



# COVID-19 immunity certificates: science, ethics, policy, and law

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## ABSTRACT

There is much discussion of adopting COVID-19 immunity certificates to allow those proven to have antibodies to the SARS-CoV-2 virus that causes COVID-19 to resume normal life and help restart the economy. This article points out issues that must be considered before adopting any such program. These issues fall into six categories: the uncertain science of COVID-19 immunity; the questionable quality of COVID-19 antibody tests; practical problems with issuing such certificates; deciding how the certificates might be used; ethical and social issues they would raise, especially fairness and self-infection; and potential legal barriers. It does not ultimately take a position on whether some narrow COVID-19 immunity plans should be adopted, concluding that the answer depends on too many currently unknown conditions. But its seventh part makes recommendations to decision-makers who might consider implementing such programs.

**KEYWORDS:** Covid-19, Immunity Certificates, Antibodies, Testing, Law, Ethics, Policy, SARS-CoV-2

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<sup>†</sup> Deane F. and Kate Edelman Johnson Professor of Law, Professor by courtesy of Genetics, Director of the Center for Law and the Biosciences, Stanford University. I explored this idea in a much shorter form in an opinion article published on Apr. 10, 2020: Henry T. Greely, COVID-19 ‘Immunity Certificates’: Practical and Ethical Conundrums, *StatNews* (Apr. 10, 2020), <https://www.statnews.com/2020/04/10/immunity-certificates-covid-19-practical-ethical-conundrums/>. I want to thank my research assistants on this paper, Brittany Cazakoff and Christie Corn, as well as to acknowledge useful contributions from Patrick Skerrett at StatNews, Daniel Hemel, Jeffrey Locke and his team at the National Governors Association, Laura Butcher, John and Eleanor Greely, and two anonymous reviewers. This paper was last revised on May 24, 2020 and is relatively up-to-date through that point.

To buy a drink at a bar, you may be asked to show a document to prove your age. What if you had to prove you were immune to COVID-19<sup>1</sup>—in order to go to work, to use public transportation, to go to a concert or sporting event . . . or to go in a bar to buy a drink? The idea of ‘immunity certificates,’ ‘immunity passports,’ or ‘immunity licenses’ is being discussed with increasing seriousness in the UK<sup>2</sup>, Italy,<sup>3</sup> Chile,<sup>4</sup> Estonia,<sup>5</sup> and the USA.<sup>6</sup> It initially seemed to be most advanced in Germany, where a proposed research project has said it will provide such certificates to people who test positive for antibodies to COVID-19.<sup>7</sup>

COVID-19 immunity certificates offer the enticing promise that an increasing number of people can stop sheltering in place and instead help the world revive. They

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- 1 The current pandemic disease caused by a novel coronavirus is now often referred to as ‘COVID,’ ‘Covid,’ or ‘covid,’ with or without a ‘-19’ attached. (The ‘-19’ refers to 2019, the year it was first identified, and does not imply there were COVIDs 1 through 18—there were not.) This is a shortened version of ‘Coronavirus disease 2019.’ It is also sometimes referred to as the ‘novel coronavirus disease’ or just ‘the coronavirus.’ This article will refer to it as COVID-19.
  - 2 Adam Bienkov, The UK Plans to Issue Coronavirus ‘Immunity Passports’ So People Can Leave the Lockdown Early, *Bus. Insider* (Apr. 3, 2020 1:15 AM), <https://www.businessinsider.com/uk-plans-coronavirus-immunity-passports-so-brits-can-leave-lockdown-2020-4>.
  - 3 Jason Horowitz, In Italy, Going Back to Work May Depend on Having the Right Antibodies, *New York Times* (Apr. 4, 2020), <https://www.nytimes.com/2020/04/04/world/europe/italy-coronavirus-antibodies.html> (explaining the various Italian leaders have spoken about special ‘licenses’ and a ‘Covid pass.’)
  - 4 John Bartlett, Chile’s ‘Immunity Passport’ Will Allow Recovered Coronavirus Patients to Break Free from Lockdown, Get Back to Work, *Wash. Post* (Apr. 20, 2020), [https://www.washingtonpost.com/world/the\\_americas/chile-coronavirus-immunity-passport-antibody-testing-card/2020/04/20/8daef326-826d-11ea-81a3-9690c9881111\\_story.html](https://www.washingtonpost.com/world/the_americas/chile-coronavirus-immunity-passport-antibody-testing-card/2020/04/20/8daef326-826d-11ea-81a3-9690c9881111_story.html).
  - 5 Tarmo Virki, Estonia Starts Testing Digital Immunity Passport for Workplaces, *Reuters* (May 20, 2020), <https://uk.reuters.com/article/health-coronavirus-estonia-digital/estonia-starts-testing-digital-immunity-passport-for-workplaces-idUKKBN22W0GE>.
  - 6 The first discussion I have found in the USA is in an article published on Mar. 25, 2020 in a conservative ‘web magazine’ called *The Federalist*. This advocated that people intentionally infect themselves in order to become immune. ‘Once a patient reliably tests negative for an active infection, he or she receives a certified clean bill of immunity (CCBI) and is allowed to re-enter the community.’ Douglas Perednia, How Medical ‘Chickenpox Parties’ Could Turn the Tide of the Wuhan Virus, *The Federalist* (Mar. 25, 2020), <https://thefederalist.com/2020/03/25/how-medical-chickenpox-parties-could-turn-the-tide-of-the-wuhan-virus/>. (I am not a fan of self-infection but Perednia’s article actually raises some thoughtful concerns about his own plan.) The next discussion seems to be a rather indirect mention in Neel V. Patel, The Coronavirus Test That Might Exempt You from Social Distancing—If You Pass, *MIT Tech. Rev.* (Apr. 2, 2020), <https://www.technologyreview.com/2020/04/02/974964/the-coronavirus-test-that-might-exempt-you-from-social-distancing-if-you-pass/>. This article alludes, in its title and in one sentence, to immunity certificates but focuses on problems with antibody testing. On April 6, Aaron Edlin and Bryce Nesbitt published an opinion article in *StatNews* advocating recognition and use of ‘the certified recovered.’ Aaron Edlin & Bryce Nesbitt, The Certified Recovered from COVID-19 Could Lead the Economic Revival, *StatNews* (Apr. 6, 2020), <https://www.statnews.com/2020/04/06/the-certified-recovered-from-COVID-19-could-lead-the-economic-recovery/>. On April 10, the *New York Times* published a broader news article on the issue. Apoorva Mandavilli & Katie Thomas, Will an Antibody Test Allow Us to Go Back to School or Work? *N.Y. Times* (Apr. 4, 2020) <https://www.nytimes.com/2020/04/10/health/coronavirus-antibody-test.html>. It would not surprise me if there were earlier discussions. After those early discussions, the idea has continued to be discussed in the media and some policy circles in the USA although without any announced decisions to implement it.
  - 7 Adam Bienkov, Germany Could Issue Thousands of People Coronavirus ‘Immunity Certificates’ So They Can Leave the Lockdown Early, *Bus. Insider* (Mar. 30, 2020 4:45 AM), <https://www.businessinsider.com/coronavirus-germany-COVID-19-immunity-certificates-testing-social-distancing-lockdown-2020-3?r=US&IR=T>. Chile and Estonia may have passed Germany in likely adoption in May 2020. See n. 4 and n. 5, *supra*.

might play an important role until we have an effective vaccine or excellent treatments, a period we all hope will be short but whose actual length is unknowable. But they raise problems we must consider, problems that are just beginning to be surfaced<sup>8</sup>—about the science of immunity, about how to provide and police the certificates, and, most important, about a country split between the largely free and the mainly confined.

This article begins what will need to be a much longer and deeper discussion—if the future develops along certain paths. It proceeds in seven parts. The first six of those parts argue that immunity certificates come with major problems. I start by reviewing some of the scientific questions of immunity to COVID-19 and, second, look at antibody tests. The third and fourth parts discuss some of the practical problems they raise, first in issuing COVID-19 immunity certificates and then in how such certificates might be used. (Although not scientifically or ethically exciting, and hence thus far rarely discussed, these may turn out to be the biggest barriers to the implementation of such immunity certificates anytime soon.) Only then, in the fifth and sixth parts, I begin to consider the ethical and social issues stemming from immunity certificates and possible legal barriers to their adoption and use. The last part shifts gears. Although I believe such certificates should ‘not’ be implemented now, I end with seven suggestions for decision-makers considering them in a less uncertain future.

The article raises far more questions than it answers, but it raises questions that will need to be answered, carefully and rigorously, if immunity certificates are to be tried. I hope laying out the issues may help others discuss and debate such answers.

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8 Although it is certainly possible, and perhaps likely, that COVID-19 immunity certificates were being discussed skeptically in print in March (or earlier), the first critical publication I know of is a blog post by the Nuffield Council’s Peter Mills, posted on April 1 (which I did not see until April 10). Peter Mills, *Liberty, Solidarity and the Biopolitics of COVID-19*, <https://www.nuffieldbioethics.org/blog/liberty-solidarity-and-the-biopolitics-of-COVID-19>. Mills looked at both the scientific and the ethical problems with the proposal. Patel’s article in the MIT Technology Review on April 2, *supra* n. 6, raised concerns about antibody testing. On April 9, Patel returned to the topic, discussing COVID-19 immunity certificates more directly but again in the context of scientific uncertainty. *Why It’s Too Early To Start Giving Out ‘Immunity Passports,’ MIT Tech. Rev.* (Apr. 9, 2020), <https://www.technologyreview.com/2020/04/09/998974/immunity-passports-cornavirus-antibody-test-outside/>. The next day I published an opinion piece in StatNews raising, in 10% of the words, most of the issues discussed in more depth in this article. Henry T. Greely, *COVID-19 ‘Immunity Certificates’: Practical and Ethical Conundrums*, StatNews (Apr. 10, 2020), <https://www.statnews.com/2020/04/10/immunity-certificates-covid-19-practical-ethical-conundrums/>. Since then, and since initial submission of this article, the topic has increasingly been discussed. On Apr. 24, 2020, the World Health Organization (“WHO”) issued a statement recommending against immunity certificates because of uncertainties about immunity. <https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19>. And academics have been many pieces on the topic, pro and con. Six that I found of particular interest are (in order of publication) Françoise Baylis & Natalie Kofler, *COVID-19 Immunity Testing: A Passport to Inequity*, *Issues in Sci. & Tech.* (Apr. 29, 2020); Alexandra L. Phelan, *COVID-19 Immunity Passports and Vaccination Certificates: Scientific, Equitable, and Legal Challenges*, *The Lancet* 395 (published on-line May 24, 2020), [https://doi.org/10.1016/S0140-6736\(20\)31034-5](https://doi.org/10.1016/S0140-6736(20)31034-5); Govind Persad & Ezekiel Emanuel, *The Ethics of COVID-19 Immunity-Based Licenses (‘Immunity Passports’)*, *J. Am. Med. Ass’n* (May 6, 2020), <https://jamanetwork.com/journals/jama/fullarticle/2765836>; Mark A. Hall & David M. Studdert, *Privileges and Immunity Certification During the COVID-19 Pandemic*, *J. Am. Med. Ass’n*, (May 6, 2020), <https://jamanetwork.com/journals/jama/fullarticle/2765835>; Daniel Hemel & Anup Malani, *Immunity Passports and Moral Hazard*, SSRN (May 8, 2020), at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3596569](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3596569); and Natalie Kofler and Françoise Baylis, *Ten Reasons Why Immunity Passports Are a Bad Idea*, *Nature* (May 21, 2020), <https://www.nature.com/articles/d41586-020-01451-0>.

