working on Coronavirus Treatments or Vaccines—Here's where Things Stand*, MARKETWATCH, <https://www.marketwatch.com/story/these-nine-companies-are-working-on-coronavirus-treatments-or-vaccines-heres-where-things-stand-2020-03-06> (accessed Mar. 30, 2020).

eventually, be available.<sup>3</sup> When it is, one potential question states will have to address is whether the vaccine should be mandated for school children and anyone else. This article examines this question; the answer, naturally, is ‘it depends’, but this article offers guidance about the ethical and legal considerations for making the decision. The article will address this in three parts: the ethical considerations that affect whether a COVID-19 vaccine mandate is appropriate, potential legal constraints, and practical and political considerations.

One challenge in examining this issue is that our knowledge about COVID-19 is at an early stage: the virus only emerged in late December 2019.<sup>4</sup> And although the intense global focus on the disease has led to an explosion of research on it, many unknowns remain. Uncertainty remains about whether exposure to the virus confers immunity. However, public policy often has to be made in conditions of uncertainty. Public policy cannot wait. It must draw on what is known, try to manage what is uncertain, and prepare for the future and its likely challenges and opportunities.

School mandates have been a staple of US policymaking since the 19th century, and currently, all 50 states and the District of Columbia require vaccines for school.<sup>5</sup> Adult mandates are less common and usually adopted in specific contexts, for example, the famous *Jacobson* case addressed a mandate for a smallpox vaccine in the context of an outbreak.<sup>6</sup> In another recent context, flu shot mandates are targeted at healthcare workers.<sup>7</sup>

There is a large literature about school mandates, and a somewhat more limited literature on adult mandates, but there is less principled discussion of when is it appropriate to mandate a specific vaccine. Field and Caplan suggested an ethical framework to consider when school mandates ought to apply.<sup>8</sup> They suggested that a principled, neutral way to assess a vaccine mandate is to treat it as an intersection of competing values and examine the factors that strengthen or weaken each value in the circumstances. Their framework explains that autonomy, beneficence, utilitarianism, justice, and non-maleficence are the values affected by immunization mandates. Applying the framework here provides important insights on the suitability of a COVID-19 vaccine mandate.

Autonomy focuses on the right of individuals to govern their own behavior and requires both ability to comprehend the choice, the alternatives, the consequences, and freedom from outside limitations. Children generally have less autonomy than adults, because their capacity to make decisions is less.<sup>9</sup> The autonomy in question here is

3 Elizabeth Mahase, *Covid-19: What do We Know So Far about A Vaccine?* 369 BMJ (2020), <https://www.bmj.com/content/369/bmj.m1679> (accessed May 15, 2020).

4 Jeannette Guarner, *Three Emerging Coronaviruses in Two Decades: The Story of SARS, MERS, and Now COVID-19*, 153 AM. J. OF CLIN. PATHOL. 420, 420–21 (2020).

5 Dorit Rubinstein Reiss, *Litigating Alternative Facts: School Vaccine Mandates in the Courts*, 21 U. PA. J. CONST. L. 207, 212 (2018).

6 *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

7 Arthur L. Caplan, *Time to Mandate Influenza Vaccination in Health-Care Workers*, 378 LANCET 310 (2011); Douglas J. Opel et al., *Vaccination without Litigation—Addressing Religious Objections to Hospital Influenza-Vaccination Mandates*, 375 N. ENGL. J. MED. 785 (2018).

8 Robert I. Field & Arthur L. Caplan, *A Proposed Ethical Framework for Mandates: Competing Values and the Case of HPV*, 18 KENNEDY INST. OF ETHICS J. 111, 113–16 (2008).

