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Managing COVID-19: Legal and Institutional Issues

Yong-Shik Lee

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Managing COVID-19: Legal and Institutional Issues

Yong-Shik Lee*

ABSTRACT

The spread of the recent pandemic, COVID-19—which began in Wuhan, in December of 2019—has created an unprecedented impact on public health in the United States and across the world. As of October 2021, the United States reported over 44 million infection cases and over 720,000 deaths. Those cases represent over 18 percent of the reported infection cases in the world, whereas the population of the United States is less than four percent of the world population. The United States has not been successful in managing this pandemic and stopping its spread effectively even though it has the largest medical, financial, and administrative resources in the world. This article analyzes the legal and institutional causes of this failure and explores possible remedies in three areas: provision of public healthcare to combat the pandemic; the regulation of public conduct to prevent the spread of the pandemic; and public access to information. The article also calls for a new approach; it explains why a law and development approach is relevant and applies the General Theory of Law and Development to assess the proposed remedies. The article advocates for law and institutions as remedies to fill the gaps created by ineffective political leadership in the management of COVID-19.

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INTRODUCTION

The current global pandemic of a coronavirus (SARS-CoV-2)—which began in Wuhan, China, in December 2019 (hereinafter “COVID-19”)—has had an unprecedented impact on public health in the United States and around the world. As of August 18, 2021, there were over 44.8 million cases and nearly

720,000 deaths in the United States.¹ The pandemic has also resulted in enormous economic and social costs: unemployment reached unprecedented levels with more than 40 million unemployment benefit claims filed² and the unemployment rate peaked at 14.7 percent, higher than any previous period since the Second World War.³ The Congressional Budget Office (CBO) estimated in May 2020 that the gross domestic product (GDP) would be \$3.9 trillion lower over the 2020–2021 period than the January 2020 estimates.⁴

The United States has failed to manage COVID-19, as evidenced by its large numbers of infections and deaths.⁵ The number of infection cases in the United States accounts for over 18 percent of the reported infection cases across the world,⁶ whereas the population of the United States is around 4 percent of the world population.⁷ The rate of infection, 13.6 percent of

1. *COVID Data Tracker*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 16, 2021), https://covid.cdc.gov/covid-data-tracker/#trends_dailycases [<https://perma.cc/RG3J-TA2K>] [hereinafter *COVID Data Tracker*].

2. Mathieu Despard et al., *COVID-19 Job and Income Loss Leading to More Hunger and Financial Hardship*, BROOKINGS (July 13, 2020), <https://www.brookings.edu/blog/up-front/2020/07/13/covid-19-job-and-income-loss-leading-to-more-hunger-and-financial-hardship/> [<https://perma.cc/N4N2-7L3Z>].

3. Elizabeth Weeks, *Private Insurance Limits and Responses*, in ASSESSING LEGAL RESPONSES TO COVID-19 95, 95 (Scott Burris et al. eds., 2020), https://static1.squarespace.com/static/5956e16e6b8f5b8c45f1c216/t/5f4d6578225705285562d0f0/1598908033901/COVID19PolicyPlaybook_Aug2020+Full.pdf [<https://perma.cc/WQ2H-B4G3>] (describing the effect of the COVID-19 pandemic on unemployment rates and the pandemic's relation to the private insurance market).

4. Letter from Phillip Swagel, Dir., Cong. Budget Office, to Nancy Pelosi, Speaker of the House, U.S. House of Representatives (June 9, 2020) (on file with Congressional Budget Office), <https://www.cbo.gov/system/files/2020-06/56395-CBO-Pelosi-Letter.pdf> [<https://perma.cc/E8FL-JB7H>].

5. Scott Burris et al., *Summary of Findings and Recommendations*, in ASSESSING LEGAL RESPONSES TO COVID-19, *supra* note 3, at 1.

6. See *COVID Data Tracker*, *supra* note 1 (showing United States COVID-19 cumulative cases which was approximately 44.8 million on October 18, 2021); *WHO Coronavirus (COVID-19) Dashboard*, WORLD HEALTH ORGANIZATION (Aug. 16, 2021), <https://covid19.who.int/> [<https://perma.cc/P7SV-QXAS>] (showing worldwide COVID-19 cumulative cases: approximately 240 million on October 18, 2021).

7. See *U.S. and World Population Clock*, U.S. CENSUS BUREAU, <https://www.census.gov/popclock/> (last visited Oct. 18, 2021) (showing the United States population on October 18, 2021, was 332,854,281); *International Data Base (IDB)*, U.S. CENSUS BUREAU, https://www.census.gov/data-tools/demo/idb#/country?COUNTRY_YR_ANIM=2021&menu=countryViz&COUNTRY_YEAR

the population as of October 18, 2021, was 20.6 times higher than the infection rate of South Korea, 0.66 percent of the population.⁸ This outcome is baffling considering the vast medical, financial, and administrative resources that the United States has at its disposal and several measures that it has taken, including travel restrictions imposed in January 2020, the declaration of a national emergency and enactment of COVID-19 legislation in March, stay-at-home orders imposed by early April in most states,⁹ and the availability of vaccines to most of the population since the spring of 2021.¹⁰

All these efforts did not effectively work to control the spread of the pandemic, as there was a crucial missing link: the United States failed to conduct timely testing, contact tracing, quarantine, and treatment (TCQT) that was critically important to control the spread of the disease (and minimize subsequent deaths)¹¹ in the first few crucial weeks of the pandemic, in the

=2021 (last visited Sept. 26, 2021) (showing midyear world population of 7,772,850,805).

8. The rates are calculated from the infection cases as of October 18, 2021. See *COVID Data Tracker*, *supra* note 1; *Coronavirus Disease-19 (COVID-19), Republic of Korea*, KOREA DISEASE CONTROL & PREVENTION AGENCY (Oct. 18, 2021), <http://ncov.mohw.go.kr/> [<https://perma.cc/S2AA-EKS6>] [hereinafter *Coronavirus in Korea*] (showing cumulative cases on October 18, 2021 was 343,445); *The World Factbook: South Korea*, CENT. INTEL. AGENCY, <https://www.cia.gov/the-world-factbook/countries/korea-south/#people-and-society> (last updated Sept. 22, 2021) (estimating July 2021 South Korea population of 51,715,162).

9. Lindsay K. Cloud et al., *A Chronological Overview of the Federal, State, and Local Response to COVID-19*, in *ASSESSING LEGAL RESPONSES TO COVID-19*, *supra* note 3, at 10–19.

10. See Julie Bosman & Lauren Leatherby, *U.S. Coronavirus Death Toll Surpasses 700,000 Despite Wide Availability of Vaccines*, N.Y. TIMES (Oct. 7, 2021), <https://www.nytimes.com/2021/10/01/us/us-covid-deaths-700k.html> [<https://perma.cc/JKQ2-MD6S>] (detailing how the United States reached the milestone of 700,000 COVID deaths despite the vaccines being widely available for months).

11. There is widespread agreement that test-trace-isolate (quarantine) is the bare minimum for an effective pandemic response. See, e.g., Selina Rajan, Jonathan Cylus & Martin McGee, *Successful Find-Test-Trace-Isolate-Support Systems: How to Win at Snakes and Ladders*, 26 EUROHEALTH 34, 34 (2020) (“Any country thinking of easing COVID-19 lockdowns must be confident that they have a robust system in place to find, test, trace, isolate, and support (FTTIS) new cases.”). Reports also confirm that countries that adopted a test, track, and treat approach gained an early edge against COVID-19. *Test, Track, Treat*, GLOB. HEALTH NOW, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH (Apr. 1, 2020), <https://www.globalhealthnow.org/2020-04/test-track-treat> [<https://perma.cc/8Q8K-8Q8K>].

months of February 2020 through early March 2020.¹² Facing the unprecedented pandemic, the Trump administration failed to ensure that a sufficient number of test kits were made available for those who needed testing.¹³ By comparison, in late February, South Korea was testing more than 10,000 people each day, reportedly four times the number that the United States had tested over the previous one and a half months.¹⁴ By mid-March, when the number of infections was sharply increasing in the United States,¹⁵ South Korea had tested more than a quarter-million people, whereas the United States had

[://perma.cc/3XCG-G9QL](https://perma.cc/3XCG-G9QL)]. The value of therapeutic treatment can be marginal, particularly for patients with mild symptoms or asymptomatic patients, but it is more important for patients with more serious conditions. *Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 16, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html> [<https://perma.cc/MC4U-EFVA>]. Treatment is, thus, an essential component of disease control, the notion that includes recovery of patients from the disease.

12. See Michael D. Shear et al., *The Lost Month: How a Failure to Test Blinded the U.S. to Covid-19*, N.Y. TIMES (Mar. 28, 2020), <https://www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html> [<https://perma.cc/UV3-QZL8>]. A recent article suggests, based on evidence, that limited United States community transmission likely began in late January or early February 2020 when there was no extensive testing or contact tracing in place. Michelle A. Jordan et al., *Evidence for Limited Early Spread of COVID-19 Within the United States, January–February 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 680, 680 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6922e1.htm?s_cid=mm6922e1_w [<https://perma.cc/YC2R-RMB2>]; see also Lindsay Maizland & Claire Felter, *Comparing Six Health-Care Systems in a Pandemic*, COUNCIL ON FOREIGN REL. (Apr. 15, 2020), <https://www.cfr.org/background/comparing-six-health-care-systems-pandemic> [<https://perma.cc/36LA-DRQ4>]; cf. Sean Fleming, *South Korea's Foreign Minister Explains How the Country Contained COVID-19*, WORLD ECON. FORUM (Mar. 31, 2020), <https://www.weforum.org/agenda/2020/03/south-korea-covid-19-containment-testing/> [<https://perma.cc/VPS4-4QQ8>] (summarizing South Korea's efforts to battle COVID-19 through a rapid and extensive testing plan).

13. Shear et al., *supra* note 12.

14. Matt Berger, *How South Korea Successfully Battled COVID-19 While the U.S. Didn't*, HEALTHLINE (Mar. 30, 2020), <https://www.healthline.com/health-news/what-south-korea-has-done-correctly-in-battling-covid-19> [<https://perma.cc/XU8J-F3D7>].

15. *COVID Data Tracker*, *supra* note 1 (charting cumulative cases per day dating back to January 2020). Since the first suspected case of COVID-19 in the United States on January 19, 2020, the number of cumulative cases increased to 1,661 on March 5; 11,837 on March 15; 100,580 on March 25; and 406,788 on April 6. *Id.*

tested fewer than 60,000 people.¹⁶ Not only South Korea but virtually every other OECD country that had more than one-hundred COVID-19 infection cases by mid-March (except Mexico) tested more than the United States (per thousand).¹⁷

Without sufficient tests to identify those infected, contact tracing could not be effectively performed, and no extensive contact tracing system was in place, allowing for rapid transmission of the disease.¹⁸ Isolation and quarantine were left to the discretion of infected individuals and others who may have contracted the virus, without any mechanism for enforcement or monitoring in place. As to treatment, successful countries, such as South Korea, isolated all COVID-19 patients, categorized them into one of two groups—one for patients with mild or no symptoms and the other for patients with more serious conditions—and treated the former in Community Treatment Centers (CTCs)¹⁹ (residential clinics converted from existing facilities) and the latter in hospitals.²⁰ By contrast, this type of isolated care was available in the United States only to patients with serious conditions; patients with mild or no symptoms had to wait at home until their conditions deteriorated enough to be admitted for such care or until they recovered, risking the spread of the disease to others during the unmonitored wait.²¹

16. Rebecca Ballhaus, *U.S. vs. South Korea: Behind the Coronavirus Testing Numbers*, WALL ST. J. (May 12, 2020), <https://www.wsj.com/articles/u-s-vs-south-korea-behind-the-coronavirus-testing-numbers-11589324531> [https://perma.cc/5NXV-ZFWM].

17. *Coronavirus Pandemic (COVID-19)*, OUR WORLD IN DATA, <https://ourworldindata.org/coronavirus-testing> [https://perma.cc/K88Z-6KUU] (last visited Nov. 18, 2020).

18. See *COVID Data Tracker*, supra note 1 (showing the increase in COVID-19 infections).

19. Won Suk Choi et al., *Community Treatment Centers for Isolation of Asymptomatic and Mildly Symptomatic Patients with Coronavirus Disease, South Korea*, 26 EMERGING INFECTIOUS DISEASES 2338, 2338 (2020), <https://dx.doi.org/10.3201/eid2610.201539> [https://perma.cc/2QHK-PAWK].

20. In December 2020, South Korea also started to show a lack of hospital beds for COVID-19 patients. Thomas Maresca, *South Korea Hits New COVID-19 Record, Faces Hospital Bed Shortage*, UPI (Dec. 16, 2020), https://www.upi.com/Top_News/World-News/2020/12/16/South-Korea-hits-new-COVID-19-record-faces-hospital-bed-shortage/4901608104740/ [https://perma.cc/L367-4ANN].

21. The CDC guidelines have recommended that COVID-19 patients with mild symptoms “stay home” (except to get medical care), but there is no apparent provision for enforcement of quarantine, monitoring, or treatment of

Without effective testing (both lack of sufficient test kits and effective test protocols), contact tracing, and quarantine,²² the number of infections increased rapidly in early March 2020,²³ prompting states to issue stay-at-home orders²⁴ to slow the spread of the virus and to buy time to secure needed medical resources and facilities.²⁵ The infection curve began to flatten in early April²⁶ when most states had stay-at-home orders in place,²⁷ but the weeks under such orders (i.e., closure of businesses except those deemed “essential”)²⁸ put enormous economic pressure on businesses, causing a record number of job

these patients with milder symptoms. *What to Do If You Are Sick*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html#:~:text=Stay%20home.,Do%20not%20visit%20public%20areas> [<https://perma.cc/6YQD-CZD8>] (last updated Sept. 11, 2020).

22. The term “quarantine” traditionally has not been applied to people who were infected, but the term includes the notion of “isolation” that is applied to patients. *Quarantine v. Isolation*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/easy-to-read/COVID-19-Quarantine-vs-Isolation.html#:~:text=Quarantine%20Helps%20Slow%20the%20Spread,people%20in%20their%20home> (last updated Jan. 8, 2021).

23. See *COVID Data Tracker*, *supra* note 1 (showing increasing infection cases from early March to early April).

24. Stay-at-home orders, lockdown orders, or shelter-in-place orders restrict the movement of individuals. These terms are used interchangeably throughout this article without distinction. For a discussion of lockdown orders imposed by states, see Lindsay K. Cloud et al., *A Chronological Overview of the Federal, State, and Local Response to COVID-19*, in *ASSESSING LEGAL RESPONSES TO COVID-19*, *supra* note 3, at 10–19.

25. See *id.* at 12.

26. *COVID Data Tracker*, *supra* note 1.

27. Amanda Moreland et al., *Timing of State and Territorial COVID-19 Stay-at-Home Orders and Changes in Population Movement — United States, March 1–May 31, 2020*, 69 *MORBIDITY & MORTALITY WKLY. REP.* 1198, 1200 fig.1 (2020), <https://www.cdc.gov/mmwr/volumes/69/wr/mm6935a2.htm> [<https://perma.cc/Y3TW-BVAC>].