But, first, I need to provide an important warning. Our knowledge about all aspects of this pandemic is changing rapidly and it could well be that everything we know is wrong.<sup>9</sup> This article is based on what seemed to me the best information available at the time it was initially submitted, April 20, 2020, as updated as of the time of its last revision, May 25, 2020. Some of its ‘facts’ will almost certainly be wrong whenever the ‘now’ is when you read it. *Caveat lector!*

### I. THE SCIENCE OF COVID-19 IMMUNITY

The human immune system is extraordinarily complicated. Over 30 years of working in law and the biosciences, I have concluded that human neuroscience is orders of magnitude more complex than (very complex) human genomics. The immune system seems, to me, somewhere between those two. The human immune system is actually a combination of a variety of different approaches, which sometimes are life-saving . . . and sometimes, when they overreact, are deadly. What follows is an enormously oversimplified depiction of just one part of the immune system, but it should be useful.

On the other hand, if you are not interested in the science behind immunity questions, or already know it well, you can skip to the next part. You just need to know that we do ‘not’ know whether people infected with COVID-19 have any immunity, have some but not 100% immunity, or have partial immunity that mitigates symptoms but does not prevent reinfection—and for how long any of the various kinds of immunity last.

Of the immune system’s many parts, the part that is of most concern in this context is Immunoglobulin G (IgG). IgG is an antibody, a molecule that circulates in the blood, recognizes a specific ‘non-self’ virus or cell by some of its molecules (called ‘antigens’), binds to them, and leads to a variety of attacks on the invading virus or cell. The human immune system makes many kinds of antibodies but various forms of IgG make up about three-quarters of the antibodies found in blood. (IgG is also found in non-blood fluids outside of cells, such as lymph). Some of those antibodies will last a lifetime. It is part of what is called the ‘humoral immune system.’<sup>10</sup>

White blood cells known as ‘B’ cells produce the so-called ‘B-cell receptors.’ The receptors lead the B cells to bind to specific molecules or molecular structures found on or as a result of an invader. These molecules or molecular structures are known generically as ‘antigens.’ When these B cells encounter ‘their’ antigens, the B-cell receptor binds to it and the B cells multiply and change into what are then called ‘plasma cells.’

These plasma cells release IgG and other antibodies. They ramp up to enormous production of IgG in the days after an infection—a ‘foreign’ invasion. Each individual plasma cell produces several thousand antibodies per second. After the infection has passed, production decreases markedly. But some of the B cells that specialized in the particular antigen found on that particular invader can survive for decades. If the body detects that same antigen again on an invader, those cells can quickly lead to massive

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9 See Alfred Matthew (Weird Al) Yankovic, *Everything You Know Is Wrong, on Bad Hair Day* (Scotti Brothers 1996).

10 Humoral immunity is also called antibody-mediated immunity.

production of antibodies. These cells are known as ‘memory B cells.’ Memory B cells form one of the bases for our continuing and often lifelong immunity to some diseases, such as measles. Unfortunately, this immunity does not last long for all disease-causing entities. Some of them, like the various human influenza viruses, change so rapidly that last year’s antibodies will not recognize this year’s influenza. For others, IgG production and the memory B cell stockpiles are weak or quickly lost.

When people are infected with SARS-CoV-2 (the virus that causes COVID-19),<sup>11</sup> their immune systems seem generally to produce IgG that spots and binds to specific proteins on that virus.<sup>12</sup> This process takes several days. The exact time range is not clear but it appears to be about 7 to 10 days from infection to production of significant amounts of the relevant IgG.<sup>13</sup>

The immune system produces another kind of antibody, called Immunoglobulin M (IgM). This appears more quickly but is not nearly as specific. IgM can bind to many antigens on different kinds of invaders and can lead, again through different paths, to their destruction. IgM appears very quickly after infection but also fades away quickly. For SARS-CoV-2 the early evidence is that IgM appears within 2 days but begins to fade after a week or two, by which time IgG should be common.<sup>14</sup>

How do we know when a SARS-CoV-2 infection (and hence a case of COVID-19) has begun or has ended? We test the patient for the virus’s genetic code. All life uses DNA to store its genetic code except (or “but”—whether viruses are ‘alive’ is controversial) for some viruses, which use DNA’s cousin, RNA. SARS-CoV-2 uses a single strand of RNA for its genes; that RNA strand, the virus’s ‘genome,’ is 29,811 bases long and codes for (provides instructions for) 29 proteins.<sup>15</sup> An exact sequence of parts of the SARS-CoV-2 genome—a sequence not found in humans or in other viruses or microbes found in humans— can be used to detect whether a sample from a person contains any of the virus’s RNA using a technique called ‘polymerase chain reaction’

11 This is the name given the virus that causes COVID-19. It is sometimes referred to as ‘the novel coronavirus’ or ‘the virus’ but this article will use its formal name. SARS-CoV-2 is a species of ‘coronavirus,’ a term that refers to a large family of viruses that infect humans and other animals. The name comes from the fact that they have spikes that, through an electron microscope, look like a ‘crown,’ which in Latin is called a ‘corona.’ At least seven species of coronavirus are known to infect humans. Four of them cause common colds; three cause more serious illnesses. The virus that causes COVID-19 genetically very similar to the coronavirus that, in 2002–2003, caused a deadly epidemic of Sudden Adult Respiratory Syndrome (SARS). As a result, the virus causing COVID-19 has been named SARS-CoV-2 (and the virus that causes SARS has had a ‘1’ added to its name.) The third deadly coronavirus is MERS-CoV, which causes Middle East Respiratory Syndrome, or MERS. <https://www.cdc.gov/coronavirus/types.html>.

12 Kelvin Kai-Wang To, Temporal Profiles of Viral Load in Posterior Oropharyngeal Saliva Samples and Serum Antibody Responses during Infection by SARS-CoV-2: An Observational Cohort Study, *Lancet Infectious Disease* (forthcoming 2020) (published online Mar. 23, 2020, <https://www.sciencedirect.com/science/article/pii/S1473309920301961?via%3DIihub>). For a summary of the To article, see Yu Chen & Lanjuan Li, SARS-Cov-2: Virus Dynamics and Host Response, *Lancet Infectious Disease* (Mar. 23, 2020), [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30235-8/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30235-8/fulltext).

13 Chen & Lanjuan, *supra* note 12, at 1 (noting study subjects showed increases in IgG and IgM after about ten days of symptom onset); US Food & Drug Admin., Fact Sheet For Healthcare Providers 2 (2020), <https://www.fda.gov/media/136623/download> [hereinafter ‘FDA Fact Sheet’] (noting IgG antibodies develop about seven to ten days post-infection).

14 See FDA Fact Sheet, *supra* note 13, at 1–2.

15 Alla Katsnelson, What Do We Know About the Novel Coronavirus’s 29 Proteins?, *C&EN* (Apr. 1, 2020), <https://cen.acs.org/biological-chemistry/infectious-disease/know-novel-coronavirus-29-proteins/98/web/2020/04>

or 'PCR.' This 'viral RNA' test is commonly used to decide whether or not people are infected with SARS-CoV-2 and thus 'have' COVID-19, whether or not they show any symptoms.

It must be noted, though, that it is not clear that all patients who have a positive viral RNA test will have developed detectable IgM or IgG antibodies to the virus.<sup>16</sup> Some may not because they became infected within the last day or two and have not yet had time to produce IgM, let alone IgG. But, as discussed below there is concern that some infected people, particularly those with milder cases, may never produce detectable antibody levels of IgM or IgG.

Infection with SARS-CoV-2 seems generally to last for about 2 to 3 weeks. The symptoms may be visible for much less time, or, in substantial percentage of cases (a percentage still deeply unclear and disputed), may never appear. Some patients will have symptoms and remain in very serious condition much longer than that. This is not always because they still have active virus but may be because they develop other conditions the virus has caused, such as the often deadly overreaction called an 'immune storm' or secondary bacterial infections.<sup>17</sup> This means that many and probably most people who have IgM antibodies will still be infected with active virus. By the time patients begin producing IgG, the infection may be fading and could already be gone. The IgG though, unlike the IgM, should last long after all the virus is gone.

The fact that a patient has developed IgG antibodies to a virus does not necessarily mean that the patient will develop lasting immunity. For many viruses, such as influenza, the antigens on the virus mutate so quickly that last year's, or last month's, IgG antibodies may not recognize the new version. Influenza antigens change unusually quickly.<sup>18</sup> For some other viruses that cause disease, such as measles or polio, the viral antigens remain unchanged and antibodies may protect former patients for the rest of their lives.

In other cases, the antibodies are either too weak to prevent a new infection or dissipate or even disappear in a short time. And in still other cases, like HIV-infection, the infection, and the patient's ability to infect others, will persist even in the face of robust antibody production. These different outcomes may be functions of the particular virus involved or may stem from a patient's other conditions. The immune system weakens as people age; the elderly may no longer be able to mount a strong immune response to a known antigen. Similarly, people with immune systems weakened by some diseases or by some treatments, such as chemotherapy or radiation therapy for cancer, may not be able to fight off the previously seen invader. The same may be true of people taking immune suppression drugs as a result of some organ transplants or as treatment for some diseases caused by an overactive immune system.

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16 See FDA Fact Sheet, *supra* note 13, at 1–2.

17 Meredith Wadman et al., *How Does Coronavirus Kill? Clinicians Trace a Ferocious Rampage Through the Body, From Head to Toe*, *Science* (Apr. 17, 2020 6: 45 AM), (noting at least some clinicians suspect SARS-Cov-2 can trigger a cytokine storm); Oliver Schacht, *COVID-19 Patients Need to Be Tested for Bacteria and Fungi, Not Just the Coronavirus*, *Sci. Am.* (Apr. 16, 2020), <https://blogs.scientificamerican.com/observations/COVID-19-patients-need-to-be-tested-for-bacteria-and-fungi-not-just-the-coronavirus/> (explaining many hospitalized patients have secondary bacterial infections that can be life-threatening).

18 Ctrs. for Disease Control & Prevention, *How the Flu Virus Can 'Drift' and 'Shift,'* (last reviewed Oct. 15, 2019) (explaining influenza viruses are 'constantly changing.')

Some viruses managed to hide successfully from the immune system, going dormant for a long time before recurring. The virus that causes chicken pox, *Herpes zoster*, can do that, often re-emerging decades later as the painful condition called shingles.

Note well that immunity can be weak in various ways. It can protect fewer than all of those infected, it can protect them for only a limited time, it can provide the limited but often valuable protection of weaker symptoms—or it can do any combination of the above. There seems to be no particular reason to expect SARS-CoV-2 to pose extreme problems for human immune systems but, at this point, we just cannot know. We have, at most, 6 months of experience with this virus in humans.

We do know something about its relatives. SARS-CoV-1, the disease that caused the outbreak of SARS in 2002–2003, did provoke strong antibody responses with IgG lingering for at least several years. There are no confirmed reports of patients being reinfected with SARS-CoV-1, but we have very limited experience with SARS. From November 2002 through March 2003, the WHO counted about 8100 probable cases, 774 of whom died. The disease then disappeared, making a very small return in China with about 10 possible cases in April 2004.<sup>19</sup> CDC reports that, since 2004, no human cases of SARS have been identified.<sup>20</sup>

We also have some experience with other coronaviruses, including those responsible for about 10 to 15% of Americans' 'common colds.'<sup>21</sup> Some of those other coronaviruses lead the body to produce antibodies, and immunity, for a few months or a year.