9 *Id.* at 118.

that of parents to make medical decisions for their children and that autonomy is more limited, since the primary focus is on the child's benefit, with the parent or guardian acting as their agent.<sup>10</sup>

It is unclear what age COVID-19 vaccines will be recommended for, but if adolescents, there may be more of an argument for autonomy and in that case, it is worth considering not just a mandate, but the right of a minor to consent to a vaccine over parental opposition.<sup>11</sup>

For adults, of course, the autonomy argument is stronger but not overwhelming depending on context. Healthcare workers sacrifice some of their autonomy by entering, voluntarily, a highly regulated service profession, where they accept certain requirements (and certain risks) in favor of their patients.<sup>12</sup> Some states, for example Rhode Island, have also enacted mandates for day care workers, and various occupations including military service, offshore oil work and some private employers require vaccination without exceptions except for medical reasons.<sup>13</sup>

The argument for autonomy that an adult might invoke weakens as the risk to others by their non-participatory conduct increases: it is more justified to limit autonomy when its invocation harms others. COVID-19 (unlike influenza, which has more of a bi-modal distribution, where both the old and the very young are at greater risk), is both more contagious and far more lethal than influenza, though the risk of death and hospitalization increases with age.<sup>14</sup>

While the risk to healthy children is less, healthy unvaccinated children who do not receive the vaccine can get—and transmit—the virus both to vulnerable classmates, for example, children with medical conditions that put them at high risk if they get COVID-19, and to high-risk teachers (such as the teacher, administrator, or janitor who is over 60 years old, those who are immunocompromised or have conditions like diabetes or heart disease).<sup>15</sup> There may be additional risks not yet discovered, for example, recent findings from the UK suggest that COVID-19 may cause a severe but rare syndrome in children, though the data are yet too limited to be certain.<sup>16</sup>

Adults can certainly infect others too. In the hospital, there is a substantial risk for both healthcare workers, not just the healthcare workers themselves, discussed below, but also their colleagues including cleaners, technicians, food preparation, first responders, transporters, security, parking, chaplains, social workers, and potentially

10 *Id.*

11 Ross D. Silverman, Douglas J. Opel & Saad B. Omer, *Vaccination Over Parental Objection—Should Adolescents Be Allowed to Consent to Receiving Vaccines?* 381 *NEJM* 104, 104–5 (2019).

12 Field & Caplan, *supra* note 7, at 118.

13 Cary Burke, *No Vaccine? No Job! Court Affirms Employer's Ability to Condition Employment on Vaccination*, NATIONAL LAW REVIEW, <https://www.natlawreview.com/article/no-vaccine-no-job-court-affirms-employer-s-ability-to-condition-employment-upon> (accessed Dec. 12, 2018).

14 Dale Fisher & David Heymann, *Q&A: The Novel Coronavirus Outbreak Causing Covid-19*, 18 *BMC MED.* [https://bmcmecine.biomedcentral.com/articles/10.1186/s12916-020-01533-w?utm\\_source=sn&utm\\_medium=referral&utm\\_content=null&utm\\_campaign=BSLB\\_1\\_CA01\\_GL\\_BSLB\\_AWA\\_CA01\\_GL\\_LSGR\\_PubH\\_Coronavirus\\_LandingPage](https://bmcmecine.biomedcentral.com/articles/10.1186/s12916-020-01533-w?utm_source=sn&utm_medium=referral&utm_content=null&utm_campaign=BSLB_1_CA01_GL_BSLB_AWA_CA01_GL_LSGR_PubH_Coronavirus_LandingPage) (accessed May 15, 2020).

15 Jonas F. Ludvigsson, *Systematic Review of COVID-19 in Children Shows Milder Cases and a Better Prognosis Than Adults*, *ACTA PAEDIATR*, DOI: 10.1111/apa.15270.

16 Amy Woodyatt & Jacqueline Howard, *Coronavirus Could be Tied to a Rare but Serious Illness in Children, UK Doctors Say*, CNN, <https://www.cnn.com/2020/04/27/health/children-covid-19-illness-intl-scli-gbr/index.html> (accessed Apr. 27, 2020).

vulnerable patients.<sup>17</sup> Given the risk to others and the need to keep the health system functioning, the argument for autonomy in any healthcare setting broadly understood seriously weakens. Mandates will surely be imposed with almost no if any exceptions.