28. Essential businesses include utilities, gas stations, hospitals, grocery stores, pharmacies, and others that are considered essential for maintaining life. See, e.g., Margaret A. Honein et al., *Summary of Guidance for Public Health Strategies to Address High Levels of Community Transmission of SARS-CoV-2 and Related Deaths, December 2020*, 69 *MORBIDITY & MORTALITY WKLY. REP.* 1860, 1864 (2020), <https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e2.htm> [<https://perma.cc/D7QN-X5BL>] (“Essential (critical infrastructure) workers include health care personnel and employees in other essential workplaces (e.g., first responders and grocery store workers).”).

losses.²⁹ As the stay-at-home orders were lifted in many states and the summer began, the number of infections started to soar in June 2020.³⁰ The center of the pandemic also moved from the Northeast United States to the South (Georgia, Texas, and Florida) and West (California).³¹ At the time of writing, the number of infection cases across the United States has passed another peak, reaching 192,211 new cases on September 1, 2021 (despite the availability of vaccines), which was substantially higher than in the period from March to August 2020 (peaked at 78,252 infection cases on July 17, 2020).³² As of October 2021, over 40 percent of the United States population has not been fully vaccinated,³³ creating the risk of further spread of the disease and mutation of the virus such as the Delta and Lambda variants.³⁴

This article examines the legal and institutional issues in the management of the pandemic in the United States. Other countries that have controlled the pandemic more successfully were more effective in TCQT in the early stages of the pandemic.³⁵ For example, South Korea, thanks to an intense TCQT campaign in the first few weeks of the pandemic, never resorted to economically burdensome measures such as stay-at-home orders but successfully controlled the spread of the disease

29. In April 2020 alone, over 20.5 million jobs were lost. *Payroll Employment Down 20.5 Million in April 2020*, U.S. BUREAU OF LABOR STATISTICS (May 12, 2020), <https://www.bls.gov/opub/ted/2020/payroll-employment-down-20-point-5-million-in-april-2020.htm> [https://perma.cc/ZA2J-27DM].

30. See *COVID Data Tracker*, *supra* note 1 (showing an increase in daily average cases in June).

31. See *id.* (charting daily new case rate per 100,000 people in HHS Regions 1, 2, 3, 4, 6, and 9).

32. See *id.*

33. As of October 17, 2021, 42.8 percent of the population has not been fully vaccinated. *U.S. COVID-19 Vaccine Tracker: See Your State's Progress*, MAYO CLINIC, <https://www.mayoclinic.org/coronavirus-covid-19/vaccine-tracker> [hereinafter *U.S. COVID-19 Vaccine Tracker*].

34. According to reports, the available vaccines may not be fully effective against the Delta and Lambda variants. See Nancy Lapid, *Delta Infections Among Vaccinated Likely Contagious; Lambda Variant Shows Vaccine Resistance in Lab*, REUTERS (Aug. 2, 2021), <https://www.reuters.com/business/healthcare-pharmaceuticals/delta-infections-among-vaccinated-likely-contagious-lambda-variant-shows-vaccine-2021-08-02/>.

35. See, e.g., Fleming, *supra* note 12; Berger, *supra* note 14; Ballhaus, *supra* note 16.

at a much lower level.³⁶ In South Korea, laws not only authorize but *require* the government to provide testing and treatment for infectious diseases and to cover the costs.³⁷ There was also a publicly trusted disease control center in South Korea, Korea Disease Control and Prevention Agency (KDCA, formerly The Korea Centers for Disease Control and Prevention), supported by political leaders, including the President of the country, functioning as an institutional command center that guided the implementation of TCQT.³⁸

On the contrary, the laws and institutions in the United States have failed to function effectively to control the spread of the disease at an acceptable level. The President has vast statutory powers to adopt measures necessary to mandate TCQT under the Public Health Services Act (PHSA),³⁹ but the Trump administration failed to coordinate effectively with state and local governments⁴⁰ to implement TCQT in a timely manner.⁴¹ Former President Trump downplayed the risk of the pandemic and encouraged premature re-opening of schools and businesses to minimize the economic impact of the disease, which was expected to affect his presidential re-election in November

36. As of October 18, 2021, South Korea had a 0.66 percent per capita infection rate (343,445 infected in a population of roughly 51.71 million), a small fraction of the 11.2% per capita infection rate in the United States (37.2 million infected in a population of roughly 332.6 million). *Compare Coronavirus in Korea, supra* note 8, with *COVID Data Tracker, supra* note 1 (illustrating the infection numbers per capita in each country).

37. Specifically, the law provides that “[e]ach citizen shall have the right to receive the diagnosis and medical treatment of any infectious disease under this Act at a medical institution, and the State and local governments shall bear expenses incurred therein.” Infectious Disease Control and Prevention Act, Act No. 17475, Aug. 12, 2020, art. 6(3) (S. Kor.), *translated in* Korea Legislation Research Institute online database, https://elaw.klri.re.kr/eng_service/main.do (search required).

38. See *About KDCA*, KOR. DISEASE CONTROL & PREVENTION AGENCY, <http://www.kdca.go.kr/contents.es?mid=a30101000000> [<https://perma.cc/7MTB-YPGU>] (last updated Sept. 11, 2020).

39. See *generally* 42 U.S.C. §§ 201-300mm-61 (codified provisions of the PHSA).

40. Throughout this paper, the term “local government” includes tribal governments of Indigenous Native Americans.

41. See Lindsay Wiley et al., *Health Reform Reconstruction*, 55 U.C. DAVIS L. REV. (forthcoming 2022) (manuscript at 34–35), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3760086 [hereinafter *Health Reform Reconstruction*].

2020.⁴² The split authority between the federal and the state and local governments, which are characteristic of the United States federal legal structure, did not allow a consistent and effective response to COVID-19 throughout the nation without strong political leadership at the presidential level.⁴³

Some attribute the failure to bad politics and characterize the failed COVID-19 management as a political failure,⁴⁴ rather than an institutional failure, but it is an institutional failure; i.e., effective laws and institutions are functional in the prevailing political reality. Such laws and institutions reduce the adversarial political effects, even though they may not operate completely outside politics and increase chances for success. Laws and institutions that fail to do so, such as those currently operating in the United States, require adjustments and reform. The administration may have changed, but there is no assurance against the recurrence of dysfunctional politics. Also, the sluggish vaccination campaign, which has left a large portion of the population unvaccinated,⁴⁵ indicates that there is a fundamental structural issue regardless of politics and the change of the administration. The gaps and flaws of the current laws and institutions must be identified, and necessary adjustments must be made to improve their effectiveness in the political reality that we have experienced.

42. Brian Bennett, *Why Coronavirus May Be the Biggest Threat Yet to Donald Trump's Re-election*, TIME (Mar. 10, 2020), <https://time.com/5800093/coronavirus-donald-trump-2020-election> [<https://perma.cc/Q6C3-FKYF>]; see Anita Kumar & Nicole Gaudiano, *Trump Wants to Reopen Schools. Hint: It's Not Just About Education*, POLITICO (July 8, 2020), <https://www.politico.com/news/2020/07/08/trump-reopen-schools-353245> (discussing Donald Trump's plan to prematurely reopen schools to help boost the economy); see also John E. Owens, *Donald Trump's Re-election Prospects*, 11 POL. INSIGHT 8, 8 (2020), <https://journals.sagepub.com/doi/abs/10.1177/2041905820958815?journalCode=plia> [<https://perma.cc/Y6EB-87CR>] (analyzing the effects of the COVID-19 pandemic, along with other factors, on Donald Trump's reelection prospects).

43. Lindsay F. Wiley, *Federalism in Pandemic Prevention and Response*, in ASSESSING LEGAL RESPONSES TO COVID-19, *supra* note 3, at 65–70 [hereinafter *Federalism in Pandemic Prevention and Response*].

44. See, e.g., George Pearkes, *America's COVID Response Was Always Doomed to Fail*, BUS. INSIDER (Oct. 16, 2020), <https://www.businessinsider.com/us-covid-19-response-destined-fail-because-political-economic-system-2020-10> (analyzing America's COVID-19 response as a “function of pre-COVID political economy”).

45. As of October 17, 2021, over 40 percent of the population has not been fully vaccinated. *U.S. COVID-19 Vaccine Tracker*, *supra* note 33.

Part I of the article analyzes structural problems in three areas: healthcare provision in the context of the pandemic; regulation of conduct for disease control; and public access to information. Part II examines the current legal and institutional frameworks for healthcare (as applied to the pandemic management) and public access to information. The regulatory gaps in the current frameworks necessitate reform. The article calls for a new approach to resolve these problems. Part III discusses the relevance of the law and development approach to addressing the problems associated with COVID-19 management and introduces the recently-developed General Theory of Law and Development (the General Theory) as a new analytical device to assess the impact of the proposed reform. Part IV applies the General Theory⁴⁶ and assesses such impact against its analytical factors, such as regulatory design, regulatory compliance, and the quality of implementation. Part V draws conclusions.

I. STRUCTURAL PROBLEMS

A. COPING WITH COVID-19 UNDER THE PRIVATE HEALTHCARE SYSTEM

To combat COVID-19 effectively, there must be unfettered access to necessary medical services, including diagnostic tests and treatment. The United States is known to possess the world's most advanced medical technology, highly trained medical professionals, and state-of-the-art facilities and equipment, but its patchwork delivery system has exposed flaws and weaknesses, particularly in the course of this unprecedented pandemic.⁴⁷

46. Section III.B *infra* introduces the General Theory; *see also* Yong-Shik Lee, *General Theory of Law and Development*, 50 CORNELL INT'L L. REV. 415, 423–56 (2017) [hereinafter *Gen. Theory*] (discussing the background and framework of the General Theory of law and development); YONG-SHIK LEE, *LAW AND DEVELOPMENT: THEORY AND PRACTICE* 38–61 (2019) [hereinafter *THEORY AND PRACTICE*] (introducing the framework and basic elements of the General Theory of law and development).

47. *See* Weeks, *supra* note 3, at 95 (“The COVID-19 pandemic exposed a number of existing flaws in the United States’ patchwork approach to paying for and providing access to medical care.”); *see also* *Health Reform Reconstruction*, *supra* note 41, at 34 (“The U.S. response to the COVID pandemic was dependent on an incoherent and inequitable state-by-state

Unlike most other industrialized countries, which maintain publicly-funded, universal healthcare systems, the United States maintains a predominantly private healthcare system.⁴⁸ In 2019, private insurance programs covered 55.5 percent of the population,⁴⁹ and supplementary public healthcare coverages such as Medicare and Medicaid, applying only to select qualified groups (Medicare for the elderly and Medicaid for low-income families and individuals), covered 34 percent at some point during 2019.⁵⁰ Employer-sponsored insurance (ESI), with varied terms, premium rates, and coverages, command a plurality share in the insurance market—49.6 percent of Americans depended on ESI coverage in 2019.⁵¹ As a result, access to medical services varies widely among Americans, depending on the terms of their insurance. In 2019, the average annual

patchwork approach to distributing the burdens and benefits of public investments in health.”). Wiley et al. describe the problems caused by the predominantly private health care system in the pandemic response. They observe, “The privatized nature of the U.S.’s health care system has hampered the COVID pandemic response. A system that depends on private health financing lacks the breadth, capacity, and financial incentives to deliver widespread public health measures, such as testing or vaccination, at levels necessary to be effective and equitable. Instead, our private health insurance system creates cost-barriers to basic public health measures at every step.” *Id.* at 38.

48. See Chris Slaybaugh, *International Healthcare Systems: The US Versus the World*, AXENE HEALTH PARTNERS, <https://axenehp.com/international-healthcare-systems-us-versus-world/> (last visited Sept. 26, 2021) (discussing the healthcare systems of industrialized countries and stating that “[t]he United States is the only industrialized country in the world that does not have Universal Health Coverage for all citizens.”).

49. *Health Insurance Coverage of the Total Population*, KAISER FAM. FOUND., <https://www.kff.org/other/state-indicator/total-population/?currentTmeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> [<https://perma.cc/LS96-FKN9>] [hereinafter *Health Insurance Coverage*].

50. *Id.* 9.2 percent of the population was uninsured in 2019. KATHERINE KEISLER-STARKEY & LISA N. BUNCH, HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2019, at 3 (2020), <https://www.census.gov/content/dam/Census/library/publications/2020/demo/p60-271.pdf> [<https://perma.cc/HBX4-HANC>]. For a review of the United States healthcare system, see LEIYU SHI & DOUGLAS A. SINGH, ESSENTIALS OF THE U.S. HEALTH CARE SYSTEM (5th ed. 2018) (providing an overview of the United States healthcare system and its primary characteristics); see also RAYMOND L. GOLDSTEEN ET AL., JONAS’ INTRODUCTION TO THE U.S. HEALTH CARE SYSTEM (9th ed. 2020) (providing a description of, and commentary on, the United States healthcare system).

51. *Health Insurance Coverage*, *supra* note 49.

premium for employer-based family coverage amounted to \$20,576; for single coverage, \$7,188.⁵² Employers contribute to the premium, but the rate of contribution varies.⁵³

The high cost of insurance premiums resulted in 29.6 million Americans being uninsured in 2019.⁵⁴ However, the number of uninsured individuals has substantially declined since the adoption of the Patient Protection and Affordable Care Act (ACA) in 2010 that removed some of the barriers to obtaining health insurance, such as pre-existing condition exclusions, and created the government-sponsored Marketplace (subsidizing premium payments through a direct tax credit in accordance with income level).⁵⁵ The ACA reform had its limits: without a public insurance option,⁵⁶ it did not eliminate the uninsured who were not eligible for Medicaid or Medicare but could not afford even the subsidized premium available on the Marketplace. Moreover, the United States Supreme Court's decision in *NFIB v. Sebelius* weakened another important ACA coverage strategy, which was to expand Medicaid to United States citizens and qualified non-citizens below 138 percent of the federal poverty level, by finding that states had an option, not an obligation, to expand Medicaid under the terms of the ACA.⁵⁷ This resulted in, to date, thirty-eight states and Washington, D.C. expanding Medicaid and twelve states not expanding it.⁵⁸

52. Weeks, *supra* note 3, at 100.

53. *See id.* (detailing health insurance options for the unemployed).

54. KEISLER-STARKEY & BUNCH, *supra* note 50, at 3.

55. *See* Weeks, *supra* note 3, at 95–96 (discussing how the ACA reformed United States private insurance).

56. The ACA instead introduced the Consumer Operated and Oriented Plan (CO-OP) Program, which sought to increase market competition by offering nonprofit plans from insurers with “a strong consumer focus,” but many failed shortly after launch. Sabrina Corlette et al., WHY ARE MANY CO-OPS FAILING?: HOW NEW NONPROFIT HEALTH PLANS HAVE RESPONDED TO MARKET COMPETITION 7, 9 (2015), https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2015_dec_1847_corlette_why_are_many_coops_failing.pdf [<https://perma.cc/87E2-UMNM>] (quoting 42 U.S.C. § 18042(c)(3)(C)).

57. Weeks, *supra* note 3, at 95; *NFIB v. Sebelius*, 567 U.S. 519, 548–58 (2012) (finding that mandating the Medicaid expansion provision of the Affordable Care Act exceeded Congress's spending power under the Constitution).

58. Weeks, *supra* note 3, at 95. Missouri approved Medicaid expansion in the summer of 2020. Alex Smith, *Missouri Voters Approve Medicaid Expansion Despite Resistance from Republican Leaders*, NPR (Aug. 5, 2020) <https://www.npr.com/2020/08/05/881111111/missouri-voters-approve-medicaid-expansion>.