As to SARS-CoV-2 itself, here's the little we currently know about it and immunity.<sup>22</sup> The best test of immunity is whether the virus can re-infect an already recovered patient. A few scattered and poorly documented reports from China claim some recovered COVID-19 patients have become re-infected.<sup>23</sup> Initially more worryingly, South Korean authorities reported that over 160 people had positive viral RNA tests, recovered, had negative viral RNA tests—but then had positive RNA tests again.<sup>24</sup> Subsequently, Korean researchers concluded that the subsequent positive tests were false positives, caused by the continuing presence in the former patient of fragments of the virus, but not functional viral particles.<sup>25</sup>

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19 Ctrs Disease Control & Prevention, Frequently Asked Questions About SARS, (last reviewed May 3, 2005).

20 SARS (10 Years After), Ctrs Disease Control & Prevention, (last reviewed Mar. 3, 2016).

21 Terho Heikinnen & Asko Jarvinen, The Common Cold, 361 *The Lancet* 51, 52 (2003).

22 The points below, and more, are summarized in this nice review: Andrew Joseph, Everything We Know About Coronavirus and Antibodies—And Plenty We Still Do not, *StatNews* (Apr. 20, 2020), <https://www.statnews.com/2020/04/20/everything-we-know-about-coronavirus-immunity-and-antibodies-and-plenty-we-still-dont/>.

23 Hillary Leung, Can You Be Re-Infected After Recovering from Coronavirus? Here's What We Know About COVID-19 Immunity, *Time* (as updated Apr. 13, 2020), <https://time.com/5810454/coronavirus-immunity-reinfection/>.

24 See Yonhap News Agency, Coronavirus Relapse Cases Continue to Rise in S. Korea, (Apr. 18, 2020), <https://en.yonhap.co.kr/view/AEN20200417006800320>; Josh Smith, South Korea Reports More Recovered Coronavirus Patients Testing Positive Again, *Reuters* (Apr. 13, 2020), <https://www.reuters.com/article/us-health-coronavirus-southkorea-idUSKCN21V0JQ>.

25 Kim Bo-gyung, Tests in Recovered Patients Found False Positives, Not Reinfections, Experts Say, *The Korea Herald* (Apr. 29, 2020), [www.koreaherald.com/view.php?ud=20200429000724](http://www.koreaherald.com/view.php?ud=20200429000724).

One other piece of direct evidence about re-infection does exist. Researchers infected rhesus monkeys (macaques) with SARS-CoV-2.<sup>26</sup> The monkeys showed symptoms of COVID-19 but survived. The researchers then determined that the monkeys made antibodies to one of the two key antigens of the virus, the so-called spike protein. The researchers later re-infected two of the monkeys with the virus; they developed a slight fever but no other signs of the infection, including no viral RNA.<sup>27</sup> Again, this research is only published as a non-peer reviewed preprint.

More evidence about immunity comes from antibodies. If people who have recovered show no antibodies (notably IgG specific to SARS-CoV-2), it is unlikely they have much immunity. One scientific paper from China, so far available (like most of the research papers on this virus) only as a non-peer reviewed preprint, finds that a surprisingly large percentage of people who were known to have had COVID-19 infections show few or no antibodies,<sup>28</sup> although this article has been criticized for focusing on only one of the two major antigens produced by SARS-CoV-2.<sup>29</sup> A subsequent Chinese paper, that looked at 287 patients, concluded that every one of them developed strong antibody responses.<sup>30</sup> And third paper, from scientists at the Rockefeller Institute, showed that some recovered patients had no detectable antibodies and many had very low levels of antibodies.<sup>31</sup>

There is no strong evidence that infection with SARS-CoV-2 or a diagnosis of COVID-19 fails to confer at least some immunity, in at least most of the people it infects. But there is also no strong evidence that it does, and, if so, how strongly and for how long. One respected epidemiology, Marc Lipsich of Harvard University, recently summed up his view:

After being infected with SARS-CoV-2, most individuals will have an immune response, some better than others. That response, it may be assumed, will offer some protection over the medium term—at least a year—and then its effectiveness might decline.<sup>32</sup>

We may get a clearer answer soon, as the specific papers, or preprints of papers, cited here are supplemented, or supplanted, by others. (Of course, we can never know

26 Linlin Bao et al., Reinfection Could Not Occur in SARS-CoV-2 Infected Rhesus Macaques (Mar. 13, 2020) (preprint), <https://www.biorxiv.org/content/10.1101/2020.03.13.990226v1.full.pdf>; see also Katarina Zimmer, Monkeys Develop Protective Antibodies to SARS-CoV-2, *The Scientist* (Mar. 17, 2020), <https://www.the-scientist.com/news-opinion/monkeys-develop-protective-antibodies-to-sars-cov-2-67281>.

27 *Id.*

28 See Fu Wan, Neutralizing antibody responses to SARS-CoV-2 in a COVID-19 recovered 2 patient cohort and their implications (Mar. 30, 2020) (preprint), <https://www.medrxiv.org/content/10.1101/2020.03.30.20047365v1.full.pdf>. For a summary of the Wan article, see Stephen Chen, Coronavirus: Low Antibody Levels Raise Questions About Reinfection Risk, *South China Morning Post* (Apr. 7, 2020), <https://www.scmp.com/news/china/science/article/3078840/coronavirus-low-antibody-levels-raise-questions-about>.

29 Ravji Pandit, Twitter Post, Apr. 7, 2020 9:14 PM, [https://twitter.com/ravji\\_pandit/status/1247739636740472832](https://twitter.com/ravji_pandit/status/1247739636740472832) (noting the Wan study only focused on the COVID-19 surface spiked protein antigen).

30 Quan-Xing Long, Antibody Responses to SARS-CoV-2 in Patients with COVID-19, *Nature Med.* (Apr. 29, 2020), <https://www.nature.com/articles/s41591-020-0897-1>.

31 Davide F. Robbiani, et al., Convergent Antibody Responses to SARS-CoV-2 Infection in Convalescent Individuals *BioRxiv* (May 15, 2020), <https://www.biorxiv.org/content/10.1101/2020.05.13.092619v1>.

32 Marc Lipsich, Who Is Immune to the Coronavirus?, *New York Times* (Apr. 13, 2020), <https://www.nytimes.com/2020/04/13/opinion/coronavirus-immunity.html>.



whether, for example, immunity lasts for 5 years until at least 5 years from the first cases.) But while the uncertainty persists, it is vitally important to the question of immunity certificates. If people receive certificates granted on the basis of positive antibody tests but they are not, in fact, immune, not only can they be (re)infected but they can infect others.

## II. ANTIBODY TESTING

But let us assume SARS-CoV-2 infection provides some degree of immunity for most of those infected, probably for at least 1 year, before declining. Then how could we test for that immunity?

The best way would be to test people directly for SARS-CoV-2 antibodies. (Remember—this is ‘different’ from testing for infection, which looks for the RNA of the SARS-CoV-2 virus.) Antibody tests are well understood, and research laboratories and firms around the world are developing such tests for SARS-CoV-2 antibodies.<sup>33</sup> On April 1, 2020 FDA allowed the first such test to be used.<sup>34</sup> More followed.

These tests are important and exciting. Viral RNA tests tell you who currently has viral RNA and so either is, or very recently was, infected with SARS-CoV-2. Antibody tests, especially if they test for IgG antibodies, can tell you who ‘was’ infected (assuming infected people generate IgG antibodies). That gives you a history of the pandemic and its growth. It tells you how much of your population has been and has yet to be infected. It lets you calculate an accurate percentage of how many of those actually infected, not just seen as infected, get hospitalized, get put on a ventilator, or die from COVID-19 (or, at least, get counted as dying from it). And, if IgG antibodies do confer substantial immunity, it tells you both how much of your population and ‘who’ in your population—is now immune to the disease. This information is crucial and many voices are crying for widespread antibody testing as a vital next step.<sup>35</sup> In early April, some researchers, including some at Stanford,<sup>36</sup> began to do such widespread testing while others, notably in Germany, are proposing large scale testing projects, seeking to test 100,000 Germans for these antibodies.<sup>37</sup> By mid-May many studies had been done, in the USA and around the world, finding antibodies in anywhere from 0.7% of

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33 Matthew P Cheng et al., Diagnostic Testing for Severe Acute Respiratory Syndrome–Related Coronavirus-2: A Narrative Review, *Annals Internal Med.*, Apr. 13, 2020, <https://annals.org/aim/fullarticle/2764737/diagnostic-testing-severe-acute-respiratory-syndrome-related-coronavirus-2-narrative> (reviewing the tests available for SARS-CoV-2 around the world).

34 U.S. Food & Drug Admin., Opinion Letter on Emergency Use Authorization for qSARS-CoV-2 IgG/IgM Rapid Test (Apr. 1, 2020), <https://www.fda.gov/media/136622/download>.

35 Dan Mangan, The US Economy Cannot Reopen Without Widespread Coronavirus Testing. Getting There Will Take A Lot of Money and Work, *CNBC* (Apr. 16, 2020), <https://www.cnbc.com/2020/04/16/coronavirus-testing-needs-to-be-widely-done-before-economy-reopens.html>; Geoff Brumfield, To End the Coronavirus Crisis, We Need Widespread Testing, Experts Say, *NPR* (Mar. 24, 2020), <https://www.npr.org/sections/health-shots/2020/03/24/820157519/to-end-the-coronavirus-crisis-we-need-widespread-testing-experts-say>.

36 Erin Digitale, Testing for Antibodies Against Novel Coronavirus Developed at Stanford Medicine, *Stanford Med.* (Apr. 10, 2020), <https://med.stanford.edu/news/all-news/2020/04/stanford-medicine-develops-antibody-test-for-coronavirus.html>.

37 Katrin Bennhold, With Broad, Random Tests for Antibodies, Germany Seeks Path Out of Lockdown, *New York Times* (Apr. 18, 2020), <https://www.nytimes.com/2020/04/18/world/europe/with-broad-random-tests-for-antibodies-germany-seeks-path-out-of-lockdown.html>.

over 5600 Major League Baseball employees tested<sup>38</sup> to about 20% of people in New York City.<sup>39</sup> Most of the results outside the hardest hit locations were between about 2% and 6%.

But . . . no test is perfect. For example, physicians and researchers are increasingly suggesting that as many as one-third of the positive tests for viral RNA may be false negatives.<sup>40</sup> Just like viral RNA tests, antibody tests are imperfect. Some will detect antibodies that do not exist (false positives), others will miss antibodies that do exist (false negatives). False positives may be a particular problem here, as sometimes the tests might signal positive for SARS-CoV-2 either completely inaccurately or when they are really detecting antibodies to the cold-causing coronaviruses.

Although the US FDA has not ‘approved’ any such tests, it has allowed some to be used and other tests have been deployed in other countries. Their accuracy is deeply suspect. For example, the UK had planned to embark on a major survey of antibody rates in its population. It contracted for 17.5 million antibody tests, from nine different firms.

The government is working with nine companies that have developed coronavirus antibody tests, which screen for whether someone has recovered from the disease and is likely to be immune. The tests are being assessed by researchers at Oxford university—but each one has so far proven unreliable . . .