Beneficence involves acting for the benefit of others, including by preventing harm to them. A vaccine against COVID-19 would have some benefit for children, since some children get seriously ill from the disease, and rarely, children may die from it.<sup>18</sup> They may also suffer from long-term harms yet to be established, as mentioned above. But most children are asymptomatic or mildly ill with COVID-19, so the known benefits directly to the children are limited (though real). Healthcare workers, in contrast, suffer disproportionately severe disease from COVID-19, and for adults generally, the risks and the corresponding benefits from a vaccine mandate increase with age.<sup>19</sup>

On the other hand, utilitarianism—acting for the benefit of the greatest number for society as a whole—supports a COVID-19 mandate, as it supports other vaccine mandates. School mandates are very effective at increasing vaccine rates and reducing the risk of outbreaks.<sup>20</sup> Hospital mandates are also effective.<sup>21</sup> Although data on adult mandates are limited since they have not often been used in recent times (though New York City imposed a temporary mandate for the measles, mumps, and rubella vaccine during its recent outbreak), data from other contexts suggest they increase rates. The current pandemic is causing harms in lives and suffering, and also economic harms as preventing loss of more life requires measures like sheltering at home, closing businesses, and the closing of public spaces. Preventing these staggering costs is a huge social benefit.

Once a vaccine is available, the justification for measures like shelter at home will decrease, but preventing harms will depend on vaccine use. A mandate will increase use, boost herd immunity and reduce costs. The only caveat is that the balance of costs and benefits depends on the safety of the vaccine. One concern is that the pressure to license and recommend a vaccine quickly, with perhaps less evidence than

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17 James G. Adams & Ron M. Walls, *Supporting the Health Care Workforce During the Covid-19 Global Epidemic*, 323 JAMA 1439, 1439 (2020).

18 Ian P. Sinha et al., *COVID-19 Infection in Children*, LANCET RESPIR. MED. [https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(20\)30152-1/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30152-1/fulltext) (accessed May 15, 2020).

19 Zunyou Wu & Jennifer M. McGoogan, *Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention*, JAMA, (2020), DOI: 10.1001/jama.2020.2648.

20 Nina R. Blank et al., *Exempting Schoolchildren from Immunizations: States with Few Barriers Had Highest Rates of Nonmedical Exemptions*, 32 HEALTH AFF. 1282, 1289 (2013) (confirming the inverse relationship “between non-medical exemptions rates and the complexity of exemption applications procedures”); Jennifer S. Rota et al., *Processes for Obtaining Nonmedical Exemptions to State Immunization Laws*, 91 AM. J. PUB. HEALTH 645, 645 (2001) (finding that less complex nonmedical exemption application processes increase the number of parents claiming exemptions for children); Stephanie Stadlin et al., *Medical Exemptions to School Immunization Requirements in the United States—Association of State Policies with Medical Exemption Rates (2004–2011)*, 206 J. INFECT. DIS. 989, 989 (2012) (finding that states with easier medical exemption methods had an increased number of exemptions); W. David Bradford & Anne Mandich, *Some State Vaccination Laws Contribute to Greater Exemption Rates and Disease Outbreaks in the United States*, 34 HEALTH AFF. 1383, 1383 (2015); Jana Shaw et al., *Immunization Mandates, Vaccination Coverage, and Exemption Rates in the United States*, 5 OPEN FORUM INFECT. DIS. OFY. 130 (2018); Sindiso Nyathi et al., *The 2016 California Policy to Eliminate Nonmedical Vaccine Exemptions and Changes in Vaccine Coverage: An Empirical Policy Analysis*, 16 PLOS MED. 1 (2019).