The absence of a publicly-funded, universal healthcare system created uncertainty for public access to COVID-19 testing and treatment.⁵⁹ In the early weeks of the pandemic, when a large number of tests and treatment should have been made available to the public to contain the disease, unclarity concerning out-of-pocket cost⁶⁰ discouraged the public, particularly those without insurance or with only limited coverages, from seeking testing and treatment, contributing to the failure to contain the disease in the early stages of the pandemic.⁶¹ In contrast, other countries operating a publicly-funded universal healthcare system were able to confirm that the testing and treatment would be provided free of charge or at an affordable rate so that the cost concern would not impede the effort to contain the disease.⁶²

pr.org/sections/health-shots/2020/08/05/898899246/missouri-voters-approve-medicaid-expansion-despite-resistance-from-republican-le [https://perma.cc/UQL8-VEZA].

59. See *Health Reform Reconstruction*, *supra* note 41, at 15 (“[T]he diffusion of authority between levels of government, fragmented fiscal supports, and the many diverse providers in our largely privatized health care system have led to a U.S. failure to fairly allocate, adequately supply, or constrain prices for essential testing, therapeutics, and vaccines. Widespread public health measures may be delivered more effectively in countries with a centralized and unified public health care delivery system.”).

60. According to a report, a single symptomatic case of COVID-19 could cost an individual a median of \$3,045 during the course of infection. Sarah M. Bartsch et al., *The Potential Health Care Costs and Resource Use Associated With COVID-19 in the United States*, 39 HEALTH AFF. 927, 929 (2020), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00426> [https://perma.cc/LN7H-R8GH].

61. See Dan Witters, *In U.S., 14% With Likely COVID-19 to Avoid Care Due to Cost*, GALLUP (Apr. 28, 2020), <https://news.gallup.com/poll/309224/avoid-care-likely-covid-due-cost.aspx> [https://perma.cc/PR2P-CMNS]. For example, some states’ websites, such as California (ca.gov) and Georgia (georgia.gov), made it clear that COVID-19 testing was free to patients, but others, including Minnesota (mn.gov) and North Dakota (nd.gov), did not make the information as clear. This was partly because there could be charges associated with visiting a doctor outside of the test, even though COVID-19 tests were supposed to be free. Federal and state governments referred individuals to their insurance companies to confirm costs.

62. See, e.g., Infectious Disease Control and Prevention Act, Act No. 17475, Aug. 12, 2020, art. 6(3) (S. Kor.), *translated in* Korea Legislation Research Institute online database, https://elaw.klri.re.kr/eng_service/main.do (search required) (declaring that in South Korea the State has the responsibility to cover the cost of tests and treatment).

The limited availability of test kits in the early weeks of the pandemic, as well as the absence of a cure or vaccine, were as much an impediment as cost, so not all of the early failure can be attributed to the patchwork healthcare system in the United States. Moreover, adjustments were made to the law, such as a requirement that all ACA-compliant and other comprehensive group and non-group health insurance plans cover testing for detection or diagnosis of COVID-19 as well as vaccinations without cost-sharing.⁶³ Another adjustment was a mandate that required reimbursement of hospital costs for the treatment of uninsured patients.⁶⁴ Also, a substantial number of workers who had lost their jobs and ESI during the pandemic were able to obtain health insurance through the Marketplace and Medicaid.⁶⁵ In addition, the ACA provided states with an option to expand Medicaid coverage,⁶⁶ and most hospitals (i.e., all of the

63. The Families First Coronavirus Response Act (FFCRA) of 2020 §§ 6001–6004, 42 U.S.C. §§ 1320b–5, 1395l, 1396d(a)(3) (2020); Coronavirus Aid, Relief, and Economic Security Act (CARES Act) of 2020 § 3201 (amending FFCRA § 6001 to apply coverage without cost-sharing to out-of-network tests), § 3203(a), 41 U.S.C. § 300gg-13 (2020). The Trump administration’s guidance on the CARES Act and FFCRA reduced the scope of coverage by requiring insurers to cover the costs of COVID-19 testing for “diagnostic purposes” and when deemed “medically appropriate” by an individual’s attending medical provider. See *FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 43*, CTRS. FOR MEDICARE & MEDICAID SERVS. 5–6 (June 23, 2020), <https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf> (interpreting Section 6001 of the FFCRA to not cover COVID-19 testing unless medically appropriate and diagnostic, and excluding coverage for “testing conducted to screen for general workplace health and safety (such as employee ‘return to work’ programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19”).

64. See Coronavirus Aid, Relief, and Economic Security (CARES) Act § 3211, § 42 U.S.C. 254b(r) (amended). Wiley et al. report the risk that an uninsured patient could nevertheless be charged for their COVID-19 care. *Health Reform Reconstruction*, *supra* note 41, at 40.

65. See Weeks, *supra* note 3, at 99–100 (explaining that state insurance Marketplaces opened enrollment due to the pandemic and that “[i]n April 2020 alone, Marketplace enrollment due to unemployment increased by 139% compared to April 2019”).

66. See *Status of State Action on the Medicaid Expansion Decision*, KAISER FAM. FOUND., <https://www.kff.org/health-reform/state-indicator/state-activity-around-expanding-medicare-under-the-affordable-care-act/?currentTimeframe=0&sortModel=%7B%22collId%22:%22Location%22,%22sort%22:%22asc%22%22>

Medicare-participating hospitals) were not allowed to turn down patients requiring emergency care, including COVID-19 patients, due to cost considerations.⁶⁷

These adjustments, however, were not sufficient to contain the pandemic. The costly split between federal and state authorities over healthcare and insurance regulation has caused further delay in removing uncertainty inherent in the patchwork system, blocking a uniform remedy in the early stages of the pandemic.⁶⁸ The cost of COVID-19 treatment was not addressed by legislation; coverage limits, existing among private insurance plans, as well as cost-sharing requirements, remained applicable, with elements of “surprise” medical bills.⁶⁹ In the absence of any federal initiative to provide universal coverage for testing and treatment of COVID-19,⁷⁰ states may attempt to fill the gap by enacting broader COVID-19 coverage requirements.⁷¹ But federal preemption currently in place limits the effect of state reform: the Employee Retirement Income Security Act of 1974 (ERISA) precludes additional state requirements from application to self-insured ESI plans that cover the majority (60 percent) of people who receive insurance

7D (last updated Sept. 8, 2021); Patient Protection and Affordable Care Act (ACA) of 2010, § 2001, 42 U.S.C. § 1396a (amended) (2010).

67. The Emergency Medical Treatment and Labor Act (EMTALA) of 1986, 42 U.S.C. § 1395dd(a) (2018); *see also* *Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications Related to Coronavirus Disease 2019 (COVID-19) (Revised)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Mar. 30, 2020), <https://www.cms.gov/files/document/qso-20-15-hospital-cah-emtala-revised.pdf> [<https://perma.cc/L735-QCGU>] [hereinafter *EMTALA Requirements*].

68. Nicole Huberfeld et al., *Federalism Complicates the Response to the COVID-19 Health and Economic Crisis: What Can Be Done?*, 45 J. HEALTH POL., POL'Y & L. 951, 951–52 (2020).

69. *See* Weeks, *supra* note 3, at 98; *see also* Mark Fendrick, *COVID-19 Care is (Mostly) Free to Patients. Should Other Vital Care Be Too?*, U. MICH. HEALTH LAB BLOG (May 19, 2020), <https://labblog.uofmhealth.org/industry-dx/covid-19-care-mostly-free-to-patients-should-other-vital-care-be-too> [<https://perma.cc/A Y2S-LJ4N>].

70. The CARES Act required insurers to cover the cost of COVID-19 tests but did not impose a maximum amount that providers can charge for the tests, inviting price gouging. *See* Coronavirus Aid, Relief, and Economic Security (CARES) Act, § 3202, 42 U.S.C. § 256b. The funding made available through the FFCRA and CARES Act did not remove the cost uncertainty.

71. Some states, such as New Mexico, Massachusetts, Vermont, and Minnesota, have required health plans to limit or eliminate the cost of COVID-19 treatment. Weeks, *supra* note 3, at 99.

through employers;⁷² thus, most ESI-insured individuals are covered by insurance plans not subject to state regulation, and state reform will not benefit them.⁷³

A broader initiative to expand access to healthcare services needs to be made at the federal level, but this is not to suggest that the federal government should completely overtake states' authority over healthcare regulation, which would be neither feasible nor desirable, even during the current pandemic. However, it would have been entirely possible and even necessary for the federal government to provide, after extensive consultations with states, uniform guidelines on providing affordable access to testing and treatment and to coordinate with states to ensure that those in need have timely access to testing and treatment. Nevertheless, such political leadership and federal-state cooperation were lacking, and states—many with resource shortages—were left to deal with the pandemic situation without coordinated support from the federal government.⁷⁴ The current impediment may call for a deeper overhaul of the healthcare system, such as the adoption of a public insurance option or a single-payer system that has operated successfully in other countries that have better handled the pandemic.⁷⁵ The proposed reform will not opt for either of such options but will mandate more extensive federal government engagement on healthcare issues and facilitate closer coordination between federal and state authorities.⁷⁶

Lastly, the current healthcare system does not adequately address the disproportionate effect that the pandemic has on different racial and income groups.⁷⁷ According to studies, racial minorities and low-income communities have an increased risk of hospitalization and death from COVID-19.⁷⁸ Racial

72. *Id.* at 97.

73. *See id.*

74. *Federalism in Pandemic Prevention and Response*, *supra* note 43, at 65; *see also* Scott Burris et al., *Summary of Findings and Recommendations*, in *ASSESSING LEGAL RESPONSES TO COVID-19*, *supra* note 3, at 2.

75. *See* Maizland & Felter, *supra* note 12.

76. This point is further explained in Section III.B *infra*.

77. *See Health Reform Reconstruction*, *supra* note 41, at 15–16.

78. Wyatt Koma et al., *Low-Income and Communities of Color at Higher Risk of Serious Illness if Infected with Coronavirus*, KAISER FAM. FOUND. (May 7, 2020), <https://www.kff.org/coronavirus-covid-19/issue-brief/low->

minorities, for instance, reportedly require hospitalization at nearly five times the rate of white adults⁷⁹ likely due, in part, to higher levels of underlying health conditions, such as obesity, asthma, and chronic metabolic diseases, including diabetes and cardiovascular disease.⁸⁰ These health issues are often clustered in low-income communities due to environmental factors, such as air, water, and soil pollutants that exacerbate the complications of airborne viruses, including COVID-19.⁸¹ Additional adverse factors include crowded housing conditions, jobs that cannot be performed remotely, inconsistent access to healthcare, and stress leading to weaker immunity.⁸² Minorities and lower-income groups, despite being at a higher risk of having more serious complications related to COVID-19, are more likely to avoid healthcare due to fears of out-of-pocket expenses—a conclusion demonstrated in a survey that shows 58 percent of non-White respondents have concerns or “extreme” concerns about the out-of-pocket costs for COVID-19 treatment, “compared to 32 percent of white respondents.”⁸³ The fear of healthcare costs exposes the weakness of the current system and necessitates reform.

income-and-communities-of-color-at-higher-risk-of-serious-illness-if-infected-with-coronavirus/ [https://perma.cc/E43S-BL5R].

79. *COVID-19 Hospitalization and Death by Race/Ethnicity*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 18, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html> [https://perma.cc/7SDS-77LX].

80. See CDC, WEEK 26, COVID VIEW: A WEEKLY SURVEILLANCE SUMMARY OF U.S. COVID-19 ACTIVITY, 9–11 (June 27, 2020), https://www.cdc.gov/coronavirus/2019-ncov/covid-data/pdf/covidview-07-03-2020.pdf?utm_source=link_newsv9&utm_campaign=item_316052&utm_medium=copy [https://perma.cc/D54Y-6NWL] (collating increased rate of hospitalization among racial minorities with statistics on underlying medical conditions in hospitalized adults).

81. Katherine Bagley, *Connecting the Dots Between Environmental Injustice and the Coronavirus*, YALE ENV'T 360 (May 7, 2020), <https://e360.yale.edu/features/connecting-the-dots-between-environmental-injustice-and-the-coronavirus> [https://perma.cc/7GX6-EXHM].

82. Sherita Hill Golden, *Coronavirus in African Americans and Other People of Color*, JOHNS HOPKINS MED. (Apr. 20, 2020), <https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/covid19-racial-disparities> [https://perma.cc/BR8J-24E3].

83. Sara Heath, *More Non-White Patients Dread Out-of-Pocket Costs for COVID-19*, PATIENT ENGAGEMENT HIT (Aug. 4, 2020), <https://patientengagementhit.com/news/more-non-white-patients-dread-out-of-pocket-costs-for-covid-19> [https://perma.cc/9XBP-M3R4].

B. FRAGMENTED AUTHORITIES

Fragmentations in authorities have caused another structural problem that impeded successful management of COVID-19. Successful control of the pandemic requires regulating individual conduct, such as the enforcement of stay-at-home orders to reduce physical contact and buy time for the government to make preparations, social distancing to slow the spread of the disease, and face covering to protect the public from the virus.⁸⁴ Although the United States federal system splits authorities that enforce these measures among federal, state, and local governments to create checks and balances, in the current pandemic, the system has created fragmentations and clashes among authorities, resulting in a lack of effective and coordinated response to the pandemic,⁸⁵ which, in turn, contributed to the government's ultimate failure to control the disease.⁸⁶ This section examines government authorities on regulation of individual conduct and analyzes issues created by lack of coordination and subsequent conflicts among them.

At the federal level, the government has the authority to impose quarantine and isolation, drawn from the Commerce Clause in the United States Constitution.⁸⁷ Under Section 361 of the PHS Act, the Secretary of the United States Department of Health and Human Services ("HHS Secretary") has the authority to take measures to prevent the entry and spread of communicable diseases from foreign countries into the United

84. See Lindsay K. Cloud et al., *A Chronological Overview of the Federal, State, and Local Response to COVID-19*, in *ASSESSING LEGAL RESPONSES TO COVID-19*, *supra* note 3, at 15 (cataloguing various measures taken to control the pandemic).

85. See *Health Reform Reconstruction*, *supra* note 41, at 32, 35–38 (observing that "[f]ederalism further divides authority for legal interventions in the pandemic response among federal, state, and local governments").

86. See *id.* at 35 ("[T]he federal government shunted to states responsibility that they neither asked for nor could bear—functionally or financially.").

87. The United States Supreme Court applies a broad interpretation of the Commerce Clause to control activity that has a "substantial economic effect" on interstate commerce, *Wickard v. Filburn*, 317 U.S. 111, 124, 125 (1942), or if the cumulative effect of an act could affect interstate commerce, *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 37, 38 (1937). See also *U.S. v. Darby*, 312 U.S. 100, 118 (1941) ("The power of Congress over interstate commerce is not confined to the regulation of commerce among the states [but also] extends to those activities intrastate which so affect interstate commerce or the exercise of the power of Congress over it . . .").