Downing Street confirmed on Monday that ‘no test so far has been proved to be good enough to be used’ and said it was working with the companies to improve their quality.<sup>41</sup>

How accurate are antibody tests in use in the USA? The FDA classifies tests used to detect antibodies as medical devices and claims regulatory jurisdiction over them. In theory, it will not allow them to ‘enter into interstate commerce’ unless they have been shown to be safe and efficacious. The practice is a more complicated.

For decades FDA has allowed medical laboratories to use tests FDA has not approved through the so-called Laboratory Developed Test (‘LDT’) exemption. It is not in the FDA’s statutes but the agency uses its enforcement discretion to not

38 Bill Shaikin, Fewer than 1% of MLB Employees Test Positive for COVID-19 Antibodies, L.A. Times (May 10 2020), <https://www.latimes.com/sports/story/2020-05-10/mlb-employees-test-positive-for-coronavirus-antibodies-COVID-19>.

39 New York State, Amid On-Going COVID-19 Pandemic, Governor Cuomo Announces Results of Completed Antibody Test Study of 15,000 People Showing 12.3% of Population Has COVID-19 Antibodies, (May 2, 2020). <https://www.governor.ny.gov/news/amid-ongoing-COVID-19-pandemic-governor-cuomo-announces-results-completed-antibody-testing>.

40 Yang Yang, Evaluating the accuracy of different respiratory specimens in the laboratory diagnosis and monitoring the viral shedding of 2019-nCoV infections (Feb. 17, 2020) (preprint), <https://www.medrxiv.org/content/10.1101/2020.02.11.20021493v2>; Harlan M. Krumholz, If You Have Coronavirus Symptoms, Assume You Have the Illness, Even If You Test Negative, N.Y. Times (Apr. 1, 2020); <https://www.nytimes.com/2020/04/01/well/live/coronavirus-symptoms-tests-false-negative.html> Arjun K. Manrai & Kenneth D. Mandl, COVID-19 Testing: Overcoming Challenges in the Next Phase of the Epidemic, Stat (Mar. 31, 2020), <https://www.statnews.com/2020/03/31/COVID-19-overcoming-testing-challenges/> (noting there is a growing concern that tests are imperfect, and poor sample collection could produce false negatives). It is thought that many of the false negatives are a result of bad samples; patients do not like to have swabs pushed deep into their throats or up their noses and the swabs may not penetrate far enough to find virus-laden mucus.

41 Camilla Hodgson & George Parker, UK Government Admits COVID-19 Antibody Tests Do not Work, Fin. Times (Apr. 6, 2020), <https://www.ft.com/content/f28e26a0-bf64-4fac-acfb-b3a618ca659d>.

meddle in a well-run and regulated field. These laboratories are licensed by the states, run by pathologists, and generally accredited by the College of American Pathologists. How well they perform the tests is also regulated by a federal statute called CLIA ('the Clinical Laboratories Improvements Amendments Act of 1988').

The LDT exception does not apply to test kits that laboratories, medical offices, or hospitals buy from manufacturers. Those still require FDA approval or clearance. (It also does not apply to direct-to-consumer tests, where FDA has demanded evidence that consumers can reasonably use and understand the test and its results.)

The bottom line is that FDA can regulate antibody testing very carefully or, if it is done as an LDT, almost not at all. But there is yet another path. Even if the test a kit from a manufacturer and so cannot be an LDT, the FDA can permit its use under something called an Emergency Utilization Authorization ('EUA'). This approach, created in 2004 in the aftermath of the post-9/11 Anthrax attacks, allows it, in emergencies, to regulate devices, like tests, as well as drugs or biological products (like vaccines) less stringently. If there is 'reason to believe' they 'may be effective,' FDA can grant a product an EUA and it can be used legally in the USA although the product must acknowledge that it is not 'approved' by the FDA.<sup>42</sup> In the case of COVID-19, the Secretary of the U.S. Department of Health and Human Services declared a public health emergency. The Department then said it was willing to employ EUAs in that emergency, and FDA would consider specific applications before it for such EUAs.<sup>43</sup>

FDA's regulation of COVID-19 testing got off to a disastrous start, when it effectively banned all viral RNA tests except a flawed test from the Centers for Disease Prevention and Control, hamstringing efforts to determine who was and wasn't infected and how big the epidemic was. FDA changed course in late February 2020 and allowed many viral RNA tests to proceed with EUAs.

It then proceeded to make the opposite mistake with antibody tests. On March 16, it announced that it did not intend to object to the distribution and use of serology tests to identify antibodies to SARS-CoV-2 where the test has been validated, notification is provided to the FDA, and warning statements are included with the tests, for example, noting the test has not been reviewed by the FDA and that results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.<sup>44</sup>

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42 See an excellent explanation of EUAs in Erika Lietzan, *Emergency Use Authorizations, Objective Intent* (blog) (Feb. 24, 2020), <https://objectiveintent.blog/2020/02/24/emergency-use-authorizations/>. As Professor Lietzan notes, the EUA provisions also put some restrictions on LDTs. FDA said that once the Secretary of the Health and Human Services had declared an emergency about a particular disease, a necessary prerequisites for any EUAs for that disease, qualifying laboratories would have to get an EUA even for what would otherwise be LDTs. On February 29, she notes, FDA weakened that requirement to allow labs certified for 'high complexity testing' to use their own LDT for a COVID-19 test as long as they had applied for an EUA, whether or not one had been granted.

43 *Id.*

44 FDA, *Coronavirus (COVID-19) Update: FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics* (Mar. 16, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-COVID-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help>.

EUAs were allowed but not required. The result was a flood of antibody tests on the US market, many of them of extremely dubious accuracy.<sup>45</sup> Another result was, 7 weeks later, on May 4, by which time at least 160 antibody tests were on the US market, another FDA change of position. Noting the inaccuracy, misrepresentation, and occasional outright fraud in these tests, FDA said that it would require all such tests either to have an EUA, to apply within 10 days for an EUA, or to be done in a high-complexity laboratory.<sup>46</sup> On May 21 it acted, naming 27 antibody tests that it would no longer allow to be sold.<sup>47</sup>

So how accurate are the tests that FDA is continuing to allow to be used? CellTex, the first company whose test the FDA has permitted, says that its tests 'agreed with positive results from PCR test [viral RNA tests] 93% of the time and negative results 96% of the time.'<sup>48</sup> 'Specificity' is the term used for how often a test accurately labels a sample otherwise known to be positive. The rate of false positives is 100% minus the specificity, so, in the case of the CellTex test, 7% of the test results saying that someone has SARS-CoV-2 antibodies are false. Seven percent may not sound bad, but the context is crucial, which leads to a measure called 'positive predictive value.'

With a specificity of 93%, if you test 1000 people, you will get 70 false positives. How many true positives will you get? That depends on the context, the actual rate of antibodies in the population you are testing. If it is 1%, you will get about 10 true positives. If it is 7%, you will get about 70. If it is 20%, you will get about 200. The positive predictive value is the percentage of positive tests that are true positives. In my first example, it is 10 true positives out of 80 positive test results: 12.5%. In the second example, it is 70 out of 140, of 50%. In the third, it is 200 out of 270 or 74%. What this means is that if someone has a positive antibody test on the CellTex test, the chances that they are truly positive range from 12.5% to 74% in those three scenarios. That is 'not' a good test for telling you who has antibodies, and is (potentially) immune from becoming infected or infecting others.

More tests, with better apparent accuracy, are being approved. On May 3, 2020, the respected pharmaceutical (and diagnostics) firm, Roche, announced that FDA had granted an EUA to its SARS-CoV-2 antibody test. Roche claims that, based on tests

45 Laurie McGinley, Dozens of Coronavirus Antibody Tests on the Market Were Never Vetted by the FDA, Leading to Accuracy Concerns, Wash. Post (Apr. 19, 2020), <https://www.washingtonpost.com/health/2020/04/19/fda-antibody-tests-coronavirus-review/>.

46 FDA, Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>. See Laurie McGinley, FDA Steps up Scrutiny of Coronavirus Antibody Tests to Ensure Accuracy, Wash. Post (May 4, 2020), <https://www.washingtonpost.com/health/2020/05/04/fda-steps-up-scrutiny-coronavirus-antibody-tests-ensure-accuracy/> and Anand Shah and Jeff Shuren, Insights into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy, (May 4, 2020) <https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy>.

47 Carolyn Humer, Carl O'Donnell, US FDA Names 27 Coronavirus Antibody Tests No Longer Ok To Be Sold, Reuters (May 21, 2020), <https://www.reuters.com/article/us-health-coronavirus-usa-tests/us-fda-names-27-coronavirus-antibody-tests-no-longer-ok-to-be-sold-idUSKBN22X2M9>.

48 Conor Hale, Current COVID-19 Antibody Tests Are not Accurate Enough for Mass Screening, Say Oxford Researchers, FierceBiotech (Apr. 8, 2020), <https://www.fiercebiotech.com/medtech/current-COVID-19-antibody-tests-aren-t-accurate-enough-for-mass-screening-say-oxford>.

it did with 6000 samples, its test has a specificity of 99.8%, producing only two false positives per every thousand tests.<sup>49</sup>

But this test is not ‘approved,’ it has an EUA. FDA has not carefully examined, and tried to pick apart, the studies Roche has done about it. Is the accuracy Roche announced correct? It is highly likely that Roche announced what its study showed, but one would want it replicated and rigorously examined.

Even if another laboratory did replicate it, tests often are much better in the laboratory, with laboratory specimens, than they are in clinical practice. And, of course, even if this antibody test has, in the real world, something close to their accuracy in Roche’s own study, an assessment of the test’s accuracies depends on the accuracy of the viral RNA tests to which they compare them.

In normal times, a test is not used until its accuracy and rates of false positives and false negatives have been carefully tested and optimized. These are not normal times. Such optimization has not yet been done yet for any of the tests under development, and it is not clear how long such a process will take. We still have not a single FDA ‘approved’ test.

Antibody tests, even if eventually highly accurate, raise another issue: how useable are they? Antibody tests rely on blood serum, the clear liquid that’s left when the red and white cells of the blood are eliminated. Traditionally, the serum has been derived from blood drawn from a person’s vein by trained medical personnel called phlebotomists. Even if the tests are accurate, cheap, and widely available, blood will still need to be drawn. Healthcare workers will be needed, and they will need personal protective equipment. In the US medical world at the time of writing, both trained healthcare personnel and, even more, personal protective equipment are in short supply. Widescale testing may be impossible for these apparently mundane reasons—‘for want of a nail.’

Some firms are trying to develop antibody tests that could avoid this problem. Some firms have been selling them including the firms who ‘sold’ tests to the UK government. These tests would be able to analyze a very small quantity of blood accurately, thus allowing an accurate test if the subject himself produces a finger prick’s worth of blood. The idea has been called ‘Antibody on a Stick’ and operates rather like a home pregnancy or HIV test. A manufacturer puts on a small plastic strip a protein or protein fragment that the sought-after antibodies will stick to if blood is smeared on it. If the antibody attaches to the strip, other chemical reactions will make the strip change color. It seems likely but not certain that this method, even though given a bad reputation by the Theranos fraud, can be used successfully in this context. If so, it would alleviate many of the logistical problems with antibody testing (but import some new ones, discussed below).