21 Tiffany L. Wang et al., *Mandatory Influenza Vaccination For All Healthcare Personnel: A Review On Justification, Implementation And Effectiveness*, 29 OFFICE PEDIATRICS 1, 3–5 (2017).

normally would be required by regulators, in the face of a disease causing extensive social upheaval, harms, and social fear, will lead to licensing of a vaccine that will be discovered to have unexpected risks, potentially even greater than the risks prevented. Usually testing a vaccine for licensing takes years, but at least one vaccine candidate has already skipped animal studies, moving straight to stage I trials.<sup>22</sup> Ways to shorten the process for the others are being sought out by companies and regulators.<sup>23</sup> It is possible that shortening the process will not lead to safety problems, but it increases the chances of issues being missed. If that happens, a mandate would have failed the utilitarianism and non-maleficence tests. The USA has multiple mechanisms to oversee vaccines safety, before licensing and after licensing. These include an extensive pre-licensure testing process, licensing through a long FDA process, and after-market, the passive Vaccines Adverse Events Reporting System and active monitoring systems like the Vaccine Safety Datalink and Sentinel.<sup>24</sup> Experience suggests that safety issues with vaccines are, today, rapidly discovered. For example, a rotavirus vaccine licensed in the late 1990s was found, within a short time period, to cause a severe intestinal problem in 1:10,000 cases and was removed from the market, and a flu vaccine for the 2009 pandemic associated with narcolepsy.<sup>25</sup> In both cases, the harm was discovered after the vaccine came to market, but within a short time. The legislative process in states—the process needed to mandate a vaccine—is not short. Further, besides licensing, vaccines are generally not mandated for children (or for healthcare workers) unless the Advisory Committee for Immunization Practices (ACIP) recommends them for the relevant age group, and that also requires a determination that benefits outweigh the risks, which also requires ongoing surveillance.<sup>26</sup> Multiple oversight systems would have to fail to allow a mandate to apply to a vaccine whose risks outweigh its benefits. So although the discovery of a problem may be a possibility, it would require a combination of unlikely events, and for which the chances are very low. Further, since the 1980s the USA provided compensation for vaccine injuries using a no-fault system, in other words, in the rare cases of harms from a vaccine, recipients can be compensated without having to show negligence or a defect in the vaccine, making compensation more easily accessible than in the regular courts.<sup>27</sup> To be covered by the program, a vaccine needs to be recommended by ACIP for either children or pregnant women, so a COVID-

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22 Eric Boodman, *Researchers Rush to Test Coronavirus Vaccine in People without Knowing How Well it Works in Animals*, STATNEWS, <https://www.statnews.com/2020/03/11/researchers-rush-to-start-moderna-coronavirus-vaccine-trial-without-usual-animal-testing/> (accessed Mar. 11, 2020).

23 Peter Sullivan, *Controversial Idea to Speed Coronavirus Vaccine Gains Ground*, THE HILL, <https://thehill.com/policy/healthcare/494417-controversial-idea-to-speed-coronavirus-vaccine-gains-ground> (accessed Apr. 24, 2020).

24 F. DeStefano, P. A. Ofit & A. Fisher, *Vaccine Safety*, in 1584–1600 VACCINES (S. A. Plotkin, W. A. Orenstein, P. A. Ofit, K. M. Edwards eds., 7th ed. 2018).

25 United States cases: Centers for Diseases Control and Prevention, *Rotavirus Vaccine (Rotashield<sup>®</sup>) and Intussusception*, <https://www.cdc.gov/vaccines/vpd-vac/rotavirus/vac-rotashield-historical.htm> (accessed Mar. 30, 2020). United States cases: Centers for Diseases Control and Prevention, *Narcolepsy Following Pandemrix Flu Vaccination in Europe*, <https://www.cdc.gov/vaccinesafety/concerns/history/narcolepsy-flu.html> (accessed Mar. 30, 2020).

26 Jean Clare Smith, *The Structure, Role, and Procedures of the U.S. Advisory Committee on Immunization Practices (ACIP)*, 285 VACCINE A68, A68 (2010).

27 Cody H. Meissner et al. *The National Vaccine Injury Compensation Program: Striking a Balance Between Individual Rights and Community Benefits*, 321 JAMA 343 (2019).