States and among states.⁸⁸ The authority for performing these functions on a daily basis has been delegated to the Director of the Centers for Disease Control and Prevention (CDC), and the CDC may order the quarantine or isolation of specific individuals if it suspects infection.⁸⁹ Although the issuances of such orders are rare,⁹⁰ non-compliance is punishable by fines or imprisonment.⁹¹

The statutory powers cited above provide the federal government with authority to impose travel restrictions. In January 2020, the President restricted the entry of all aliens who were physically within China during the preceding fourteen days.⁹² As of October 2020, several Presidential proclamations were in effect, restricting entry into the United States from China, the United Kingdom, the Republic of Ireland, Brazil, Iran, and scores of countries across continental Europe.⁹³ However, there is a controversy as to whether the federal government has the authority to impose a “national” quarantine; e.g., whether the federal government may directly place New

88. 42 U.S.C. § 264 (2008). Originally, this statute conferred this power on the Surgeon General, but all statutory powers and functions of the Surgeon General were subsequently transferred to the Secretary of Health, Education, and Welfare, Reorganization Plan No. 3 of 1966, 31 Fed. Reg. 8855 (June 25, 1966), which became the HHS Secretary. 20 U.S.C. § 3508.

89. 42 C.F.R. §70.6(a) (2017). The CDC control is limited to diseases listed by President’s executive order. *See generally* Section II.A *infra* (outlining federal and state healthcare frameworks in general and during a pandemic).

90. *Cf.* Lauren Sloss, *Quarantine and Travel: Strict Penalties, Rare Enforcement*, N.Y. TIMES, (Aug. 31, 2020), <https://www.nytimes.com/2020/08/21/travel/quarantine-enforcement.html>.

91. 42 U.S.C. § 271.

92. Proclamation No. 9984 of January 31, 2020, 85 Fed. Reg. 6709 (Jan. 31, 2020) [hereinafter Proclamation 9984]. The President’s travel restriction relies on immigration laws—§§ 212(f) and 215(a) of the Immigration and Nationality Act (INA)—instead of § 361 of the PHSA. Proclamation 9984, at 6710. *Compare* 8 U.S.C. §§ 1182(f), 1185(a), *and* 3 U.S.C. § 301 (INA provisions cited in Proclamation 9984), *with* 42 U.S.C. § 264 (PHSA provisions). Professor Polly Price opines that the President used immigration provisions to circumvent HHS and CDC involvement and rulemaking, which would be involved if he used PHSA provisions. Email from Polly J. Price, Asa Griggs Candler Professor of Law, Professor of Glob. Health, Emory Univ. Sch. of Law, to author (Jan. 26, 2021, 9:11 PM) (on file with author).

93. *Travelers Prohibited from Entry to the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 14, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/travelers/from-other-countries.html> [https://perma.cc/2555-L23Y].

York, New Jersey, and Connecticut residents under a quarantine.⁹⁴ There is a view that quarantine within a state is an exclusive state power, not within the federal government's authority; i.e., the federal quarantine power is limited to preventing the spread of communicable diseases into the country or across state lines.⁹⁵ Regardless of the legal issue, it would be politically difficult for the federal government to bypass states and impose quarantines directly within state territories,⁹⁶ unless it is abundantly clear that the states in question are unable to control a massive spread of the pandemic beyond their state boundaries.

States have the primary authority to enact and enforce quarantine laws under their police power.⁹⁷ States may also declare their own state of emergency,⁹⁸ under which governors are authorized to adopt a broad range of public policy measures, including quarantine and isolation mandates.⁹⁹ State public health codes also delegate authority to local governments to adopt their own measures; for example, the Texas Public Health and Safety Code provides in part:

The governing body of a municipality or the commissioners court of a county may enforce any law that is reasonably necessary to protect

94. Brian Naylor, *Fact Check: A Blanket National Quarantine Is Likely Not Legal*, NPR (Apr. 2, 2020), <https://www.npr.org/2020/04/02/825293201/a-president-is-not-able-to-order-a-national-quarantine-experts-say> [https://perma.cc/26YE-G6B3].

95. See Wendy E. Parmet & Michael S. Sinha, *The Law and Limits of Quarantine*, 385 NEW ENG. J. MED. e28, e28(1)–(2) (2020), <https://www.nejm.org/doi/pdf/10.1056/NEJMp2004211?articleTools=true> [https://perma.cc/8M2F-A37F].

96. See Scott McDonald, *NY Governor Cuomo Says a Federal Quarantine by Trump Would be a 'Declaration of War,' Trump Renegotiates*, NEWSWEEK (Mar. 28, 2020), <https://www.newsweek.com/ny-governor-cuomo-says-federal-quarantine-ordered-trump-would-declaration-war-states-1494857> [https://perma.cc/7DLL-4BPC] (describing tension between President Trump and Governor Cuomo over a potential federal quarantine of New York, New Jersey, and Connecticut).

97. *Compagnie Francaise de Navigation a Vapeur v. La. State Bd. of Health*, 186 U.S. 380, 387 (1902).

98. See, e.g., Press Release, State of Georgia, Kemp Declares Public Health State of Emergency (Mar. 16, 2020), <https://gov.georgia.gov/press-releases/2020-03-16/kemp-declares-public-health-state-emergency> [https://perma.cc/7MZB-UFS7].

99. See, e.g., N.Y. Exec. Order No. 202 (Mar. 7, 2020), <https://www.governor.ny.gov/news/no-202-declaring-disaster-emergency-state-new-york> [https://perma.cc/ML5J-3KBD].

the public health The governing bodies of municipalities and the commissioners courts of counties may cooperate with one another in making necessary improvements and providing services to promote the public health¹⁰⁰

Split authority among federal, state, and local governments has raised controversies as to the legitimacy of the proposed and implemented government measures. Toward the end of March, when the pandemic was fast spreading in the Northeast United States, former President Trump reportedly discussed the possibility of a federal quarantine in the tri-state area of New York, New Jersey, and Connecticut.¹⁰¹ State governors resisted the idea, as well reflected by the New York State Governor's comment that "[the imposition of the federal quarantine] would be a declaration of war on states. A federal declaration of war."¹⁰² Polly J. Price, an expert in health law and Professor of Law at Emory Law School, also opined that quarantine within a state is exclusively within the states' power, where the quarantine does not involve entry into the country or cross-state movement but requires people to stay home or close business.¹⁰³ The question is whether the federal government's quarantines within state territories will qualify as measures to prevent the entry and spread of communicable diseases "*from foreign countries into the States or possessions, or from one State or possession into any other State or possession.*"¹⁰⁴ The quarantines in question do not specifically target movements across the state borders and, therefore, are arguably outside the ambit of the law, despite the CDC's statement that the federal government has quarantine powers.¹⁰⁵

There have also been disputes between state and local (municipal) authorities over the regulation of public conduct, such as face-covering requirements. The Governor of Georgia, for example, clashed with the Mayor of Atlanta regarding the Mayor's enactment of a mask mandate in the city. Under the mask mandate proposed by the Mayor of Atlanta, failure to wear

100. 2 TEX. HEALTH & SAFETY CODE ANN. §121.003 (West 2015).

101. McDonald, *supra* note 96.

102. *Id.*

103. See Polly J. Price, *Do State Lines Make Public Health Emergencies Worse? Federal Versus State Control of Quarantine*, 67 EMORY L. J. 491 (2018).

104. 42 U.S.C. § 264 (2018) (emphasis added).

105. Naylor, *supra* note 94.

a mask within Atlanta's city limits was punishable by a fine and up to six months in jail.¹⁰⁶ The Governor claimed that "the mayor's [sic] mask mandate violated his emergency order prohibiting local action from being more prohibitive than the state's requirements."¹⁰⁷ This dispute led to the Governor filing a lawsuit against the City of Atlanta and the Mayor, although he subsequently dropped the lawsuit.¹⁰⁸ Conversely, the Governor of Nevada criticized and objected to the Mayor of Las Vegas re-opening casinos in late April when he and many of his supporters did not consider the City of Las Vegas to be ready for re-opening in the pandemic.¹⁰⁹

In a democracy, disagreements among authorities may emerge, and these types of checks and balances among the different layers of government are embedded in the Constitution and may well be justified during normal times; however, in this unprecedented pandemic, the disputes and clashes among federal, state, and local authorities confuse the public and undermine public confidence in the government's control of the disease. The fragmentations between authorities could not have been conducive to ensuring a consistent and effective response to COVID-19 across the country. In the absence of strong federal leadership in the management of the current pandemic, federal, state, and local authorities lack coordination, leaving each state to deal with the pandemic largely on their own.¹¹⁰ The lack of precedents in a comparable-scale pandemic in recent decades

106. Atl., Ga. Exec. Order No. 2020-113.

107. Devin Cole, *Georgia Governor Withdraws Lawsuit Challenging Atlanta Mayor's Mask Mandate*, CNN (Aug. 13, 2020, 9:32 PM), <https://www.cnn.com/2020/08/13/politics/brian-kemp-atlanta-mask-lawsuit-withdrawing/index.html> [https://perma.cc/3QNL-WX5Q].

108. Nicholas Reimann, *Georgia Governor Drops Lawsuit Against Atlanta Mayor Keisha Lance Bottoms Over Mask Mandate*, FORBES (Aug. 13, 2020, 3:46 PM), <https://www.forbes.com/sites/nicholasreimann/2020/08/13/ga-governor-drops-lawsuit-against-atlanta-mayor-keisha-lance-bottoms-over-mask-mandate/#6f212a167d2a> [https://perma.cc/5N3X-FC3V].

109. Allyson Chiu, *The Public Skewering of Las Vegas Mayor Carolyn Goodman, Champion of Reopening Casinos*, WASH. POST (Apr. 23, 2020), <https://www.washingtonpost.com/nation/2020/04/23/las-vegas-mayor-coronavirus/> [https://perma.cc/6XPP-WPS9].

110. Michael D. Shear et al., *Inside Trump's Failure: The Rush to Abandon Leadership Role on the Virus*, N.Y. TIMES, <https://www.nytimes.com/2020/07/18/us/politics/trump-coronavirus-response-failure-leadership.html> [https://perma.cc/LXL9-PFLW] (last updated Sept. 15, 2020).

may have affected the poor coordination and low level of institutional readiness for the pandemic. To overcome the present fragmentation in authority, consideration should be given to a new institutional arrangement, such as a control center in charge of pandemic management, as discussed in Section III.A below.

C. PUBLIC ACCESS TO INFORMATION

Lastly, the third impediment in the management of COVID-19 has been insufficient public access to information. Ensuring public access to information is considered to be a necessary response to the pandemic.¹¹¹ The public will be made better aware of the situation and will be in a better position to protect themselves from the disease when they are granted unfettered access to necessary information, including: the status of the disease (e.g., the number and locations of infections and deaths); government response measures (e.g., stay-at-home orders, social distancing requirements, and mask-wearing mandates); public safety guidelines (e.g., hygiene recommendations); and availability of test sites, treatment, and vaccination.¹¹² Some of the information acquired through contact tracing, such as the locations and dates of the visits by those infected, is also useful to the public in their efforts to assess the risk of exposure in their daily lives, particularly in the early stages of a pandemic where the number of infections is relatively limited.

Public access to information will strengthen the ability of the public to combat the disease and improve their chances for survival through the pandemic. Ensuring public access to information will also enable the public to better understand the government's decisions related to the pandemic, evaluate and debate the decision-making process, and propose improvements to the decisions. This process builds collaboration and trust between the government and the public, which is essential to effectively responding to a pandemic.¹¹³ The right to information enhances public access to it; this right, which will be examined

111. *Ensuring the Public's Right to Know in the COVID-19 Pandemic*, ARTICLE 19, at 4 (May 2020), https://www.article19.org/wp-content/uploads/2020/05/Ensuring-the-Publics-Right-to-Know-in-the-Covid-19-Pandemic_Final-13.05.20.pdf [<https://perma.cc/YU3G-A5XS>].

112. *Id.*

113. *Id.*

further, is particularly beneficial in enabling medical experts, academics, and journalists to obtain the necessary information to inform the general public and advise the government to consider better alternatives.

In the United States, the Freedom of Information Act (FOIA) and its state equivalents¹¹⁴ facilitate the right to information. The right to information is also a fundamental component of the right to freedom of expression, as articulated by Article 19 of the Universal Declaration of Human Rights and Article 19 of the International Covenant on Civil and Political Rights.¹¹⁵ The U.N. Human Rights Committee has specified that states should proactively publish information of public interest and take steps to facilitate access to information held by public bodies by, *inter alia*, legislating freedom of information legislation.¹¹⁶ The United States federal and state FOIA models meet the latter recommendation, but the former part—proactive publication of information—is not generally required under federal or state laws.¹¹⁷ There is a need for the legal protection of this part of the right, which can be accomplished by requiring the government under the law to release the information about the pandemic promptly.

The right to information can conflict with the right to privacy, particularly when the former extends to private information of individuals, such as information on the locations where infection cases are reported and the time and location of visits made by those infected with the virus in a recent time period. This information, which is obtained through contact tracing, would be important to contain the pandemic, as such information enables the public to take precautionary action. The information required through contact tracing, however, is private in nature, and any attempt to obtain such information, either by the government or the public, raises a privacy

114. Freedom of Information Act (FOIA), 5 U.S.C. § 552 (2018); *see also* GA. CODE ANN. § 31-7-6 (2010); N.Y. PUBLIC OFFICERS LAW §§ 91–99 (McKinney 2014); OHIO REV. CODE ANN. § 3701.17(B)(4) (West 2004).

115. G.A. Res. 217(III) A, Universal Declaration of Human Rights, U.N. Doc. A/RES/217(III) (Dec. 10, 1948), art. 19; and International Covenant on Civil and Political Rights, 999 U.N.T.S. 171 (1966), art. 19.

116. General Comment No. 34, U.N. HUMAN RIGHTS COMM. on its 102nd Sess., U.N. Doc. CCPR/C/GC/34 (Sept. 12, 2011), <https://www2.ohchr.org/english/bodies/hrc/docs/gc34.pdf> [<https://perma.cc/LK8G-4D2H>].

117. 42 U.S.C. § 300u-3 (2018).

concern¹¹⁸: while the public needs to secure necessary information to combat the disease, the individual subject to contact tracing may not wish to provide private information to the government or to permit any part of the information to be released to the public. In a recent survey, most participants showed objection to publicly releasing contact tracing information.¹¹⁹ Reflecting this popular concern, contact tracing information is not released to the public in the United States. In several states, including Kansas, Minnesota, New Jersey, New York, Ohio, and Louisiana, bills have been introduced to ensure privacy and confidentiality for contact tracing and make participation voluntary, not mandatory.¹²⁰

The pro-privacy stance, currently taken by local legislatures and the general population,¹²¹ stems, at least in part, from the concern about the potential misuse of collected information. Such potential misuse would consist of any use of collected information for an unauthorized purpose. For example, a public release of private information obtained through contact tracing, such as an individual's personal address, would be a misuse; another example of misuse would be the unauthorized use of contact tracing information by a third party, who may, for example, gain access to the information to develop an exposure tracing and notification app for the government, to learn the

118. Congressional Research Service (CRS) has addressed the privacy issue in the context of digital contact tracing. ERIC N. HOLMES & CHRIS D. LINEBAUGH, CONG. RSCH. SERV., LSB10511, COVID-19: DIGITAL CONTACT TRACING AND PRIVACY LAW (2020), <https://crsreports.congress.gov/product/pdf/LSB/LSB10511> [<https://perma.cc/U3EE-YQNF>]. In response to the privacy concern, the HIPAA provides for the protection of medical records and other personal health information and prevents disclosure without patient authorization. 45 C.F.R. pt. 160(A)–(E) (2020); and 45 C.F.R. pt. 164 (2020). The HIPAA also authorizes the release of personal medical information under emergency situations. See discussion *infra* Section II.B.