### III. IMMUNITY CERTIFICATES—IMPORTANT PRACTICAL PROBLEMS

Let us assume that we think a positive antibody test is powerful evidence that someone cannot acquire or transmit the infection. And let us assume that we have good antibody tests—not perfect, but ‘good enough.’ Are there issues about using antibody tests to

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49 Denise Roland, Roche Coronavirus Antibody Test Wins FDA Approval for Emergency Use, *W.S. Journal* (May 3, 2020), <https://www.wsj.com/articles/roche-coronavirus-antibody-test-wins-fda-approval-for-emergency-use-11588505019>.

issue COVID-19 immunity certificates? You will not be surprised that my answer is ‘yes,’ for both honest and dishonest certificate issuers and applicants.

### Honest Issuers and Certificates

First, who will issue the certificates? Will they be issued by the federal government; by state or local governments; by private ‘certifying’ entities; by clinical laboratories, hospitals, doctors’ offices, or other healthcare settings? The power of the federal government to ‘issue’ such certificates is probably not questionable but its power to limit someone’s activities based on them could be.<sup>50</sup> (This article sketches out some questions of federal power in Part V below.)

State and local governments clearly would have the power, under the broad and ancient doctrine of the ‘police power,’ to issue such certificates and to give them force. But would it be the states, the counties, cities, or other governmental bodies? There is no reason to expect uniformity among the states (let alone counties or cities). But, with or without uniformity, would one state have to honor a COVID-19 Immunity Certificate issued by a different jurisdiction? States honor out-of-state drivers licenses and marriages; does the Constitution’s Full Faith and Credit Clause require that? (The answer seems disputed.<sup>51</sup>) Would it require recognition of an out-of-state COVID-19 Immunity Certificate? Could such a requirement for recognition follow from the mysterious Dormant Commerce Clause? If not, someone who is ruled safe in California may face a very different situation on a trip, for business or pleasure, to Nevada or to New York.

But what about non-governmental actors? ‘Doctor’s notes’ can play a significant role in employment or educational settings, with or without legal sanction. Would, or should, a certificate—or a letter—issued by a doctor, a hospital, or a clinical laboratory qualify a person as immune? And, of course, third party issuers may not be limited to healthcare entities. What would be the status of certificates provided by a firm calling itself ‘COVID-19 Immunity Certifiers, LLP.’ that purported to rely on test results to issue such certificates?

Barring contrary state or federal legislation, what would stop them from doing so?

It may be that any antibody tests upon which they claim to rely will have to have been done in state laboratories or under FDA’s EUA permissions. But if ‘immunity certificate firms’ do not purport to perform the tests themselves but only to provide a certificate saying that someone has proven, to the firm’s satisfaction, that they are immune, they should avoid FDA issues. They might even claim to be able to avoid much government regulation by claiming the protection of the First Amendment’s protections for non-misleading, otherwise legal commercial speech.<sup>52</sup> And, whether protected by the First

50 See Jeannie Suk Gerson, *Who’s in Charge of the Response to the Coronavirus?* *The New Yorker* (Apr. 19, 2020), <https://www.newyorker.com/news/our-columnists/whos-in-charge-of-the-response-to-the-coronavirus>.

51 See William Baude, *What About Full Faith and Credit?*, *The Volokh Conspiracy* (blog) (Dec. 14, 2011), <http://volokh.com/2011/12/14/what-about-full-faith-and-credit/> but see Larry Kramer, *Conflict of Laws, and the Unconstitutional Public Policy Exception*, 106 *Yale L.J.* 1965 (1997).

52 See *Central Hudson Gas and Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980) and the extensive ‘commercial free speech’ jurisprudence that has followed. I am not attempting, in this piece, to take a position on—or even to assess the strength of—such this argument or some of the others mentioned (notably the Dormant Commerce Clause). I am just trying to point out some non-frivolous issues.

Amendment or not, if the certifying firm says that it is convinced of a person's immunity based on an antibody status ascertained by an unapproved test or a dodgy (or foreign) laboratory, barring legislation, would anything prevent that? (We will come back in the next section to the question of the powers certificates might confer; for now we are just concerned with their issuance.)

But there is another issue. Antibody tests are not the only evidence that might be used to infer that someone is immune to SARA-CoV-2. Given enough data (or enough assumptions) about the generation of IgG COVID-19 antibodies, one might, perhaps not unreasonably, presume that anyone who has had the disease is now immune and therefore issue COVID-19 immunity certificates to them. That might even end up being scientifically justified—although it is clearly not justified yet.

Even assuming that inference is right, how will we know whether an applicant for a certificate actually had COVID-19? Will an applicant need to show a positive virus test, with a certified copy of results from an authorized laboratory, to justify a certificate? Without such testing, it can be difficult to know for sure if someone truly had COVID-19 or if they had something else, like the flu, with similar symptoms, but many people with COVID-19 symptoms have been unable to get virus tests. Many, including colleagues of mine, have been told not to try. Would a doctor's note suffice, saying that 'based on her professional judgement' the applicant had COVID-19? Or perhaps even a self-report?

If certificates can only be issued by governments (federal, state, or local) or 'government certified certifiers,' then these questions should at least have uniform answers (good or bad) within a jurisdiction. If they are issued by private parties, private parties that get paid by people applying for certificates, one might legitimately worry about a race to the bottom for standards of being certified 'immune.'

If government bodies issue the certificates—initially to tens of thousands of applicants, eventually in some states, perhaps to millions—who exactly is going to do that? What government agencies have the kind of infrastructure to deal with licensing on such a grand scale? Departments of Motor Vehicles come to mind, although not necessarily in a good way. Whatever agency is given the task, how long will it need to work out protocols, procedures, and regulations, as well as the expertise to do a good job? And how long will people, eager to get their 'Get Out of Jail Free' cards, wait? Actually, will the certificates be free? If not, they will impose some financial burdens, small or large, that will fall disproportionately on the poor.

Here's another question—whoever issues them, what should the certificates 'look like'? If they are just a doctor's letter or a form from a lab, they might be easily forged or borrowed from the true holder for use by someone else. Perhaps they should be like driver's licenses, but, as many underage kids seeking alcohol and others figured out, fraudulent drivers licenses are not that hard to buy or to make. We could require more serious identification methods, like fingerprints or retinal scans. Or we could do an online system: anyone claiming immunity would provide some kind of personal identification and would then have the existence of certified immunity checked through an online database. Of course, that way a computer knows every time and place your immunity has been checked—perhaps every restaurant or bar you have been to. The privacy concerns are not as great as those involved

in proposals for automated quarantine, isolation, and contact tracing, but they are not small.<sup>53</sup>

Now consider one last question about (honest) certificates from legitimate certifiers—how long should they last? If the basis for issuing the certificate (antibody levels, past documented infection, or something else) is known to last, at full strength, for a lifetime, then the certificates can last for a lifetime. But we do not know that—and, in fact, ‘cannot’ know that for a long time (quite literally, ‘for’ a lifetime). Should these certificates be like drivers’ licenses that must be renewed every few years? And, if so, for how many years? At some point, if we know the immunity is not lasting, we may know how often the certificates would need to be renewed. But, at the start, how long should they last? One year, two years, or three? We must, of course, hope that prevention or great easy treatments or effective vaccines will come along within a short time and make the whole question moot—but we cannot assume that. Someone has to set a reasonable initial term for the certificates.

### Cheaters

Then there is another problem: outright fraud. If immunity certificates provide real benefits, people are going to want them. Some people are going to want them enough to lie and cheat. An entire black market industry might spring up to meet this demand—though, more likely, those who already provide false social security cards or driver’s licenses may expand their offerings.

Assume a person shows up applying for an immunity certificate with a document that purports to be a test result saying ‘Henry T. Greely’ has a qualifying level of SARS-CoV-2 IgG antibodies. How does the certificate issuer know the document is authentic instead of forged? Computers, software, and printers can make fraud easy. Unless we require the lab reports to be on counterfeit-proof paper, fraudulent documents will be a problem—bought on the black market but also from some ‘do it yourself’ forgers.

Now assume the lab result document is authentic—but the applicant is not. He says he is Henry T. Greely. How hard do we make him prove it? A driver’s license (which may not be authentic)? More? Less? Part of the answer to that will depend on the incentives of the person providing the certificate. Having a reputation for low standards could easily lead to more business—and, of course, frank bribery is possible. A newly established industry, or newly established government certifying offices, may well lack the kinds of controls and bureaucratic oversight that reduces fraud and corruption in more established contexts.

Remember—the stakes with immunity certificates may be very high. If a person who is not immune has an immunity certificate—because of error, fraud, or other reason—that person might contract the disease, with or without symptoms, and pass it on to others.<sup>54</sup>

53 Edlin and Nesbitt have recognized the serious problems of potential fraud and are drafting a proposal for using a centralized database to resolve some of the issues. Email from Bryce Nesbitt, April 15, 2020, on file with author. As far as I know, they have not yet published this.

54 It appears that about 40% of those infected with SARS-CoV-2 never show any symptoms but have the same viral load, and, presumably, the same ability to infect others, as those with symptoms. See Eric Topol, <https://twitter.com/EricTopol/status/1252412650790678529> and the sources he cites. (The absence of some symptoms, such as coughing and sneezing, however, may reduce to some extent how contagious the asymptomatic carriers are.)



#### IV. USING IMMUNITY CERTIFICATES

How would COVID-19 immunity certificates be used—and under both whose and what authority? This question is crucial but has, as far as I can tell, not been significantly addressed, let alone systematically. Will immunity certificates be required, allowed, or forbidden and in what combinations?

Consider four different scenarios. First, a government demands that people who want to engage in particular activities must show a valid COVID-19 Immunity Certificate. Second, a government does not demand that people be required to show certificates but authorizes, and perhaps immunizes, other actors, private or governmental, to require them. Third, a government may forbid the use of COVID-19 immunity certificates for some purposes. Or, fourth, the government does nothing about immunity certificates but private parties (or perhaps governments acting in quasi-private capacities, such as in their role as owners of local sports arenas or stadiums) choose to require them. Combinations are both possible and likely—governments might require them for some purposes (air travel, nursing home attendants), authorize others to require them for some activities (sporting events), ban their use in other contexts (grocery stores or voting), and says nothing about their use in still others (restaurants).

Of course, if governments are involved, two other questions arise: ‘which’ governments are involved, and based on what claim of authority—a statute, inherent powers, or something else. Part V raises these issues. For now I will only note that the permutations of subjects of immunity certificates, the acting government, and its claimed authority are too many to list. But they make a difference in the legality, and perhaps the acceptability and workability, of any immunity plan.

Never forget, though, that there will usually be at least one other player. Governments may require what they want, but if the individuals on the front line at the grocery store, bar, or football stadium do not care, it may make no difference. Remember, many of those private actors will, at least at first blush, have a strong interest in concluding that people have valid COVID-19 immunity certificates, in order to make them employees or customers. (At some point a reputation for exclusivity, strict enforcement, and consequent safety of the customers might play an important role. Or not.)

When I was a freshman at Stanford, long ago in a galaxy far, far away, the legal drinking age was 21 in California. Two people in my dorm made and sold fake driver’s licenses. They had a big poster board on which they had printed what purported to be an Iowa driver’s license. The poster had a rectangular hole. The purchaser would put his head behind the hole, they would take a Polaroid photo<sup>55</sup> and, after laminating it, hand it over as a fake id. One of the purchasers of a fake Iowa license later told me that, at one local student bar, the bartender had looked at him, said ‘you spelled license wrong’ (‘lisence’), but sold him beer anyway. The best security measures possible for making ‘secure’ immunity certificates will not help if those at the doors who are supposed to demand them instead ignore them.