19 vaccine licensed for adults only will not be covered without further legal change.<sup>28</sup> The compensation program is the easiest and most just way to handle the rare cases of vaccine harms, and having those cases covered under it would be an important complement to a mandate.

Justice requires allocating scarce resources based on a principled, reasoned system. In the context of mandates, a precondition to a mandate is a system for providing access to the vaccine. For recommended vaccines, the vaccines for children program addresses many access issues, and again, vaccines are not generally mandated unless they are recommended.<sup>29</sup> However, recent data highlights access issues faced by some children, especially children on Medicaid or children in rural areas.<sup>30</sup> Adults may face additional barriers. A mandate for adults would require proactive efforts by the state to assure that all children and all adults have access to the vaccine. Furthermore, international justice may also support a US mandate, since infected people in the USA will seek to travel abroad.

Non-maleficence requires not harming others. Most currently mandated vaccines have very low risks.<sup>31</sup> Current technology led to the development of vaccines that may have relatively high levels of mild side effects, like sore arms or low fevers, but only rarely cause severe or long-term harm. For example, severe allergic reactions from vaccines, which can be fatal, occur at a rate of about one per million.<sup>32</sup> We do not know yet what form the coronavirus vaccine will take, or what risks it will have. A higher risk vaccine is less likely to justify a mandate, because a mandate could mean more children or adults will be hurt. For children, especially in the context of a disease whose harms increase with age, even though children are still harmed, mandating a vaccine that has more than minimal risks would be an issue. But for both adults and children, the question stands.

In addition, in a recent article Shachar and Reiss pointed out that precedent and context also affect the reasonableness of adopting a vaccine mandate.<sup>33</sup> In the USA, school immunization mandates are a traditional, well-established rule (though they are accompanied by exemptions), and quite a few were adopted in response to general public health needs, which was the driving force behind the smallpox school mandates in the 19th century and the spread of measles mandates, for example, in the 1960–70s.<sup>34</sup> This history also supports a school mandate. Coming out of a large outbreak, and in the context of a country seeking to improve long-term safety from this highly lethal

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28 HRSA, *National Vaccine Injury Compensation Program: Covered Vaccines*, <https://www.hrsa.gov/vaccine-compensation/covered-vaccines/index.html> (accessed Apr. 28, 2020).

29 See Vaccines.Gov, DEP'T OF HEALTH & HUM. SERVS., *How to Pay*, <https://www.vaccines.gov/getting/pay> (accessed May 15, 2020).

30 Holly A. Hill et al., *Vaccination Coverage Among Children Aged 19–35 Months—United States, 2017*, MMWR MORB MORTAL WKLY REP. 1123, 1127 (2018), <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6740a4-H.pdf> (accessed May 15, 2020).

31 Francis E. Andre, *Vaccination Greatly Reduces Disease, Disability, Death and Inequity Worldwide*, 86 B. WORLD HEALTH ORGAN. 81, 81 (2008), <https://www.who.int/bulletin/volumes/86/2/07-040089/en/> (accessed May 15, 2020).

32 Michael McNeil et al., *Risk of Anaphylaxis After Vaccination in Children and Adults*, 137 J. ALLER. CLINI. IMMUN. 868 (2016).

33 Carmel Shachar & Dorit Rubinstein Reiss, *When are Vaccine Mandates Appropriate*, 22 AMA J. OF ETHICS E36, E38 (2020).

34 James Colgrove & Ronald Bayer, *Manifold Restraints: Liberty, Public Health, and the Legacy of Jacobson v Massachusetts*, 95 AJPH 571, 573 (2005).

virus, this context supports one. Adult mandates, however, are no longer common, and have rarely been used (though New York City, experimenting with one, offers a recent precedent<sup>35</sup>). Healthcare worker mandates are in between, somewhat common, but far from universal.