119. LUCY SIMKO ET AL., COVID-19 CONTACT TRACING AND PRIVACY: STUDYING OPINION AND PREFERENCES 11 (May 8, 2020), <https://arxiv.org/pdf/2005.06056.pdf> [<https://perma.cc/98C8-KZJZ>].

120. Ass'n State & Territorial Health Officials, *State and Territorial Contact Tracing Legislation*, ISSUE BRIEF (July 2, 2020), <https://www.astho.org/COVID-19/State-and-Territorial-Contact-Tracing-Legislation/> [<https://perma.cc/VW6T-QYH4>].

121. *Id.*; see also SIMKO ET AL., *supra* note 119 (discussing public concerns between the need for technology-based contact tracing and maintaining privacy).

pattern of customer movements for a commercial purpose.¹²² The government use of contact tracing information for a purpose unrelated to the pandemic, such as to trace criminal suspects, enforcing immigration rules, and monitoring national security threats, could also be considered a misuse, despite the collateral benefits to the public.¹²³

Privacy rules embedded in existing federal and state laws and the new state bills seeking to strengthen the protection of privacy in the process of contact tracing¹²⁴ will attempt to prevent such misuses, but the possibility of misuse cannot be eliminated by legal prescriptions alone. An external security breach is always a possibility; thus, security measures, such as a physical separation of the database that stores contact tracing information, might be necessary to reduce the possibility of a breach and potential misuse. Additional preventive measures may also be adopted to ensure the integrity of the process; for example, consideration should also be given to minimizing a line of reporting for the investigators who perform contact tracing and process contact tracing information, thereby minimizing the number of people who access the information. Contact tracing should also be subject to independent oversight and periodic reviews to ensure the protection of confidentiality and privacy in the process of contact tracing and the use of the information. Digital contact tracing, which instills anonymity in the collection of information and notification of exposure, may also reduce the

122. Some states are using digital contact tracing technology created by IT companies such as Google and Apple, which relies on smartphones using Bluetooth to determine when devices are in close proximity. Robert A. Fahey & Airo Hino, *COVID-19, Digital Privacy, and the Social Limits on Data-Focused Public Health Responses*, 55 INT'L J. INFO. MGMT. 1 (Dec. 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7328565/> [<https://perma.cc/SD7J-BTDF>]. While this approach seeks to protect privacy, it is still subject to misuse. *Id.* at 2–3.

123. Thus, the New York State Legislature has passed companion bills A10500 and S8450C that would require that all information collected by COVID-19 contact tracers remain confidential and inaccessible to law enforcement without a court order. Ass'n State & Territorial Health Officials, *supra* note 120. See also *Assembly Bill A10500C*, N.Y. STATE SENATE, <https://www.nysenate.gov/legislation/bills/2019/a10500/amendment/c> [<https://perma.cc/V8UT-NWZ5>]; *Senate Bill S8450C*, N.Y. STATE SENATE, <https://www.nysenate.gov/legislation/bills/2019/s8450> [<https://perma.cc/N5QH-3R4E>].

124. Ass'n State & Territorial Health Officials, *supra* note 120.

possibility of misuse, although this technology also does not eliminate the privacy concerns.¹²⁵

There is a conflict between the right to information and the right to privacy in a pandemic situation, where the information sought pertains to individual privacy. In a pandemic, the society has to decide whether it is ready to accept certain limitations on privacy, along with the risk of misuse, by allowing the government to obtain personal information and use it in the interest of controlling the pandemic.¹²⁶ The question is the extent of acceptable limitations on privacy and of allowable use by the government. The point of balance may vary by public preferences, social traditions, and cultural aspirations. In the United States, individualism prevailing in society has generated a strong preference for privacy, resulting in no public release of contact tracing information and the pro-privacy stance in contact tracing legislation.¹²⁷ Participation in contact tracing is also made voluntary rather than mandatory.¹²⁸ Considering the large number of infections and continuing deaths from COVID-19, efforts should be made to increase public access to information, including some of the information acquired by contact tracing while seeking to protect essential privacy (such as personal

125. See HOLMES & LINEBAUGH, *supra* note 118 (discussing privacy issues in digital contact tracing). The concern about misuse is well reflected by the recent remarks of Senator Josh Hawley of Missouri, who opined that “Americans are right to be skeptical of this project . . . Too often, Americans have been burned by companies who calculated that the profits they could gain by reversing privacy pledges would outweigh any later financial penalty.” Evan Halper, *Lawmakers Warn Coronavirus Contact-Tracing is Ripe for Abusive Surveillance*, L.A. TIMES (Apr. 26, 2020), <https://www.latimes.com/politics/story/2020-04-26/privacy-americans-trade-off-trace-coronavirus-contacts>.

126. Yong-Shik Lee & Hye Seong Mun, *COVID-19: Public Access to Information – Legal and Institutional Frameworks*, 13 L. DEV. REV. 535, 539 (2020).

127. See Ass’n State & Territorial Health Officials, *supra* note 120. For example, New York bill S8327 would make it unlawful to knowingly disseminate contact tracing information to an unauthorized person. *Id.* A New Jersey bill, A 4170, for another example, would limit the use of contact tracing data to contact tracing purposes and require the collected data to be deleted no later than 30 days after it is received. *Id.*

128. *Id.* See also *Contact Tracing Resources for Health Departments*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-nCoV/php/contact-tracing/contact-tracing-resources.html> [<https://perma.cc/GX3W-X9GG>] [hereinafter *Contact Tracing Resources for Health Departments*] (last updated Sept. 1, 2020), (recommending voluntary, rather than mandatory, participation in contact tracing).

identities and addresses). The digital exposure notification apps currently used in the United States provide the subscribers with exposure alerts, but they have limits in that they do not provide the public with necessary information, such as time and location of visits made by those infected with COVID-19.¹²⁹

As seen in the preceding discussions, the structural flaws in healthcare provision in the United States, fragmented authorities in the regulation of public conduct (to prevent the spread of the disease), and insufficient public access to information impeded an effective response to the pandemic. These flaws necessitate a systemic reform, such as legal and institutional adjustments. An assessment of the current legal and institutional apparatus would be a necessary next step to identify the specific areas for reform. The following discussions examine the legal and institutional frameworks for healthcare (as applied to the pandemic) and public access to information for this purpose.

II. LEGAL AND INSTITUTIONAL APPARATUS

The regulatory gaps in the current legal and institutional frameworks, such as lack of the mandatory provisions requiring the government to ensure timely access to TCQT or public access to information and lack of a politically-independent control center in charge of the pandemic management, have impeded pandemic management and require reform. Based on the examination of the current frameworks, Section III.A will propose specific legal and institutional reform.

A. LEGAL AND INSTITUTIONAL FRAMEWORKS FOR HEALTHCARE

1. Law

In the United States, regulatory power over healthcare is shared among federal, state, and local governments.¹³⁰ At the

129. Several other countries that have successfully managed COVID-19, such as South Korea, Singapore, and Hong Kong, have also collected and released the tracing information to the public, with details of the released information determined by pre-set guidelines. Mi Jung Park, *COVID-19 Tracing Investigation and Privacy, South Korea, 2020*, BRIC VIEW STATUS REP. (2020).

130. Rebecca L. Haffajee & Michelle M. Mello, *Thinking Globally, Acting Locally – The U.S. Response to Covid-19*, 382 NEW ENG. J. MED. 2020; e75,

federal level, statutes such as the ACA,¹³¹ the Health Insurance Portability and Accountability Act (HIPAA),¹³² and the Social Security Act,¹³³ include operative provisions for healthcare in the United States. As discussed above, the ACA overhauled the United States healthcare system by removing some of the barriers to obtaining health insurance, such as pre-existing condition exclusions, and creating the government-sponsored Marketplace.¹³⁴ The framers of the ACA also sought to expand Medicaid to increase coverage.¹³⁵ The HIPAA provides, *inter alia*, the ability to transfer and continue health insurance coverage for American workers and their families when they change or lose jobs and also requires confidential handling of protected health information.¹³⁶ The Social Security Act and its amendments provide for public coverages such as Medicare (for those over sixty-five years old and certain people with disabilities), Medicaid (for low-income individuals and families), and the Children's Health Insurance Program (CHIP, for children in low-income families not qualified for Medicaid).¹³⁷ The absence of a universal healthcare system means that a large number of individuals without insurance (29.3 million as of 2019)¹³⁸ are not covered for medical treatment, except in emergencies: the Emergency Medical Treatment and Labor Act (EMTALA) requires hospitals that participate in Medicare (about 98 percent of hospitals in the United States) to provide emergency care, regardless of the individual's insured status or

e75(1) (2020), <https://www.nejm.org/doi/pdf/10.1056/NEJMp2006740?articleTools=true> [<https://perma.cc/BBE9-7V9G>].

131. Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 *et seq.* (2018).

132. Health Insurance Portability and Accountability Act (HIPAA) of 1996, 42 U.S.C. § 201 *et seq.* (2018).

133. Social Security Act of 1935, 42 U.S.C. § 301 *et seq.* (2018).

134. *See Weeks, supra* note 3, at 95–96.

135. *Id.* at 95.

136. 29 U.S.C. § 1181 (2018); 42 U.S.C. 1320d–6 (2018).

137. 42 U.S.C. § 402 (2018); 42 U.S.C. § 1395j (2018); 42 U.S.C. 1397aa (2018).

138. *Health Insurance Coverage, supra* note 49.

ability to pay.^{139,140} Under the PHSA, the federal government also has a general mandate to assist states and local authorities in the prevention and suppression of communicable diseases and concerning other public health matters.¹⁴¹ Under the Commerce Clause authority, the federal government has authority for prevention and control of disease at the borders or interstate.¹⁴²

At the state level, laws grant state governments plenary authority concerning healthcare administration (to the extent that the authority is not preempted by federal law).¹⁴³ Thus, laws reflect healthcare policy adopted by each state and regulate both public and private provision of healthcare through a variety of statutory mechanisms. For example, state laws regulate the professional practice of healthcare by requiring that all providers first obtain a license or permit before rendering medical service.¹⁴⁴ State laws also provide for much of the funding to healthcare providers necessary for the operation of

139. The EMTALA extends its treatment mandate to patients presenting with an “emergency medical condition,” as determined by an initial medical screening examination. 42 U.S.C. § 1395dd(a) (2018). The EMTALA allows the determination to be made “within the capability of the hospital’s emergency department.” *Id.* Once the hospital staff determines a patient has a legitimate emergency medical condition, the hospital must provide either the appropriate examination and treatment within the capability of “the staff and facilities available at the hospital” to stabilize the patient’s condition, or transfer to another medical facility under limited conditions. 42 U.S.C. § 1395dd(b)(1) (2018).

140. On March 9, 2020, the Centers for Medicare & Medicaid Services (CMS) issued a memorandum reaffirming hospitals’ obligation to provide access to emergency medical care for all those in need, including and especially patients suspected of infection. *EMTALA Requirements*, *supra* note 67. Under CMS’s guidance, emergency departments (EDs) may not “use signage that presents barriers to individuals who are suspected of COVID-19 from coming to the ED,” or “refuse to provide an appropriate [medical screening exam] to anyone who has come to the ED for examination or treatment of a medical condition.” *Id.* at 5. When individuals are deemed infected, hospitals are expected to “isolate the patient immediately.” *Id.*

141. 42 U.S.C. §243(a) (2018).

142. 42 U.S.C. § 264 (2018); *see also* U.S. CONST. art. I, § 8, cl. 3.

143. Eileen Salinsky, *Governmental Public Health: An Overview of State and Local Public Health Agencies*, NAT’L HEALTH POLICY FORUM, Paper 244 (Aug. 18, 2010), https://hsrc.himmelfarb.gwu.edu/sphhs_centers_nhpf/244/.

144. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 1253 (1996); GA. CODE ANN. § 31-7-3; GA. CODE ANN. § 31-7-301 (2020); N.Y. PUB. HEALTH CODE § 3605 (2019); N.Y. PUB. HEALTH CODE § 2801-a (2019).

medical facilities.¹⁴⁵ Finally, state statutes provide for a comprehensive scheme for governmental oversight of healthcare facilities, personnel, and services.¹⁴⁶

At the local level, laws regulate healthcare only to the extent allowed by states, which have primary authority over healthcare.¹⁴⁷ Thus, local laws are generally limited to the implementation and enforcement of state mandates on healthcare.¹⁴⁸ For these reasons, there exists significant variation among local jurisdictions with respect to the scope of laws governing healthcare. In the realm of public health, local laws do, however, play a significant role in the public health code enforcement process by establishing within local governmental agencies powers of inspection, investigation, and adjudication of particular offenses.¹⁴⁹ Local laws may impose recordkeeping and information-reporting requirements upon healthcare providers,¹⁵⁰ which state and federal officials may then compile to better inform their public health policy decisions.

During periods of a public health crisis, the following statutes empower the federal government to adopt emergency measures: the PHSA, the Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act), and the National Emergencies Act (the NEA).¹⁵¹ The PHSA serves as the primary

145. See, e.g., GA. CODE ANN. § 31-8-1 (2009); N.Y. PUB. HEALTH CODE § 2807-k (2020). Such funding is especially important for privately owned providers, which might not otherwise be able to afford to treat their indigent patients.

146. See, e.g., GA. CODE ANN. § 31-7-2.1 (2011); VT. STAT. ANN. tit. 18 § 1852 (2019); VT. STAT. ANN. tit. 18 § 1854 (2019); WIS. STAT. § 250.03 (2009).

147. *Health Reform Reconstruction*, supra note 41, at 65; see, e.g., ATLANTA, GA., MUN. CODE § 5-1 (2020).

148. See GA. CODE ANN. § 31-3-4 (2020); MICH. COMP. LAWS § 333.2433 (2020); W. VA. CODE § 16-2-11 (2020).

149. See Cook County, Ill. § 38-32 (2020); Fulton County, Ga. § 34-2 (2020); LEXINGTON-FAYETTE COUNTY, KY. § 11-7 (2020); CHARLESTON, W. VA. § 58-1 (2020).

150. LEXINGTON-FAYETTE COUNTY, KY. § 11-7 (2020); PORTLAND, OR. § 8.24.070 (2020).

151. Public Health Service Act, 42 U.S.C. §§ 201-300mm-61 (2018); Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121 *et seq.* (2018); National Emergencies Act, 50 U.S.C. §§ 1601 *et seq.* (2018). See also Lindsay K. Cloud et al., *A Chronological Overview of the Federal, State, and Local Response to COVID-19*, in ASSESSING LEGAL RESPONSES TO COVID-19, supra note 3, at 10.

legal instrument for public health crises.¹⁵² Section 319 of the PHSA vests in the HHS Secretary broad legal authority to respond to such crises, including the powers to declare a public health emergency (PHE).¹⁵³ Declaration of a PHE under the PHSA triggers multiple mechanisms in federal law by which public health officials can exercise broader discretion to effectively respond to the emergency. For example, Section 319 of the PHSA empowers the HHS Secretary to make grants, provide awards for expenses, enter into contracts, and conduct and support investigations into the cause, treatment, or prevention of the disease or disorder.¹⁵⁴

The Stafford Act addresses several issues relating to disaster preparedness and response¹⁵⁵ by ensuring an “orderly and continuing means of assistance” from federal to state and local governments.¹⁵⁶ As for public health, the Stafford Act authorizes the President to provide technical and advisory assistance to affected state and local governments for public health and safety information, including dissemination of such information, provision of health and safety measures, and management, control, and reduction of immediate threats to public health and safety.¹⁵⁷ The Act also authorizes the President to direct any federal agency to utilize its authorities

152. 42 U.S.C. §§ 201-300mm-61 (2018); U.S. Department of Health and Human Services, *Legal Authority*, PUB. HEALTH EMERGENCY, <https://www.phe.gov/Preparedness/planning/authority/Pages/default.aspx> [https://perma.cc/T99P-R5EH] (last reviewed Sept. 18, 2019).