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55 Polaroid cameras produced ‘instant’ photographs (within a minute or less) without requiring developing or printing. See the Wikipedia entry on ‘Instant Cameras’: [https://en.wikipedia.org/wiki/Instant\\_camera](https://en.wikipedia.org/wiki/Instant_camera).

## V. ETHICAL AND SOCIAL ISSUES

I hope the article to this point has convinced you that COVID-19 immunity certificates raise many questions. But the scientific and practical questions discussed thus far, though very important, are conceptually easy compared with the questions this section discusses, the ethical and social issues as well as the legal issues. This article takes only the quickest and shallowest look at them, but even that should be daunting.

I can see many hard ethical and social issues raised by immunity certificates and I am confident that there are many more which I am not seeing. In this article, I will focus on only two: fairness and self-infection.

### Fairness

Contemplate a country where, stretching for unknown months or years into the future, some lucky people will be able to work, travel, shop, and entertain themselves freely. Others will be restricted, more or less strictly, from some or all of those activities. The criterion on which this rigorous scheme, akin in some ways to the old South African apartheid, is based is not any kind of merit or positive actions, but, like race or ancestry, something that most people will have had little or no control over—who has, and who has not, contracted COVID-19. To many concerned people, immunity certificates will be the key to reopening the country and the economy, and thus limiting the many truly bad consequences of a severe recession (genuinely bad for stockholders, employees, and almost everyone in the country). For those who have been infected—and who have survived—a COVID-19 immunity certificate would be the key to a return to a normal life. But for those who are not immune, the certificates lead to gross and deeply unfair discrimination. And they will say ‘it’s not fair!’

Of course, they will be right. It will not be fair. It may make sense in terms of protecting people and their societies from the worst ravages of SARS-CoV-2, but it will not be fair. Unfairness exists in many aspects of the world and we usually accept it, either because we have no choice, because we are used to it, or because it clearly leads to better outcomes.

The third point invokes the ethical question, at least for some people. Different ethical systems can take different positions on when or where the consequences justify unfairness—when the ends justify the means? For adherents to the myriad varieties of consequentialism, they can; for others, non-consequentialists of various stripes, they may not. The answer to the ethical question then turns both on one’s own set of ethical precepts and, if a consequentialist, the likely outcomes of this program compared with its alternatives. Reasonable people can and will disagree on the first and, given our vast ignorance of this pandemic, no one can now be confident about the second. Different, reasonable, views will exist. And that is all I have to say about this deep ethical issue.

But fairness has social implications beyond ethical theory. Most Americans, I believe, live mainly by some form of limited consequentialism, limited by differing sets of exceptions for some means that ends can never justify. These might include killing, lying, restricting speech or religion, abortion, or a host of other issues perceived as especially important. For only a few would being able to work at a particular job or going to a bar fall into the ‘special’ categories.

Of the three reasons we accept unfairness, neither ‘no choice’ nor history of acceptance do not apply. A newly imposed set of COVID-19 immunity certificate restrictions

would clearly be something where the authorities made a choice and it would not be longstanding discrimination, made familiar, and acceptable by long usage. Precedents can be found in some limited ways, such as having to show some immunity to travel to some places or to practice some professions in some positions. But these precedents affect only a small number of people and involve immunities that, for almost all of that small percentage, could be acquired by vaccination, not by the random chance of infection and recovery.

To what extent and for how long would COVID-19 immunity certificates be tolerated by Americans? Fraud and outright disobedience would grow. It probably would not reach the stage of significant active unrest. More likely, the political pressures for watering down the certificate requirements, or for softening or removing the restrictions that the certificates could overcome, would soon prove irresistible. Whether ethical or not, I strongly suspect that the social and political effects of a substantial immunity certificate program would be sustainable for only a limited time.

### Self-Infection

The second problem is harder, both ethically and practically. If COVID-19 immunity certificates are useful and if vaccination is not yet a way to obtain one, some people will be tempted to become infected in order to obtain SARS-CoV-2 antibodies and an immunity certificate—if they survive.

Already we have seen talk of ‘COVID-19 parties,’ along the lines of the measles or chicken pox parties that many parents let their children attend, parties mixing infected and uninfected children in the hopes that the uninfected ones would acquire what were extremely common and relatively very (but not perfectly) safe childhood diseases at a convenient time.<sup>56</sup> In a fascinating exploration of the ‘moral hazard’ of self-infection in this context, Daniel Hemel and Anup Malani have calculated that, based on certain assumptions about the economic value of an immunity certificate (mainly for employment purposes), this could be economically a very tempting, and rational, decision for many people.<sup>57</sup>

Why does this raise hard ethical questions? We let competent adults take risks and, at least for young (20–44) and otherwise healthy people, the risks of death from a COVID-19 infection currently appear to be quite small, 0.2% or lower. (The risks of being hospitalized and quite ill are substantially higher, in the range of 14 to 20%; the risks of serious longer term bad effects from the illness are currently unknown but that there are such risks seems plausible.)<sup>58</sup>

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56 Douglas Perednia, How Medical ‘Chickenpox Parties’ Could Turn the Tide of the Wuhan Virus, *The Federalist* (Mar. 25, 2020), <https://thefederalist.com/2020/03/25/how-medical-chickenpox-parties-could-turn-the-tide-of-the-wuhan-virus/>. To his credit, Perednia, a physician, does call for this ‘Controlled Voluntary Infection’ (‘CVI’) to be done in a socially responsible way with quarantines, thus limiting the risk of spreading the virus to others who had not consented. He notes ‘(Given the recent example of spring break 2020 for college students in Florida, one could imagine CVI even becoming a social activity.)’

57 Daniel Hemel and Anup Malani, Immunity Passports and Moral Hazard, *supra* fn. 8.

58 The Federalist author takes the risk percentages from a credible source: CDC COVID-19 Response Team, Severe Outcomes Among Patients with Coronavirus Disease 2019 (COVID-19)—USA, Feb. 12–Mar. 16, 2020, 343 Morbidity and Mortality Week Review, issue 12, 343 (Mar. 27, 2020), <https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e2.htm>.

If competent adults are fully informed of the risks, why should not we let them take those risks? Often we do—we let people ride motorcycles. Sometimes we do not—we do not, in most states, let them ride motorcycles without helmets. Ethical theories again will disagree among themselves; the answers ultimately are political and cultural.

But the Covid party scenario is not the same as the motorcycle helmet. To a large extent, helmetless ‘donor cyclists’<sup>59</sup> harm only themselves. Someone infected with SARS-CoV-2, even someone showing no symptoms at any time during the infection, can infect others. These infections would be externalities, falling on people who had no voice in the self-infecting people’s decisions or, most likely, no role in their calculations. If the infected people were carefully isolated in ways that precluded any significant risk that they would infect others (as the author of *THE FEDERALIST* article urges), this externality would largely disappear, but that would require success at a different kind of COVID-19 response, isolation and contact tracing, which has not worked so far in the USA. The extent of these unconsented secondary infections should play a role in a consequentialist assessment of the ethics of self-infection and would surely play a role in political decisions about it. And that extent, of course, cannot be known in advance.

That’s the ethical problem—what’s the practical one? If people want to become infected, how could we plausibly stop them? Only the most rigid isolation for everyone known to be infected might work, isolation not only of the person but of objects touched by that person. And if home infection testing becomes available, which many are seeking because of its advantages in identifying COVID-19 cases, those who learn through a self-administered home test that they are infected could help others become infected before any authorities in charge of their isolation know they are tested positive. Some of those form will last a lifetime.

## VI. LEGAL QUESTIONS

The complexities of the various forms of possible immunity certificates and their intersections with the laws of different US jurisdictions are enormous and so are the questions they raise. Perhaps ironically—for an article published by a law professor in a law journal—this section will not try to answer any of them, but, instead, will try to point out four of the issues that seem both largest and most obvious: the authority of the federal government, the legality of executive as opposed to statutory actions, independent constitutional bars to immunity certificates, and statutory obstacles to them.

### **The Power to Regulate**

One big question is authority, particularly that of the federal government but also of the states and of private actors. Under the Constitution, the federal government is, at least in theory, one of only limited and enumerated powers. COVID-19 immunity certificates might be used for things that seem clearly within the scope of federal power such as interstate methods of transportation. Others are the kinds of local activities that are traditionally regulated by the states and their subordinate local governments. One

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<sup>59</sup> This term refers to the role helmetless motorcycle riders can play as common organ donors. The term is more often used (inappropriately, I think) to refer to the motorcycles and not their riders. See, e.g., Stacy Dickert-Conlin, Todd Elder, and Brian Moore, *Donorcycles: Motorcycle Helmet Laws and the Supply of Organ Donors*, 54 *J. L. & Econ.* 907 (2011).

might imagine the federal government regulating airplane travel but states, counties, or cities regulating buses or restaurants.<sup>60</sup> The possibilities for inconsistency and confusion are great.

The most likely source of a broad federal power would be the Interstate Commerce Clause, but we still do not know just how far it reaches, other than that it does not reach everywhere: to violence against women,<sup>61</sup> to gun sales near schools,<sup>62</sup> or to forcing people to buy health insurance.<sup>63</sup> The federal government might, for example, assert it to require immunity certificates at, say, restaurants and other public accommodations. It would have precedent in its favor though its success could not be guaranteed.<sup>64</sup> But could it regulate private (or public) schools? And, under the obscure case law of state power under the 21st Amendment (which repealed Prohibition), could it regulate bars?<sup>65</sup> These questions do not have clear answers; I leave their further exploration for constitutional scholars.

This is primarily an issue for the federal government. State governments have the broad powers of sovereignty, including particularly the so-called police power. They may be constrained by their own constitutions or by federal law but their underlying authority exists. Private actors, at least if they are competent adults, typically have no ‘authority’ issues—they can do anything that is not forbidden. (Effective limitations on the actions of corporate ‘persons’ as ‘ultra vires’ or beyond the powers conferred upon them by the chartering authority or their own foundational documents have largely disappeared.)

### Legislative or Executive Action

With regard to governments (though not individuals) action on immunity certificates will depend not only on which government but acting under what authority. A certificate plan laid out in recently passed legislation is different from one depending on executive action based on an assertion of emergency powers, whether based on broad statutes or claimed as inherent.

The cleanest solution, at any level, would be new legislation. New legislation, at either the federal or the state level, avoids a host of possible legal questions about whether the immunity certificates are legally authorized. It also would avoid some questions of legitimacy to the public. Although not impossible, it is harder to rail against a legislative dictatorship than one imposed by a governor or President. Fresh legislation may well increase public support for the measure. It would also afford at least the

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60 One might expect to see some governments use COVID-19 certificates in pursuit of other goals. Just as some states have used the COVID-19 emergency to forbid abortions as ‘non-essential medical care,’ a government might strongly require the use of certificates for behavior of which it disapproved, from questionable massage parlors to head shops—and possibly try to make the identity of the certificate users public.

61 *United States v. Morrison*, 529 U.S. 598 (2000).

62 *United States v. Alfonso D. Lopez, Jr.*, 514 U.S. 549 (1995).

63 *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012).

64 *Katzenbach v. McClung*, 379 U.S. 294 (1964), holding that the Interstate Commerce Power justified the application of the Civil Rights Act of 1964’s ban on discrimination in public accommodations to Ollie’s Barbeque.