The current legal framework provides states extensive leeway to mandate school immunizations, and in the past, courts have refused to step into evaluating the specific vaccines mandated, leaving that decision, by implication, to the legislature.<sup>36</sup> In fact, the classic *Jacobson* case, in which the court upheld a vaccine mandate, expressly stated that the court is deferring to the legislature.<sup>37</sup> Since all vaccines currently mandated are recommended by an expert committee, ACIP, and subject to extensive professional monitoring, it is reasonable for courts to allow legislatures to choose among these expert-recommended vaccines. But after the initial smallpox mandates, there have not been cases challenging only the mandating of an individual vaccine. The COVID-19 vaccine can raise questions for child mandates because, as mentioned, the main benefits are likely to accrue to others than the children themselves.

Adult mandates are trickier. Healthcare worker mandates will likely be constitutional, because healthcare workers work with a vulnerable population.<sup>38</sup> But they will be subject to federal anti-discrimination laws and may be challenged if they do not offer a religious or medical exemption, though such challenges have always not succeeded.<sup>39</sup> Although *Jacobson* upheld an adult mandate, it has been a long time since *Jacobson*, and the question is less certain today. A detailed analysis of *Jacobson*'s validity is beyond this paper, but it is an important topic.<sup>40</sup> There would have to be evidence of a clear public health necessity, maybe in an emergency situation and maybe a reasonably narrowly tailored approach.<sup>41</sup>

Such questions could have arisen for other vaccines intended for children in the past, except that such vaccines have been bundled with others. For example, rubella

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35 Tyler Page & Jeffery C. Mays. *New York Declares Measles Emergency, Requiring Vaccination in Parts of Brooklyn*, THE NEW YORK TIMES, <https://www.nytimes.com/2019/04/09/nyregion/measles-vaccination-williamsburg.html> (accessed Apr. 9, 2019).

36 Dorit Rubinstein Reiss & Lois A. Weithorn, *Responding to the Childhood Vaccination Crisis: Legal Frameworks and Tools in the Context of Parental Vaccine Refusal*, 63 BUFF. L. REV. 881, 904–907 (2015).

37 *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905).

38 Rene F. Najera & Dorit R. Reiss, *First Do No Harm: Protecting Patients Rough Immunizing Health Care Workers*, 26 HEALTH MATRIX 363 (2016).

39 Id. And see Douglas J. Opel et al., *Vaccination without Litigation—Addressing Religious Objections to Hospital Influenza-Vaccination Mandates* 375 N. ENGL. J. MED. 785 (2018); Dorit R. Reiss & VB Dubal, *Influenza Mandates and Religious Accommodation: Avoiding Legal Pitfalls*, 46 JLME 756, 757 (2018).

40 Reiss & Weithorn, *supra* note 34, at 895–900 discuss that literature, as of 2015. However, *Jacobson* is already in play in the COVID-19 jurisprudence and may change. In a recent blog post, scholars Wiley and Vladeck summarize their coming piece on the issue: Lindsay F. Wiley & Steve Vladeck, *COVID-19 Reinforces the Argument for “Regular” Judicial Review—Not Suspension of Civil Liberties—In Times of Crisis*, HARV. L. REV. BLOG, <https://blog.harvardlawreview.org/covid-19-reinforces-the-argument-for-regular-judicial-review-not-suspension-of-civil-liberties-in-times-of-crisis/> (accessed Apr. 9, 2020).

41 For a narrow approach see, eg Ben Horowitz, *A Shot in the Arm: What a Modern Approach to Jacobson v. Massachusetts Means for Mandatory Vaccinations During a Public Health Emergency*, 60 AM. U. L. REV. 1715, 1730–1740 (2011). For other discussions, see: James Colgrove & Ronald Bayer, *Manifold Restraints: Liberty, Public Health, and the Legacy of Jacobson v. Massachusetts*, 95 AM. J. PUB. HEALTH 571 (2005); Lawrence O. Gostin, *Jacobson v. Massachusetts at 100 Years: Police Power and Civil Liberties in Tension*, 95 AM. J. PUB. HEALTH 576 (2005).