153. 42 U.S.C. § 247d (2018).

154. *Id.* Under Section 1135 of the Social Security Act, the HHS Secretary is authorized during a PHE to waive or modify certain Medicare, Medicaid, CHIP, and HIPAA requirements to “ensure that sufficient health care services and providers are available during an emergency.” Nicole Huberfeld & Sidney Watson, *Medicaid’s Vital Role in Addressing Health and Economic Emergencies*, in ASSESSING LEGAL RESPONSES TO COVID-19, *supra* note 3, at 105; *see also* 42 U.S.C. § 1320b-5 (2018).

155. 42 U.S.C. § 5121(a) (2018). Issues posed by disasters include loss of life, human suffering, loss of income, property loss and damage, and interruption of normal governmental functions and communities. *Id.*

156. 42 U.S.C. § 5121(b) (2018). To achieve this primary objective, the Stafford Act empowers the federal government to i) revise and broaden the scope of existing disaster relief programs, ii) encourage state and local development of comprehensive disaster preparedness plans and hazard mitigation efforts, iii) facilitate increased intergovernmental coordination, and iv) provide economic assistance for disaster-related losses. *Id.*

157. 42 U.S.C. § 5170a(3) (2018).

and resources (including personnel, equipment, supplies, facilities, and managerial, technical, and advisory services) in support of state and local emergency assistance efforts to protect public health.¹⁵⁸ The Act further imposes a duty upon the HHS Secretary to “set priorities and preparedness goals and further develop a coordinated strategy” to improve state, local, and hospital preparedness for and response to public health threats.¹⁵⁹

Recognizing the need for broader executive power during times of emergency, Congress enacted the NEA in 1976.¹⁶⁰ The NEA empowers the President to declare a national emergency.¹⁶¹ Declaration of a national emergency under the NEA triggers latent emergency powers vested in the President by other statutes.¹⁶² For example, the President is authorized to waive confidentiality and certification requirements, sanctions, and other provisions as necessary to supply public health services.¹⁶³ The President may also utilize the Public Health Service to the extent he deems necessary to “promote the public interest.”¹⁶⁴ The NEA prescribes procedural safeguards: the President is required to specify existing statutory authority from which he derives his emergency power.¹⁶⁵ Additionally, the NEA imposes reporting requirements upon the President to ensure

158. 42 U.S.C. § 5192(a)(1) (2018).

159. 6 U.S.C. § 321g(a) (2018).

160. National Emergencies Act, 50 U.S.C. § 1601 *et seq.* (2018).

161. 50 U.S.C. § 1621(a) (2018).

162. 50 U.S.C. § 1621(b) (2018).

163. Social Security Act of 1935 § 1135, 42 U.S.C. § 1320b-5 (2018).

164. 42 U.S.C. § 217 (2018). *See* Brennan Center for Justice, *A Guide to Emergency Powers and Their Use* (Apr. 24, 2020), <https://www.brennancenter.org/our-work/research-reports/guide-emergency-powers-and-their-use> [https://perma.cc/2HTC-3C4F].

165. 50 U.S.C. § 1631 (2018). For example, the President specifically invoked Section 1135 of the Social Security Act when he directed HHS Secretary Azar to “waive or modify certain requirements of the Medicare, Medicaid, and State Children’s Health Insurance programs and of the [HIPAA] Privacy Rule.” Proclamation 9994, 85 FED. REG. 15,337 (Mar. 13, 2020).

accountability.¹⁶⁶ Congress may also terminate a President's declaration of emergency by passing a joint resolution.¹⁶⁷

Under significant pressure to combat the rapid spread of COVID-19, Congress enacted additional statutes, including the Families First Coronavirus Response Act (FFCRA)¹⁶⁸ and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).¹⁶⁹ The FFCRA mandated that health insurers provide coverage and not impose any cost-sharing requirements (including deductibles, copayments, and coinsurance) or prior authorization or other medical management requirements for diagnostic COVID-19 testing and vaccination.¹⁷⁰ The CARES Act also appropriated \$1.3 billion in supplemental awards to healthcare providers to alleviate some of the financial burden associated with COVID-19.¹⁷¹ However, neither the FFCRA nor the CARES Act specifically requires healthcare providers to cover the cost of treatment. Rather, these legislative efforts seek to broaden access to healthcare services by removing financial barriers to testing for patients and by dispensing over \$1 billion in federal funding to healthcare providers, thus increasing their capabilities as it relates to the “prevention, diagnosis, and treatment of COVID-19.”¹⁷²

State laws also empower state governors to respond to public health emergencies with heightened authorities;¹⁷³ under broadly drafted state laws, governors may exercise the power to “enforce all laws, rules, and regulations relating to emergency

166. 50 U.S.C. § 1641 (2018). These reporting requirements include maintaining a file and index of all significant orders of the President, maintaining a file and index of all executive agencies' emergency rules and regulations, transmitting to Congress all such orders, rules, and regulations, and transmitting to Congress relevant expenditure reports. *Id.*

167. 50 U.S.C. § 1622(a)(1).

168. FFCRA, Pub. L. No. 116-127, 134 Stat. 178 (29 U.S.C. § 2601 *et seq.*) (2020).

169. CARES Act, Pub. L. No. 116-136, 134 Stat. 281 (2020) (codified at 15 U.S.C. §§ 9001–9141).

170. FFCRA, Pub. L. No. 116-127, §§ 6001 - 6004, 134 Stat. 178, 201–207 (2020) (codified at 42 U.S.C. §§ 1320b–5, 1395l, 1396d(a)(3)).

171. CARES Act, Pub. L. No. 116-136 § 3211, 134 Stat. 281, 368 (2020) (codified as amended at 42 U.S.C. § 254b(r)).

172. 42 U.S.C. § 254b(r)(6) (2020).

173. See CAL. GOV'T CODE §§ 8565–8574 (2020); GA. CODE ANN. § 38-3-51(d)(4.1) (2020); MICH. COMP. LAWS § 30.405 (2020); TEX. GOV'T CODE ANN. § 418.011 (2020); TEX. GOV'T CODE ANN. § 418.015 (2020).

management and to assume direct operational control of all civil forces and helpers in the state”¹⁷⁴ State law also enumerates specific, additional emergency powers granted to the governor, such as the power to mandate that healthcare facilities provide services to individuals in need.¹⁷⁵ State departments of public health assist their respective governors in public health administration.¹⁷⁶ State law generally charges state departments of public health with developing rules and regulations “appropriate for management of any public health emergency”¹⁷⁷ As with the federal laws discussed above, state laws do not impose any specific requirement on governors to provide timely public access to TCQT, which, in the state context, would be challenging due to limited capacities.

2. Legal Institutions

The primary federal institutions charged with COVID-19 response are the HHS and its ancillary agency, the CDC, both of which operate under the President’s administrative authority. The HHS develops policies on healthcare, and the CDC is a research-based agency that provides data and recommends guidelines to healthcare providers, state and local public health officials, private entities, and schools.¹⁷⁸ The CDC is tasked with

174. GA. CODE ANN. § 38-3-51(c)(1) (2020). Similarly, Michigan state law states that the governor “is responsible for coping with dangers to this state or the people of this state presented by a disaster or emergency.” MICH. COMP. LAWS § 30.403 (2020). As another example, Texas state law charges the governor with meeting “the dangers to the state and people presented by disasters” TEX. GOV’T CODE ANN. § 418.011 (2020).

175. Georgia state law explicitly grants the governor the power to “[c]ompel a health care facility to provide services or the use of its facility if such services or use are reasonable and necessary for emergency response.” GA. CODE ANN. § 38-3-51(d)(4.1) (2020). California, Texas, and West Virginia also statutorily authorize the state’s governor to commandeer private property or personnel if the governor determines such action is necessary for effective emergency response. CAL. GOV’T CODE § 8572 (2020); TEX. GOV’T CODE ANN. § 418.017 (2020); W. VA. CODE § 15-5-6(c)(3) (2020).

176. Peter D. Jacobson et al., *Executive Decision Making for COVID-19: Public Health Science Through a Political Lens*, in ASSESSING LEGAL RESPONSES TO COVID-19, *supra* note 3, at 58.

177. GA. CODE ANN. § 31-12-2.1(b) (2020); MICH. COMP. LAWS § 333.2453 (2020); W. VA. CODE § 16-1-6(b) (2020).

178. Sarah H. Gordon et al., *What Federalism Means for the US Response to Coronavirus Disease 2019*, JAMA HEALTH FORUM (May 8, 2020), <https://jaman>

“[m]onitoring and assessing viruses and illnesses[,]” “[b]uilding and supporting surveillance and response capacity[,]” “[i]mproving vaccines and other interventions[,]” and “[a]pplying research to provide science-based enhancement of prevention and control policies and programs.”¹⁷⁹ Despite these mandates, federal institutions have shown limited effectiveness in containing the spread of COVID-19, delegating primary decision-making responsibilities to state and local officials.¹⁸⁰

At the state level, state departments of public health are the primary institutions in charge of COVID-19 management; they develop rules and regulations relating to public health emergency response and monitor and enforce its operations.¹⁸¹ In the absence of federal leadership, state departments of public health and governors’ offices have assumed primary responsibility for developing policies as well as for adopting and enforcing relevant measures to combat COVID-19, such as public testing. The state departments coordinate with local health departments across their respective states and have authority to “monitor the administration, operation and coordination of the local boards of health and local health officer”¹⁸² State departments of health have an important role in promoting consistency among public health outcomes, with the legal authority to oversee and even preempt local public health administration.¹⁸³

Without organized support from the federal government or nationwide coordination, state institutions, limited by resource constraints, have not been successful in containing COVID-19. As further discussed in Section III.A, the current institutional

etwork.com/channels/health-forum/fullarticle/2766033 [https://perma.cc/FBD7-Q7YW].

179. *What CDC Does*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/flu/pandemic-resources/1918-commemoration/what-cdc-does.htm> [https://perma.cc/9HZP-FM23] (last visited Dec. 9, 2020).

180. Peter D. Jacobson et al., *Executive Decision Making for COVID-19: Public Health Science Through a Political Lens*, in ASSESSING LEGAL RESPONSES TO COVID-19, *supra* note 3, at 60.

181. GA. CODE ANN. § 31-12-2.1(b) (2020); MICH. COMP. LAWS § 333.2453 (2020); W. VA. CODE § 16-1-6(b) (2020).

182. W. VA. CODE § 16-1-6(e) (2020).

183. Kim Haddow et al., *Preemption, Public Health, and Equity in the Time of COVID-19*, in ASSESSING LEGAL RESPONSES TO COVID-19, *supra* note 3, at 74.

framework is not effective in pandemic management, and there is a need for a new, reinforced institutional framework, such as a politically-independent national control center in the management of the pandemic, which will not be inhibited by partisan politics or resource constraints experienced by the current state institutions.

B. LEGAL AND INSTITUTIONAL FRAMEWORKS FOR PUBLIC ACCESS TO INFORMATION

Public access to information is another area in which legal and institutional frameworks affect pandemic management and requires a review in this context. The federal, state, and local governments are under broad legal mandates to collect and release information to the public,¹⁸⁴ *albeit* subject to the limitations posed by the requirements of privacy and confidentiality.¹⁸⁵ At the federal level, the PHSA requires the HHS Secretary to formulate a national strategy for promoting health information and to undertake the necessary actions to improve health knowledge in American society.¹⁸⁶ The HHS Secretary is also empowered to conduct and support activities promoting public health information and promotion, including the publication of materials to be distributed to the public which instruct individuals on how to improve and safeguard their health.¹⁸⁷ However, this provision does not contain an express

184. *See, e.g.*, U.S. CONST. art. I, § 8 (granting a legal mandate to the federal government); U.S. CONST. amend. X (granting broad police power to state governments). State law governs the authorities of local government. *See* *Bond v. United States*, 572 U.S. 844, 848 (2014) (“Because our constitutional structure leaves local criminal activity primarily to the States, we have generally declined to read federal law as intruding on that responsibility, unless Congress has clearly indicated that the law should have such reach.”).

185. 45 C.F.R. pts. 160, 164 (2020); 45 C.F.R. pt. 46; 42 U.S.C. §§ 241(d), 242m(d) (2018); 5 U.S.C. § 552a (2018); 45 C.F.R. pt. 5b.

186. 42 U.S.C. § 300u (2018). These activities include supporting the development of health education and providing technical assistance for health education. *Id.* The Secretary is also required to establish the Office of Disease Prevention and Health Promotion, which is responsible for coordinating health promotion activities in the government and the private sector and establishing a national information clearinghouse to facilitate the exchange and dissemination of health information. *Id.*

187. 42 U.S.C. § 300u-3 (2018). When carrying out these publication activities, the Secretary is required to make the published information accessible to populations of different social and economic backgrounds, and populations that speak other languages. *See* 42 U.S.C. § 300u-3(1).

standard for when the Secretary is *obligated* to carry out such publication activities; it simply provides that the Secretary is “*authorized* to conduct or support . . . such activities as may be required to make information . . . available to consumers of medical care, providers of such care, schools, and others who should be informed respecting such matters.”¹⁸⁸

Additional statutory devices, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Freedom of Information Act (FOIA),¹⁸⁹ control the collection and release of information at the federal level. Under the HIPAA, covered entities, such as hospitals, may disclose protected health information to public health authorities authorized by law to collect or receive such information to prevent or control disease¹⁹⁰ and also to individuals who may have contracted or been exposed to a communicable disease.¹⁹¹ The HIPAA also authorizes covered entities to disclose protected health information that they believe is necessary to prevent or lessen a serious and imminent threat to a person or the public, when such disclosure is made to someone they believe can prevent or lessen the threat.¹⁹² The FOIA compels the government to release requested information unless it is protected under stipulated exceptions, but this release generally necessitates an affirmative request by a member of the public per the pre-set procedure.¹⁹³

At the state and local levels, every state has laws and regulations that mandate the reporting of the occurrence of diseases and conditions, prescribe the timing and nature of the information to be reported,¹⁹⁴ and stipulate the penalties for non-compliance.¹⁹⁵ States have varied disease reporting systems: some states authorize the health commissioner or state boards to create, monitor, and revise the list of reportable

188. 42 U.S.C. § 300u-3 (emphasis added).

189. Freedom of Information Act (FOIA), 5 U.S.C. § 552 (2018); Health Insurance Portability and Accountability Act (HIPAA) of 1996, 42 U.S.C. § 201 *et seq.* (2018).

190. 42 U.S.C. § 201 *et seq.*; 45 C.F.R. § 164.512(b)(1)(i) (2021).