65 Litigation over whether and to what extent the 21st Amendment gave states more power over alcohol free from federal interference started about the time of its ratification. It has produced a dizzying jurisprudence. The most recent U.S. Supreme Court case is *Tennessee Wine & Spirits Retailers Association v. Thomas*, \_\_\_ U.S. \_\_\_, No. 18–96, decided June 26, 2019.

opportunity for committee hearings, debate, deliberation, and other mechanisms for raising (and sometimes resolving) problems with the proposal. And it would, unless a legislative majority were to ram the legislation through, allow stakeholders to have a voice in the eventual plan, and thus, perhaps, to accept it better.<sup>66</sup>

All of these procedures provide some substantial potential benefits in the substance and acceptance of legislation. They can also make for a nightmare of delay and sabotage of any bill. This seems particularly worrisome in jurisdictions where the executive and one or both of the chambers of the legislature<sup>67</sup> are not controlled by the same party. It is almost impossible for me to imagine any circumstances where, for example, President Trump, a Republican-controlled Senate, and a Democratic House of Representatives could agree on a COVID immunity certificate statute.

An alternative is for the executive to claim inherent authority to act in the case of an emergency. At the federal level, the precedents are mixed. President Lincoln claimed the emergency power to suspend the writ of habeas corpus during the Civil War; Chief Justice Taney held that he had no such power but only in an opinion in a lower federal court.<sup>68</sup> The issue never reached the Supreme Court. President Franklin Roosevelt claimed emergency powers to justify the internment of Japanese nationals and Japanese Americans. The Supreme Court upheld his authority in the notorious *Korematsu v. U.S.*<sup>69</sup> In the *Steel Seizure Case*, a majority of the Court held that President Truman, in the absence of Congressional authorization, exceeded his powers in seizing steel mills as a result of labor disputes during the Korean War.<sup>70</sup>

There is a third way. Congress over the years has passed many statutes that confer various powers on the President or other Executive branch officers in the event of a declared ‘national emergency.’ The Public Health Services Act is the most apparently relevant here. Section 319 of that Act allows the Secretary of Health and Human Services to waive a long list of requirements and to take otherwise unauthorized actions after declaring that a public health emergency exists.<sup>71</sup> The list, however, does not seem to include anything like immunity certificates.<sup>72</sup> But there are many statutes conferring emergency powers and many declared ‘states of emergency.’ As of March 23, 2020, at

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66 Note that some of those stakeholders will be businesses eager to sell products or services related to immunity certificates. This potential market has already been noticed and lobbying from such firms should be expected. See Sue Halpern, *Immunity Passports and the Perils of Conferring Coronavirus Status*, *The New Yorker* (May 22, 2020), <https://www.newyorker.com/tech/annals-of-technology/immunity-passports-and-the-perils-of-conferring-coronavirus-status?>

67 Nebraska is a special case as the only state with a unicameral legislature. Cities and counties, however, typically have only one legislative body.

68 *Ex parte Merryman*, 17 F. Cas. 144 (C.C.D. Md. 1861)

69 *Korematsu v. United States*, 323 U.S. 214 (1944). In 2018 both the Opinion of the Court and two dissents stated that *Korematsu* had been wrongly decided, but the concern was not the source of the President’s authority but how it was used in that case. *Trump v. Hawaii*, No. 17–965, 585 U.S. \_\_\_\_ (2018),

70 *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952).

71 42 U.S.C. §247d.

72 Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services, *Public Health Emergency Declaration* (Nov. 26, 2019), <https://www.phe.gov/Preparedness/legal/Pages/phe-declaration.aspx>.

least 34 national emergencies were in effect, the oldest dating to 1979 and declared by President Carter as a result of the Iranian hostage crisis.<sup>73</sup>

So, could the President impose some form or degree of COVID immunity certificate under emergency powers? I view the answer as a resounding ‘maybe’ and leave further analysis to the debates of constitutional law experts.

But the federal government is only one jurisdiction. Each state could try to adopt immunity certificates by passing new legislation, by its governor’s assertion of inherent emergency authority, or by its governor’s assertion of emergency powers under earlier (probably broad and vague) legislation. Each state’s law would have to be examined carefully to see if the second or third pathway was legal—and, in all likelihood, in many cases the answer would not be clear. In Wisconsin, at least, the state supreme court recently held that the governor had less power in the COVID-19 emergency than he thought he had.<sup>74</sup>

### Possible Constraints from Constitutional Rights

Whether immunity certificates are adopted by legislatures, executive branches, corporations, or individuals, all these actors are forbidden, by some sources of law, to do some things. The federal government is bound by the federal constitution, as well as by preexisting federal legislation (unless amended). State governments are bound by all federal sources of law—the federal Constitution, federal statutes, and federal regulations—as well as their own constitutions, statutes, and sometimes common law. And private actors are bound by federal, state, and local laws in their jurisdictions.

The possible number of federal and state constitutional, statutory, regulatory, and common law constraints on COVID-19 immunity certificates is (almost) certainly not infinite, but it may be close. If any jurisdiction or private actor decides to implement such certificates, its lawyers will have to be very busy. I am not, in this article, going to try even to list the breadth of the potentially problematic laws, let alone analyze them. Instead, I want to focus on two things that seem most likely to have broad effects on a COVID-19 immunity certificate program: the federal Constitution, in this subsection, and the Americans with Disabilities Act (ADA), in the next.

Would the requirement, authorization, or use of immunity certificates violate any federal Constitutional prohibitions? It might violate some specific rights. A federal or state statute that banned sales of guns during an emergency might violate rights to bear arms under the Second Amendment; a provision banning abortions during an emergency might violate the Due Process protections for abortion (a question we are seeing litigated in some states).<sup>75</sup> An action barring all religious services, without regard to their size, circumstances, or any infection precautions being taken, might violate

73 Congressional Research Service, National Emergency Powers, (updated Mar. 23, 2020), <https://fas.org/sgp/crs/natsec/98-505.pdf>.

74 Wisconsin Legislature v. Palm, Case No. 2020AP765-OA, <https://www.wicourts.gov/sc/opinion/DisplayDocument.pdf?content=pdf&seqNo=260868>; See Neil Vigdor, Wisconsin Supreme Court Strikes Down Stay-at-Home Order, New York Times (May 13, 2020), <https://www.nytimes.com/2020/05/13/us/corona-virus-wisconsin-supreme-court.html>.

75 See Michelle J. Bayefsky, Deborah Bartz, and Katie L. Watson, Abortion during the COVID-19 Pandemic—Ensuring Access to an Essential Health Service, *The N. Eng. J. Med.* (Apr. 9, 2020). DOI: 10.1056/NEJM2008006, <https://www.nejm.org/doi/full/10.1056/NEJM2008006>.

the First Amendment (or the arguably broader federal Religious Freedom Restoration Act).<sup>76</sup>

It might also violate some broader rights. A provision barring, say, African-Americans from some activities because of statistically higher infection and death risks from among African-Americans might violate the Equal Protection or Due Process Clauses. A provision that seemed, in its application to a particular person, completely unjustified might be found to violate the due process clause—in that specific situation. But it seems to me unlikely that a reasonably crafted plan for immunity certificates would, as a general matter, have much success under either an equal protection clause attack, which would probably be judged under the rational relationship standard, or a due process clause objection. Constitutional law experts may well disagree (with me and with each other).

### Some Statutory Barriers

In statutory law, the most attractive source of legal arguments against such actions appears to be laws barring discrimination based on disability—most prominently (but not solely) the ADA at the federal level and a wide range of varying state anti-disability discrimination statutes. These bar governments and private parties from discriminating against people for reasons that involve health. Employers cannot (generally) discriminate against blind job applicants, public accommodations like restaurants or concert halls cannot discriminate against people in wheelchairs, educational institutions cannot discriminate against the hearing impaired.

On closer examination, though, their application is very unclear. I will focus on the ADA, in the full recognition that different language or different interpretations in state statutes (or perhaps in other federal statutes involving discrimination based on disability status, such as the Rehabilitation Act) might lead to different results.

The ADA bans much discrimination against people with disabilities. Someone is a person with a disability if he or she has a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or, being regarded as having such an impairment . . .<sup>77</sup>

In *Bragdon v. Abbott* in 1998, the US Supreme Court placed major emphasis on the ‘impairment’ requirement as a prerequisite.<sup>78</sup> In deciding whether an asymptomatic HIV infected person could be classified as disabled under the ADA, it ruled that there was an impairment even before symptoms because the person’s immune system was under attack. But people with immune systems do not have antibodies to SARS-CoV-2 because that virus has not infected them, although their systems are ‘impaired’ in a

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76 John Hanna, Federal Judges Doubts Kansas COVID-19 Rule; Blocks it for Two Churches, *Time* (Apr. 19, 2020), <https://time.com/5823881/kansas-religious-gathering-people-limits/>. The judge issued a temporary restraining order allowing two plaintiff churches to proceed with in person services of more than 10 people as long as social distancing requirements were met. On the other hand, on May 22, 2020 a divided panel of the Ninth Circuit Court of Appeals denied a temporary restraining order against California governor Gavin Newsom’s ‘shelter-in-place’ order that limits religious services. South Bay United Pentecostal Church v. Newsom, Case No. 2–55533, [https://cdn.ca9.uscourts.gov/datastore/opinions/2020/05/22/20-55533\\_order.pdf](https://cdn.ca9.uscourts.gov/datastore/opinions/2020/05/22/20-55533_order.pdf).

77 42 U.S.C. 12102(1).

78 *Bragdon v. Abbott*, 524 U.S. 624 (1998).



deep way—they do not work the way we would ‘like’ them to work—seem unlikely to be viewed as having a physical impairment.

On the other hand, the third prong of the definition, ‘being regarded as having such an impairment,’ might fit. It apparently was intended for situations where people thought or assumed incorrectly that someone had a disabling impairment. One of the examples discussed at the time (the late 1980s, near the height of the US AIDS epidemic) was a man who appeared to be gay and was assumed to be HIV positive and was so treated. That was someone incorrectly regarded as having a characteristic that would clearly (at least, ‘clearly’ after *Bragdon v. Abbott*) be an impairment, not someone regarded as having something that was ‘incorrectly’ viewed as an impairment. There are, no doubt, law review articles that could be written on the application of the ‘regarded as’ prong to this situation based on statutory history, regulatory language, case law, and other sources. This is not one—for present purposes, I will just say that its applicability is unclear.

ADA law has other twists, including one that might favor susceptible people (if they were classifiable as having a disability) and one that might cut against them. The beneficial one is the reasonable accommodation requirement in the ADA’s treatment of employment discrimination: an employer may not discriminate against a person with a disability who could discharge the essential duties of the job if given ‘reasonable accommodations.’ For someone not immune to SARS-CoV-2, that might mean working from home, in an isolated workspace, with a N95 mask and other personal protective equipment, or some other change. Title III of the ADA, dealing with public accommodations, requires those places to make ‘reasonable modifications’ but the emphasis under that section has been on architectural changes; I do not know whether it might apply to a non-immune restaurant patron requested admission without a certificate but with secluded seating and, for example, an immune waiter.

On the other hand, the ADA also includes a ‘direct threat’ provision, which allows employers to discriminate against people who pose such a threat. The ADA regulations provide that ‘The term ‘direct threat’ is defined as ‘[a] significant risk of substantial harm to health or safety of self or others that cannot be eliminated or reduced by reasonable accommodation.’<sup>79</sup> The Equal Employment Opportunity (‘EEOC’) has already issued guidance that someone who is infected with SARS-CoV-2 poses such a direct threat.<sup>80</sup> It is plausible that, even if immunologically naïve people were classified as disabled, the EEOC might rule their employment, new or continuing, as such a direct threat.