is a disease that is usually mild in children. It is, however, very dangerous for the unborn, and the rubella vaccine's main value is in preventing harm to the unborn, not to children who receive it.<sup>42</sup> This could raise challenging questions about mandating the rubella vaccine, however, since the main benefit is not to school children. Those questions were, however, avoided by the fact that the vaccine for rubella licensed and used in the USA is bundled with the mumps and measles vaccines, and those are diseases that could harm and disable, or kill, children of school age. The other vaccine that could raise questions for mandates is the tetanus vaccine, which, while important to protect children from a very dangerous disease, is a vaccine for a disease that is not communicable, so the harm to others is non-existent.<sup>43</sup> That question, though, did not have to be addressed since the tetanus vaccine was bundled with the vaccine for diphtheria—a communicable, dangerous disease—and later with pertussis, also a dangerous and communicable disease.

A COVID-19 vaccine is unlikely to be bundled, at least initially. So courts are likely to face challenges, where plaintiffs ask them to address the validity of a mandate that benefits others more than the children. Under existing standards, courts should consider their high deference to states on which vaccines to mandate, as long as the vaccine is recommended by ACIP for the age group. To be recommended, the vaccine would have to have benefits that outweigh its risks, including in the target population, which means that the risks to the children would be smaller than the benefits to them, and protecting others would add to the benefits side of the equation. When that is the case, states are on reasonable grounds to recommend it. Preventing outbreaks of diseases that harm and kill is a compelling state interest and courts have consistently upheld school mandates, even against claims of strict scrutiny.<sup>44</sup> There would be no good grounds to deviate from Courts' traditional deference in this case.

Although all states currently have school mandates, states offer various exemptions; all states offer medical exemptions, exempting children whose medical conditions that makes vaccinating especially dangerous, and a majority of states offer non-medical exemptions.<sup>45</sup> A state's general approach to exemption would cover the new COVID-19 vaccine, and states can reconsider that approach in light of current events at any time. Courts have consistently ruled that states have extensive discretion to set their exemption policy, with some limits on the content of a religious exemption, if offered.<sup>46</sup>

Finally, past experience suggests that enacting school mandates or tightening them in the USA is difficult but not impossible.<sup>47</sup> Levin et al. convincingly connect it to two features of US politics: the excessive influence of highly mobilized small group with intense preferences compared to the general public, and the large number of veto

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42 Paul D. Parkman, *Making Vaccination Policy: The Experience with Rubella*, 28 CLIN. INFECT. DISEASES S140 (1999).

43 CTRS. FOR DISEASE CONTROL & PREVENTION. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. 344–345 (Jennifer Hamborsky et al. eds., 13th ed. 2015), <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/tetanus.pdf> (accessed May 15, 2020).

44 Reiss, *supra* note 5, at 238–239.

45 *Id.* at 212.

46 *Id.* at 210.

47 Hillel Y. Levin et al. *Stopping the Resurgence of Vaccine-Preventable Childhood Diseases: Policy, Politics and Law*. 2020 III, L. Rev. 233, 251–254 (2020) on file with author, <https://illinoislawreview.org/print/vol-2020-no-1/stopping-the-resurgence-of-vaccine-preventable-childhood-diseases/>.

points in the legislative process at the state and federal level.<sup>48</sup> But as they point out, circumstances—including a disease outbreak—can and have overcome those features. COVID-19 posed a major crisis for the USA, and the toll it is exacting in terms of death and economic loss provides a moment of opportunity to pass COVID-19-driven mandates by states for children and adults and an opportunity to reconsider their vaccines mandates generally.

In short, depending on the features of the vaccine, there may be good ethical grounds to mandate a COVID-19 vaccine, as long as the risk is low, and access is readily available. Our jurisprudence suggests that states will face few, if any, legal barriers in doing so, and the past political fights brought on by anti-vaccination groups are likely to be significantly weakened by the unparalleled intensity of the COVID-19 crisis.

#### CONFLICT OF INTEREST

Dorit Reiss owns regular stock in GSK, a vaccine manufacturer.

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48 *Id.* pp. 247–254.