191. 42 U.S.C. § 201 *et seq.*; 45 C.F.R. § 164.512(b)(1)(iv).

192. 42 U.S.C. § 201 *et seq.*; 45 C.F.R. § 164.512(j)(1)(i)(A)–(B).

193. 5 U.S.C. § 552(a)–(b).

194. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 1279.1 (West 2020); GA. CODE ANN. § 31-12-2 (2020); N.Y. PUB. HEALTH LAW § 2101 (McKinney 2020).

195. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 1280.4 (West 2020).

diseases and conditions under general statutory powers,¹⁹⁶ and some other states require reports under both statutes and health department regulations.¹⁹⁷ The mandatory reporting system enables state authorities to collect information from a range of professionals and organizations, including physicians, other healthcare providers, diagnostic laboratories, clinical facilities, and schools and daycare centers.¹⁹⁸ However, the compliance rates with this reporting requirement, which may affect the quality of information, vary, ranging from 6 percent to 90 percent for different common infectious conditions.¹⁹⁹ This variance is attributed to the limitations in physicians' knowledge of reporting requirements and procedures, as well as the assumption that laboratories have reported cases of infectious diseases.²⁰⁰ States may release the information subject to the limitations under their own privacy laws.²⁰¹ States also have their own versions of FOIA to compel the state agencies to release requested information.²⁰² As with the federal FOIA, its state versions also do not compel state governments to release information about the pandemic in the absence of a request by a member of the public.²⁰³

As for the institutional framework, the CDC is the primary institution that collects, compiles, and releases information pertinent to COVID-19 to the public. It provides updates on the status of the pandemic, including the number of infection

196. See, e.g., CONN. GEN. STAT. § 19a-2a (2020).

197. See, e.g., N.Y. COMP. CODES R. & REGS. tit. 10, § 2.1 (2020).

198. See, e.g., GA. CODE ANN. § 31-12-2; N.Y. PUB. HEALTH LAW §§ 2101–2105 (McKinney 2020).

199. James D. Holt et al., *The CDC Field Epidemiology Manual: Legal Considerations*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/eis/field-epi-manual/chapters/Legal.html#ref12> [<https://perma.cc/A7ZL-TB P5>] (last updated Dec. 13, 2018).

200. *Id.*

201. See, e.g., GA. CODE ANN. § 31-7-6 (2021); OHIO REV. CODE ANN. § 3701.17(B)(4) (2021); N.Y. PUB. OFF. LAW §§ 91-99 (McKinney 2020).

202. See, e.g., CAL. GOV'T CODE §§ 6250–6270.7 (West 2020); GA. CODE ANN. § 50-18-70 *et seq.* (2021); N.Y. PUB. OFF. LAW §§ 84-90 (McKinney 2020).

203. See, e.g., OHIO REV. CODE ANN. § 3701.17(C).

cases,²⁰⁴ deaths,²⁰⁵ and vaccinations²⁰⁶ daily, and publishes relevant guidelines and recommendations, such as personal hygiene recommendations.²⁰⁷ The CDC also oversees the National Notifiable Diseases Surveillance System (NNDSS), which collects data from public health departments and health care providers regarding specific diseases that have been deemed public health priorities.²⁰⁸ The NNDSS has been tasked with tracking data on COVID-19, and the CDC has been working with local public health departments to provide information regarding how to provide relevant data, as well as to provide technical assistance with reporting.²⁰⁹ The CDC also assists with contact tracing; while it does not administer a contact tracing program, it maintains a collection of resources to assist public health departments with building their own programs.²¹⁰

State health departments have broad legal mandates to supervise the work and activities of local health departments, supervise the reporting and control of the disease, and promote education in disease prevention.²¹¹ State laws authorize the state health departments to receive mandatory reports from a wide range of professionals, and this reporting system enables

204. *COVID Data Tracker*, *supra* note 1 (charting COVID-19 cumulative cases).

205. *Id.* (charting COVID-19 cumulative deaths).

206. *COVID-19 Vaccinations in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://covid.cdc.gov/covid-data-tracker/#vaccinations> [<https://perma.cc/3BHW-PWTG>] (last updated Dec. 28, 2020).

207. *See, e.g., How to Protect Yourself and Others*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html> [<https://perma.cc/2PVE-6LEF>] (last updated Sept. 11, 2020).

208. *National Notifiable Diseases Surveillance System (NNDSS)*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://wwwn.cdc.gov/nndss/> [<https://perma.cc/4G8U-EBTJ>] (last updated Mar. 13, 2019).

209. *NNDSS Supports the COVID-19 Response*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://wwwn.cdc.gov/nndss/covid-19-response.html> [<https://perma.cc/FX35-DKTE>] (last updated Aug. 10, 2020).

210. *Contact Tracing Resources for Health Departments*, *supra* note 128. These resources include a series of guidance documents for establishing and administering contact tracing in several different settings, such as schools and workplaces, documents that provide standards for evaluating the success of contact tracing programs, and digital tools for managing cases. *Id.*

211. *See, e.g., N.Y. PUB. HEALTH LAW § 201* (McKinney 2020).

the state authorities to secure and release health information.²¹² State and local health departments maintain websites that provide the public with information pertinent to the pandemic, such as the number of tests completed, the location of testing sites, available financial assistance, industry guidelines, activity guidance, and access to exposure notification apps in some localities.²¹³ However, information is scattered across numerous federal, state, and local health authority portals and websites, and there is no effective mechanism of coordination among the authorities to ensure the consistency of information to be released to the public across the nation.

III. CALL FOR A NEW APPROACH

A. PROPOSAL FOR REFORM

The preceding examination reveals that the current legal and institutional frameworks empower the federal and state governments to adopt measures to respond to health crises and collect information, but they do not compel the federal or state governments to ensure public access to TCQTs or release of information to the public. Under the current system, ensuring such public access and information release is largely left to the political discretion of the leadership with an underlying presumption that political leaders will use the legal mandate and institutional capacity to respond to the crisis. The conduct of the former Trump administration demonstrated that this presumption does not always hold. Moreover, political failures did not only exist at the federal level but also prevailed at state and local levels,²¹⁴ showing that political failure at one level is not readily remedied by success at other levels.

212. See, e.g., MINN. R. 4605.7050 (2017) (requiring reporting of certain illnesses and deaths).

213. See, e.g., *Tracking COVID-19*, CAL., <https://covid19.ca.gov/> [<https://perma.cc/X6Q8-4MLX>] (last updated Oct. 18, 2020); *COVID-19 Citywide Information Portal*, N.Y.C., <https://www1.nyc.gov/site/coronavirus/index.page> [<https://perma.cc/KDM2-JPH6>] (last updated Oct. 18, 2020).

214. See German Lopez, *Everyone Failed on Covid-19: The US's Coronavirus Epidemic Is an American Failure, Not Solely a Trump or Republican One*, VOX (Jan. 2, 2021, 10:58 AM), <https://www.vox.com/future-perfect/22176191/covid-19-coronavirus-pandemic-democrats-republicans-trump> [<https://perma.cc/UH4Y-VCLS>] (detailing the structural issues that impeded the public and states' ability to act).

Thus, some describe the failure in COVID-19 management as a political failure, but the failure is also institutional in nature, i.e., current laws and institutions have failed to deliver an effective response to the pandemic. Laws and institutions that do not effectively operate in a political reality on the ground are a failure and require reform. Given the recent transition of power, one may well hope that the adverse political reality created by the unique behavior of the Trump administration is a one-off exception, never to be repeated, but in an increasingly unpredictable political environment today, there is no assurance against its recurrence. Considering the uncertainty, a better approach would be to ensure that the laws and institutions stand better chances for success in an adverse political environment, should there be a future pandemic. Laws and institutions are not immune from bad politics and may not guarantee success by themselves, but in a society where the rule of law prevails, they can be made more effective, through reform, to guide and even mandate a better response to a crisis. This section proposes such a reform.

On the point of reform, several leading scholars and professionals, such as Gregg Gonsalves, Amy Kapczynski, and Albert Ko;²¹⁵ Scott Burris, Sarah de Guia, Lance Gable, Donna Levin, and Wendy Parmet;²¹⁶ Nicolas Terry;²¹⁷ Amy Kapczynski

215. See Letter from Gregg Gonsalves et. al., Assistant Prof., Yale Sch. Pub. Health to Mike Pence et. al., Vice-President of the United States (Mar. 2, 2020), https://law.yale.edu/sites/default/files/area/center/ghjp/documents/final_covid-19_letter_from_public_health_and_legal_experts.pdf [<https://perma.cc/S2TM-73JW>] (calling on federal officials to implement the recommendations made and act urgently to protect the public from the threat of COVID-19).

216. See Scott Burris et al., *Summary of Findings and Recommendations*, in ASSESSING LEGAL RESPONSES TO COVID-19, *supra* note 3, at 1–5 (summarizing some of the Report’s many “specific legal recommendations for the president and Congress, governors and state legislatures, and mayors and city councilors across the country”).

217. See Nicolas Terry, *COVID-19 and Healthcare Lessons Already Learned*, 7 J. L. & BIOSCI. 1, 1–12 (2020) (criticizing the United States’ “healthcare financing system that reflects individualism rather than solidarity” through the lens of COVID-19).

and Gregg Gonsalves;²¹⁸ Stuti Khemani;²¹⁹ and Lindsay Wiley, Elizabeth McCuskey, Matthew Lawrence, and Erin Fuse Brown,²²⁰ have analyzed various causes of the failure in the pandemic control and made proposals for improvement. These proposals include: implementing voluntary, rather than coercive, self-isolation;²²¹ increasing the federal government's support to healthcare safety net providers by better targeting federal emergency provider grants;²²² recalibrating the country's investments in clinical care versus public health (increasing the latter);²²³ launching federally-funded and locally-organized new jobs programs;²²⁴ better using communication to build legitimacy and trust in public institutions;²²⁵ and incrementally confronting the structural fixtures in law (individualism, fiscal fragmentation, federalism, and privatization) to construct health reform.²²⁶

In comparison, this article's proposed remedies, discussed in detail below, call for a more extensive legal and institutional reform than most of these suggestions. The extent of the proposed reform will nevertheless be justified considering the unprecedented number of infections and deaths from COVID-19

218. See Amy Kapczynski & Gregg Gonsalves, *The New Politics of Care*, BOS. REV. (Apr. 27, 2020), <https://bostonreview.net/politics/gregg-gonsalves-amy-kapczynski-new-politics-care> [<https://perma.cc/85EF-JWCD>] (advocating for, among other solutions, a "Community Health Corps." job program, contact tracing, and politics of "support and care, not separation and deprivation").

219. See Stuti Khemani, *An Opportunity to Build Legitimacy and Trust in Public Institutions in the Time of COVID-19*, WBG: RES. & POLICY BRIEFS (May 4, 2020), <https://openknowledge.worldbank.org/bitstream/handle/10986/33715/An-Opportunity-to-Build-Legitimacy-and-Trust-in-Public-Institutions-in-the-Time-of-COVID-19.pdf?sequence=1&isAllowed=y> [<https://perma.cc/PP76-793K>] (focusing on strategies for the government to build public trust during the COVID-19 pandemic).

220. See *Health Reform Reconstruction*, *supra* note 41, at 4 ("The thesis of this Article is that decades of reforms failed to prepare the United States for 2020 because health reform has been conceptually and structurally constrained, so that to transcend these constraints requires nothing short of reconstruction.").

221. Kapczynski & Gonsalves, *supra* note 212, at 4.

222. Scott Burrell et al., *Summary of Findings and Recommendations*, in ASSESSING LEGAL RESPONSES TO COVID-19, *supra* note 3, at 4.

223. Terry, *supra* note 217, at 11.

224. Kapczynski & Gonsalves, *supra* note 218.

225. Khemani, *supra* note 219.

226. *Health Reform Reconstruction*, *supra* note 41.

and the inability of the current system to address these problems adequately.

The problem is not lack of legal authority: current federal and state laws²²⁷ provide the federal and state administrations with ample authority to adopt necessary measures to combat COVID-19.²²⁸ As discussed above, the laws empower the government and grant discretion, but they *do not obligate* the government to adopt necessary measures in a timely fashion. As the President is not required to take any specific action in response to a pandemic and as it is left to his or her political discretion, the President may make a political decision not to engage fully with the pandemic, but rather to leave it to state officials who are under more immediate pressure to act, as former President Trump did in response to COVID-19.²²⁹ The lack of federal engagement has had serious ramifications; the scale of the current pandemic does not allow effective handling by individual states, as evidently shown by the failure of containing COVID-19 despite several state measures in place. The pandemic is not a crisis that can be handled solely by states, particularly in preventing transmissions and containing its spread across the nation, but a national and an international crisis that requires a full response by the federal government that has financial, technical, and administrative resources on a scale that is not available to state governments.

This suggests that relevant laws, such as the Families First Coronavirus Response Act (limited to COVID-19) or the PHS Act (generally), need to be amended to *require* the federal government to ensure public access to vaccination, testing, and treatment in a timely fashion (i.e. in pre-set timelines).²³⁰ As

227. See Public Health Service Act, 42 U.S.C. §§ 201–300mm-61 (2018); Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121 *et seq.* (2018); National Emergencies Act, 50 U.S.C. §§ 1601 *et seq.* (2018).

228. See also Lindsay K. Cloud et al., A Chronological Overview of the Federal, State, and Local Response to COVID-19, in ASSESSING LEGAL RESPONSES TO COVID-19, *supra* note 3, at 10.

229. Scott Burris et al., *Summary of Findings and Recommendations*, in ASSESSING LEGAL RESPONSES TO COVID-19, *supra* note 3, at 3.

230. In addition, the federal government should be required to ensure the supply of medical equipment: by the time the federal administration began to take proactive measures, healthcare providers faced a large number of new patients and shortages of critical medical equipment, including personal protective equipment (PPE), ventilators and intensive care beds. Eric Lipton et

discussed above, uncertainty about the out-of-pocket cost deterred people from getting timely testing and treatment, particularly in the crucial early weeks of the pandemic.²³¹ The FFCRA mandates that health insurers cover testing and vaccination without cost-sharing,²³² but the coverage must be broader (i.e., covering both insured and uninsured individuals), immediate, and unambiguous in its terms, so that the cost concern will not impede getting tests in time. This is the first crucial step to contain the pandemic. As to the cost of treatment, the FFCRA is silent, and patients may incur a cost under the terms of their health insurance, and those without insurance coverage or with insufficient coverage will be discouraged from seeking medical treatment, which, in turn, will exacerbate the spread of the disease.

The substantial risk requires the expansion of federal coverage to include the cost of treatment. The proposed amendment must clarify that the costs of COVID-19 related doctor visits, treatment, and medicine will not be billed directly to any patient so that patients are not deterred from seeking treatment until the last minute. This does not mean that the amendment should require the federal government to take up the entire cost; rather, it requires that the federal government cover the gaps between the cost and the coverage by insurance or by any other existing funding so that there is no ambiguity in coverage or cost concern to the public in seeking treatment.²³³ The rationale for the suggested federal coverage is to encourage

al., *He Could Have Seen What Was Coming: Behind Trump's Failure on the Virus*, N.Y. TIMES (May 4, 2020), <https://www.nytimes.com/2020/04/11/us/politics/coronavirus-trump-response.html?action=click&module=RelatedLink&pgtype=Article> [<https://perma.cc/HVY3-XPSK>].