Would the ADA protect people without immunity certificates from private or state discrimination? I do not know—and I do not think anyone can know with certainty. I do think protection is not clear. Might other federal and state laws forbidding disability discrimination cover them? Perhaps—in some states or in some contexts. But I doubt that any broad, general protection against the application of immunity certificates will be found to exist.

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79 29 C.F.R. § 1630.2(r).

80 EEOC, *Pandemic Preparedness in the Workplace and the Americans with Disabilities Act* (Apr. 4, 2020), [https://www.eeoc.gov/facts/pandemic\\_flu.html](https://www.eeoc.gov/facts/pandemic_flu.html).

Are there legal barriers to immunity certificates? Maybe, in some situations. Many devils lurk in those details. But, although it may be possible, I think it unlikely that existing law provides ‘broad’ protection against discrimination for those who would not qualify for such certificates.

## VII. ADVICE FOR THOSE CONTEMPLATING IMMUNITY CERTIFICATES

To me, the case for immunity certificates is not powerful, mainly because of the six classes of problems discussed so far. Scientifically, the existence and extent of SARS-CoV-2 immunity is unclear, as is the quality of antibody tests. Practically, how to issue the certificates and for what purposes raise hard issues. Ethically and socially, problems of fairness and self-infection are rampant; and many potential legal barriers exist.

On top of all of these, add the relatively unimportance of such a program while the number of immune people remains low. Even if everyone who has had a case of COVID-19 has sufficient immunity to justify granting a certificate, at the highest current plausible estimate at the time of writing, that is probably not more than 5% of the US population. If you are interested in ‘re-starting the economy,’ is there much point to creating a system of immunity certificate that allows 5% of employees to return to work, 5% of customers return to restaurants, and 5% of sports or music fans return to stadiums, arenas, or concert halls?

But that percentage seems unlikely to remain low forever, and, even while it does, such certificates might be useful in some contexts, particularly in those where the functions are important and substantial personal contact is involved. Some good candidates include attendants in nursing homes, nurses and doctors in COVID-19 wards of hospitals, police and fire fighters, lifeguards, or others whose (important) work makes highly effective protective measures difficult or impossible. The issues raised in this article lead me to offer seven specific points of advice to anyone thinking about an immunity certificate program. First, states should establish immunity certificates by binding laws; second, the evidence needed to issue a certificate should be specified carefully; third, uses of immunity certificates—requiring, allowing, or banning—should be spelled out; fourth, enforcement and fraud problems (and privacy) need to be taken seriously; fifth, self-infection should be discouraged; sixth, programs need flexibility to respond quickly to changing facts and circumstances; and, seventh, states should only adopt such programs carefully, after long and broad deliberations.

First, put the COVID-19 immunity certificates into a binding law, adopted by a legislature, regulation, or executive order. There are some benefits to national (or even, eventually, international uniformity) but I suspect state governments will be better placed than the US federal government to adopt these. They may well be more nimble, and serious than Congress or the federal executive branch, especially during a Presidential election year (and perhaps in its aftermath). State action would also avoid some difficult questions about the reach of federal authority; those areas where the federal government has exclusive jurisdiction are not likely to be crucial to such state plans. Local conditions, in the epidemic, the economy, or the culture may make local or regional variations useful, plus the states may serve as the much-lauded ‘laboratories of democracy,’ perhaps showing which approaches work better or worse. States should try to coordinate their immunity certificate provisions when possible; groups like the

National Governors Association,<sup>81</sup> the National Conference of State Legislatures,<sup>82</sup> the Uniform Law Commission (also known as the National Conference of Commissioners on Uniform States Laws),<sup>83</sup> among others, should be able to help share ideas and results across states. (It is noteworthy that already state governments have created at least three regional coalitions, on the Pacific coast, in the Midwest, and in New England and the Mid-Atlantic states).<sup>84</sup>

It is unlikely that legislation will be able to provide the detailed answers needed for such a plan as the facts on the ground change frequently (more likely, constantly). Some kind of regulatory body will need to be empowered to issue regulations to cover many details—and to change those regulations as necessary. States may want to consider whether their current requirements for administrative action (their equivalents to the Federal Administrative Procedures Act) will be adequate for frequent technical changes.

Second, those state programs need to define, very carefully, what evidence will be sufficient to allow someone to receive an immunity certificate. The programs should be clear whether antibody tests are needed or whether evidence of past but not present infection will suffice. They should specify which kinds of tests will be acceptable, either by reference to categories (e.g., ‘FDA-approved tests for SARS-CoV-2 IgG’) or perhaps specific manufacturers or laboratories. They should be specific, where appropriate, on particular test results. Thus, they might require an antibody test to show at least a certain level of particular SARS-CoV-2 IgG antibodies at a given time after the likely date of infection. And they should detail what proof will be required that the proffered evidence is authentic: original versions of laboratory tests (whether received on paper or electronically), a direct confirmation from the relevant laboratory or medical facility, an affirmative answer from a trusted database set up to store such test results. Nothing can completely eliminate the chance of fraud, but careful steps should be able to minimize it. This level of detail is an example of what probably needs to be provided by regulation or executive order rather than being enshrined in harder-to-change legislation.

Third, the program will need to define what the immunity certificates are good for. I suggest that they define three broad categories—activities (if any) for which an immunity certificate is required, activities where decision-makers such as business owners or local governments are allowed to require immunity certificates, and activities for which immunity certificates may not be required. The last group might include, for example, interactions between parents and (minor?) children, buying groceries, or

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81 National Governors Association, <https://www.nga.org/>. It is striking to me that the first item at the top of the Association’s web page as I write this footnote is entitled ‘Coronavirus: What You Need to Know.’

82 National Conference of State Legislatures, <https://www.ncsl.org/>. The top of its web page currently reads ‘NCSL COVID-19 Resources for States.’

83 Uniform Law Commission, <https://www.uniformlaws.org/home>

84 Aziz Huq, States Can Band Together To Fight the Virus, No Matter What Trump Does, *Wash. Post* (Apr. 15, 2020), <https://www.washingtonpost.com/outlook/2020/04/15/states-coronavirus-agreements-reopen/>. This discusses the Western States Pact between California, Oregon, and Washington; a Midwestern Alliance of seven states (Ohio, Kentucky, Indiana, Michigan, Illinois, Wisconsin, and Minnesota); and a group of mainly Northeastern states (Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Pennsylvania, and Delaware). See also Adam Rogers, State Alliances Are Leading the U.S. Fight Against COVID-19, *Wired*, <https://www.wired.com/story/state-alliances-are-leading-the-us-fight-against-COVID-19/> (focusing on the Western States Pact between California, Oregon, and Washington).

some form of voting. The enabling provisions, whether statutes or executive orders, probably cannot contain all the possible activities. They can set out the ideas behind the categories and provide some common ‘including but not limited to’ examples, but, again, they will almost necessarily have to give some regulatory entity the power to define them more specifically.

Fourth, the programs will have to worry about how well the activity-limiting provisions of the certificates will be implemented. If, for example, nursing homes are only allowed to hire people with immunity certificates for patient care duties, how will that be enforced—especially if both the nursing home operator and the potential employee desperately want to create a prohibited employment relationship? These questions were raised in Section IV above; states will need to think about these problems and assure that their programs use reasonably adequate verification measures.

Fifth, depending on how widely and effectively the COVID-19 immunity certificates are being used, states will have to worry about ‘COVID-19 parties’—people intentionally trying to become infected so they get a certificate. How big a problem this will turn out to be is deeply uncertain. If only a few jobs or other desirable things (restaurants, travel, and sporting events) are closed to people without certificates, few people may think intentional infection makes sense. The same will be true with more knowledge about the disease: if it turns out that younger people are very unlikely to die, or to become hospitalized, getting infected looks more attractive. If illness rates are higher, or if it turns out COVID-19 has very serious long term effects—on the heart or the brain, for example—getting infected may look worse (at least to those not living entirely in the present and immediate future). The size of the potential problem is thus unknown, and prone to shift quickly. But it could be a problem, not just for the health of those who successfully become infected but also for those whom they may end up infecting (which in turn depends on the infection testing, isolation and contact tracing system we have in place).

The size of the problem is uncertain. Even worse, the existence of any good solution is unclear. Criminalizing intentional self-infection seems very hard to enforce. Daniel Hemel and Anup Malani have suggest ‘bribing’ people to avoid self-infection through unemployment insurance.<sup>85</sup> This might be a useful solution, at least for self-infection motivated by unemployment instead of, say, a desire to go clubbing, though whether it is politically realistic seems unclear. States will need to worry about this.

Sixth, the programs will have to respond clearly and strongly to changing circumstances, on at least three different levels. At the personal level, it will probably make sense, at least at first, for the holders of these certificates to be retested at some regular interval. We need to renew our drivers’ licenses every few years; with basic knowledge about COVID-19 immunity deeply unclear, states may want to require that certificates be renewed after a stated period, based on their bearers demonstrating that they continue to meet the immunity requirements through new testing. At the implementation level, the program needs both to authorize—and to make ‘very’ clear—that its terms may be changed at any time based on new scientific knowledge. That may mean allowing more certificates to be issued based on good news about immunity; it may also mean canceling all such certificates if research shows that there is no good immunity to

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85 Hemel and Malani, *supra* at n.

COVID-19. And, then, at the program level, the system should have sunset provisions. After 2 years, 3 years, 5 years, the program should disappear unless the state government readopts it. I generally believe in sunset provisions but the scientific, economic, and cultural uncertainties this pandemic breeds make them especially important here.

Last but not least, states will have to think twice, or three times, about instituting COVID-19 immunity certificate programs. Whether and to what extent they will make sense seems, to me, very unclear, but even beyond the decision to act or not act, how to act will take thought, time, and input from many voices. I have laid out some suggestions that seem to me to make sense, but mine is just one perspective. Many stakeholders, from science and medicine, from business and education, from the general public, and from others will bring different insights into both the framing of such a program and the decision whether or not to adopt it.

The good news here is that the states have ‘some’ time. The percentage of people who could qualify for an immunity certificate currently is almost certainly very small, in almost all states, as of May 2020, under 5%. The issue will probably become more important as that percentage rises, but states do have some time to reflect, debate, and consider these programs. They have at least several months—but they certainly do not have several years.

Unless, that is, states turn out never to need to address fully the issues of COVID-19 immunity certificates. If a safe, effective, and widely accessible vaccine for SARS-CoV-2 is developed, these issues will largely disappear—largely, but not entirely. The questions then would move to vaccination certificates. Those, at least, should be available to (almost) everyone, but government and society would still have to deal with people who cannot be vaccinated—newborns, those with compromised immune systems, people with egg allergies, and the like—as well as those who object to vaccination.

Oh, and I do have one last, eighth, piece of advice to institutions considering implementing a COVID-19 immunity certificate program—lawyer up! You may win, you may lose, you may not be challenged, but you will need good legal advice, and lots of it.

## VIII. CONCLUSION

Immunity certificates might turn out to be an important part of the other side of the COVID-19 pandemic. But, as with everything in human affairs, they are complicated. Getting the details wrong could do more harm than good. We need to think carefully about them—‘before’ adopting them.