231. See Witters, *supra* note 61 and accompanying text (reporting that cost concerns deterred early testing).

232. FFCRA §§ 6001–6004, 42 U.S.C. USC §§ 1320b-5, 1395l, 1396d(a)(3) (2020); CARES Act, §§ 3201, 3203(a), 41 U.S.C. § 300gg-13 (2020).

233. The Health Resources and Services Administration (HRSA) runs the COVID-19 Uninsured Program for qualified COVID-19 related services, including tests, vaccines, and treatment, but it is the responsibility of the uninsured patient to confirm whether the healthcare provider participates in this program, and one may still be responsible for full payment of the bill if the provider did not submit a bill for COVID-19-related testing, and/or treatment to the HRSA. *COVID-19 Care for Uninsured Individuals*, U.S. DEP'T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/coronavirus/covid-19-care-uninsured-individuals/index.html> [<https://perma.cc/8ZFF-P7Q4>] (last updated Sept. 15, 2021).

the public to test and treat promptly, thereby containing the pandemic and minimizing its adverse socio-economic impact. The amendment must also enable the government to limit the maximum amount that providers can charge for the tests and control the amount the manufacturers charge for COVID-19 medicines and vaccines to eliminate price gouging, price discrimination, and waste.²³⁴ COVID-19 treatment must also be combined with effective quarantine requirements.

The proposed legal reform should also require the government to ensure timely contact tracing and isolation of those infected with COVID-19, including asymptomatic and mildly symptomatic COVID-19 patients, and their treatment (i.e., treatment in public facilities isolated from outside physical contact, such as CTCs). The amendment should also mandate that individuals who have not tested positive but have been exposed to the virus, and who have been identified, through contact tracing, to be at risk of infection, should also be placed in self-quarantine under monitoring by health authorities.²³⁵ Effective contact tracing, quarantine, and isolation would not be possible without close cooperation and coordination with state

234. See *Health Reform Reconstruction*, *supra* note 41, at 40. As for COVID-19 medicines—such as Veklury (Remdesivir) and Regeneron’s anti-body cocktail (Casirivimab and Imdevimab)—another proposal calls for an amendment of the FFCRA to stipulate the responsibility of the federal government to ensure that i) sufficient amounts of the COVID-19 medicines are produced and made available to patients, by taking necessary measures, including granting third-party manufacturers license (i.e., “march-in” rights under Bayh-Dole Act of 1980, 35 U.S.C. § 203), to increase production and lower prices; and ii) COVID-19 patients have immediate access to these medicines without bearing the burden of cost-share obligations, by requiring the federal government to have a cost-sharing agreement with suppliers, hospitals, and insurers (but no cost-sharing obligations to the public). Lee & Mun, *supra* note 126, at 535. The federal government will be required to cover the cost of these medicines to the extent that is not covered by insurers or the other existing funds. *Id.* A commentator also points out that there has been a lack of public guidance on the ethical distribution of scarce therapeutics, ventilators, ICU beds, and critical care staff among hospitals and states; when there was a shortage, those with financial resources and existing connections to the suppliers acquired them, rather than states, communities, or hospitals with strongest needs. See Megan Ranney, Valerie Griffith & Ashish Jha, *Critical Supply Shortages — The Need for Ventilators and Personal Protective Equipment During the Covid-19 Pandemic*, 382 N. ENG. J. MED. e41 (2020) (explaining the causes of the shortages and possible solutions to cure them).

235. In such cases, the cost of mandatory self-quarantine is to be reimbursed by the government up to a pre-defined limit.

and local authorities, and the law must prescribe a process by which such cooperation and coordination among the federal, state, and local authorities will be implemented.

Insufficient vaccination is another concern. Sufficient amounts of vaccines have been made available for the public since the spring of 2021, but as of October 2021, over 40 percent of the population has not been fully vaccinated.²³⁶ There has been continuing political mistrust among a large segment of the public about the need for the control of the disease and the necessity of vaccination despite the on-going pandemic accompanying large numbers of new infections and deaths on a daily basis.²³⁷ Consideration should be given to possible legal and institutional approaches that would encourage vaccination, including linking vaccination to Coronavirus Tax Relief and Economic Impact Payments that have been offered by the Biden administration.²³⁸ Relevant legislation, such as the American Rescue Plan Act of 2021,²³⁹ could be amended to authorize the government to provide greater amounts of tax relief and payments, as an incentive, for those who have been vaccinated.

Finally, the amendment should require the government to promptly release all information necessary to prevent further spread of the pandemic to the public, including some of the information obtained through contact tracing, such as the time and location of recent visits made by those infected with the disease so that the public may take appropriate precaution. Federal and state laws regulate how health information may be collected and released,²⁴⁰ but they generally do not impose an affirmative requirement on the government to release specific information to the public (without a request under the FOIA or its state versions); the laws do not mandate the timing of the release, which would be critical for the public to make timely

236. *U.S. COVID-19 Vaccine Tracker*, *supra* note 33.

237. *COVID Data Tracker*, *supra* note 1.

238. *See Coronavirus Tax Relief*, IRS, <https://www.irs.gov/coronavirus-tax-relief-and-economic-impact-payments> [<https://perma.cc/GN6R-CNJV>] (last updated Aug. 6, 2021); *Economic Impact Payments*, IRS, <https://www.irs.gov/coronavirus/economic-impact-payments> [<https://perma.cc/QGS7-H4C8>] (last updated Aug. 6, 2021).

239. American Rescue Plan Act of 2021, Pub L. No. 117-2, 135 Stat. 4 (March 11, 2021).

240. *See* discussion *supra* Sections I.C. and II.B (discussing public access to information and legal and institutional framework for public access to information).

preparations for the pandemic, or the extent of the information that these authorities *must* provide to the public, leaving them at the discretion of the authorities.

Some may not consider such a legal mandate to be necessary, as significant public concern associated with the pandemic is expected to pressure the government to provide pertinent information to the public. However, the authorities may also have an incentive to conceal or slow down the release of information for political reasons, as suspected by the public when the Trump administration required hospitals to bypass the CDC and report directly to a centralized database in Washington, D.C.,²⁴¹ in which case such a delay or concealment would be adverse to the public interest in the pandemic situation. Thus, there is a need for a legal adjustment that will not only authorize but also *require* the government to disclose relevant information to the public promptly, as successfully implemented elsewhere.²⁴²

The second part of this proposal is an institutional reform to establish a bi-partisan institutional control center, such as a national commission headed by a politically independent agency (like the politically independent CDC) in charge of controlling

241. See *COVID-19 Guidance for Hospital Reporting and FAQs for Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting*, U.S. DEPT HEALTH & HUM. SERVS. (Oct. 6, 2020), <https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf> [<https://perma.cc/G3LU-7WYW>] (explaining how hospitals were required to report COVID-19 data); see also Sheryl Gay Stolberg, *Trump Administration Strips C.D.C. of Control of Coronavirus Data*, N.Y. TIMES, <https://www.nytimes.com/2020/07/14/us/politics/trump-cdc-coronavirus.html> [<https://perma.cc/Y75S-F542>] (updated Sept. 9, 2020). Under public pressure, the Trump administration subsequently reversed this decision, allowing the CDC to collect and report COVID-19 data. Robbie Whelan, *Covid-19 Data Will Once Again Be Collected by CDC, in Policy Reversal*, WALL ST. J. (Aug. 20, 2020), <https://www.wsj.com/articles/troubled-covid-19-data-system-returning-to-cdc-11597945770> [<https://perma.cc/WG3X-ZHRN>].

242. In South Korea, for example, the government is under such legal requirements. Infectious Disease Control and Prevention Act, Act No. 17067, Mar. 4, 2020, art. 6, ¶ 2 (S. Kor.) (emphasis added), *translated* in Korea Legislation Research Institute online database, https://elaw.klri.re.kr/eng_service/lawView.do?hseq=53530&lang=ENG. The relevant Korean law, the Infectious Disease Control and Prevention Act stipulates in relevant part that “each citizen shall have the right to know information on the situation of the outbreak of infectious diseases and the prevention and control of infectious diseases and how to cope therewith, and *the State and local governments shall promptly disclose the relevant information.*” *Id.* (emphasis added).

infectious diseases (hereinafter “the Commission”). There is also no effective coordination mechanism among federal, state, and local authorities governing pandemic response. Considering the significant disarray, there is a call for an autonomous government organization whose decisions are not to be determined by political considerations.²⁴³ There is indeed a need for an institutional command center to expedite the implementation of TCQT. Such a command center must be authorized to collect and disseminate all necessary information to combat the pandemic, develop and implement effective guidelines, and coordinate with the other relevant federal departments and agencies, as well as state and local authorities for the implementation of TCQT. Successful implementation is contingent upon acquiring personal protective equipment (PPE) and other medical equipment in time, and the command center should also have the authority to secure the crucial equipment for TCQT for clinics and hospitals in cooperation with state and local authorities as well as the private sector.

The Commission would be comprised of representatives from federal, state, and select local governments,²⁴⁴ as well as representatives of the private sector (e.g., medical equipment suppliers, pharmaceutical companies, healthcare providers, and experts in public health). The proposed Commission would be charged with coordinating among federal, state, and local authorities and between the public and private sectors, in the development and implementation of policies and specific measures to combat the pandemic.

As mentioned above, securing a degree of political independence will be important for the Commission to develop policies and implement timely measures in the best interest of public health, but there is a question whether other pertinent considerations, such as economic considerations, should be completely disregarded from the Commission’s decision-making process. For example, the stay-at-home orders in April may have stabilized the number of infection cases, but they also caused an

243. See Scott Burris et al., *Summary of Findings and Recommendations, in ASSESSING LEGAL RESPONSES TO COVID-19*, *supra* note 3, at 7; see also *Federalism in Pandemic Prevention and Response*, *supra* note 43, at 69.

244. These select local governments should include the city governments of major metropolitan areas, such as New York, Los Angeles, Chicago, Atlanta, Philadelphia, Houston, Washington, D.C., and Boston.

unprecedented number of job losses.²⁴⁵ This concern will necessitate the inclusion of representatives from the federal government in the Commission, as well as representatives from state and local governments. Experts in the head agency could develop specific policies and guidelines, to be adopted by the proposed Commission after consultations and deliberation among the representatives. The adoption of the policies and guidelines would, ideally, be made by consensus of the representatives, to secure maximum cooperation for implementation from federal, state, and local governments, or by a majority vote where such consensus cannot be reached. The adopted policies and measures should, in principle, be implemented through state and local enforcement mechanisms, rather than through federal preemption.

There could also be a question whether representatives of the private sector, such as suppliers of medical equipment, pharmaceutical companies, and healthcare providers, should be invited to participate in the Commission. The proposed legal reform will not meet its regulatory objective of securing timely public access to TCQT without cooperation from the private sector. Cooperation with the private sector is, thus, essential, and it would also be important to consider their views in formulating policies and implementing measures, but there is a concern that the private sector interests, which may not always be aligned with the best interest of public health, might influence (or even dominate) the decision-making process through collusion, should they be allowed to participate in the Commission. Considering this adverse possibility, the role of the private sector representatives should be limited to an advisory one. The Commission and the government may also assist the private sector to maintain a proper level of production and healthcare capacities during the pandemic to secure timely public access to TCQT.

The proposed Commission should also oversee contact tracing and isolated treatment in systematic coordination with state and local authorities. As discussed above, it will be important to revise federal guidelines on contact tracing so that there will be uniform criteria for the collection and dissemination of sensitive private information and that the

²⁴⁵. See *Payroll Employment Down 20.5 Million in April 2020*, *supra* note 29 and accompanying text (reporting 20.5 million job losses in April 2020 alone).

intrusion upon individual privacy will be minimized while securing the information necessary for contact tracing. The status of contact tracing should be reported to the Commission's head agency, and the Commission should also provide necessary support to state and local authorities, which require assistance with their own contact tracing. As for the isolated treatment in quarantine, the Commission's task will be to ensure procurement of sites for treatment facilities, as well as medical personnel for those facilities,²⁴⁶ again, in close and systematic coordination with state and local governments, as well as hospitals, clinics, and medical schools in the region. The Commission should also develop guidelines on the monitoring process for those who are ordered to self-quarantine (i.e., those suspected of infection but not tested positive), and coordinate with state and local authorities to ensure effective monitoring.

Finally, the proposed Commission, through its head agency, should also seek to create and maintain international networks of support and cooperation with the World Health Organization (WHO) and also with public health agencies in other countries affected by COVID-19, particularly those countries that have successfully contained the spread of the pandemic in its early stages.²⁴⁷ The significant differences in many relevant factors, such as governance system, institutional frameworks, public compliance, technological environment, and healthcare system, set certain limits on the "good policies" adoptable from successful countries. Considering the failure in the United States, however, serious efforts must be made to learn the successful practices of other countries and explore ways to adopt them, perhaps after making due adjustments.²⁴⁸

B. RELEVANCE OF LAW AND DEVELOPMENT APPROACH

This article adopts a novel approach to assess the impact of the proposed legal and institutional reform concerning COVID-19 management and to identify possible issues in its implementation. The adopted approach is originated in law and

246. In South Korea, local public and private accommodations have been converted to CTCs. *See* Choi et al., *supra* note 19.

247. *See* Berger, *supra* note 14.

248. For example, extensive, IT-based contact tracing, as well as CTCs implemented in South Korea, offer exemplary references. *See* Choi et al., *supra* note 19.

development studies. “‘Law and development’ is an area of inquiry on the interrelationship between law and development”²⁴⁹ where “development” is understood as “a progressive transformation of the economy and society.”²⁵⁰ Law and development has been concerned primarily with “developing countries,” exploring the role of law for economic and social development in these countries; however, the changing economic and social realities for developed countries, such as regional economic disparity within developed countries, increasing income gaps among their citizens, and deepening racial divides, render a law and development approach relevant to address economic and social problems in developed countries, the resolution of which may require a “progressive transformation” of the underlying economic and social structure through legal and institutional reform.²⁵¹

Thus, a law and development approach is also relevant to assess the legal and institutional reform necessitated by the failure of COVID-19 management, because the proposed reform seeks to transform or overcome the underlying economic, social, and political processes that adversely affect public access to TCQT during a pandemic. The COVID-19 crisis may not be a traditional “development” issue, but it is analogous in the sense that its resolution requires a progressive transformation of the relevant economic, social, and political conditions that adversely affect timely public access to TCQT. In the pandemic context, the relevant economic condition would be the cost issue impacting public access to testing and treatment, the social condition would be the prevailing preference for individualism and privacy over collective response to the pandemic, and the political consideration would be the pervasive partisan politics and fragmented authorities in the absence of effective federal leadership for the first year of the pandemic period.

The assessment of the proposed legal and institutional reform requires the identification of a suitable analytical device. Leading scholars in law and development, such as Trubek and

249. THEORY AND PRACTICE, *supra* note 46, at 3.

250. *Id.* at 11.

251. *See id.* at 111; *see also* Yong-Shik Lee, *Law and Economic Development in the United States: Toward a New Paradigm*, 68 CATH. U. L. REV. 229 (2019); Yong-Shik Lee, *Law and Development in the United States: A Nexus with the Civil Rights*, 44 S. ILL. U. L. J. 433 (2020).

Galanter (1974),²⁵² Merryman (1977),²⁵³ Snyder (1982),²⁵⁴ North (1991),²⁵⁵ Tamanaha (1995),²⁵⁶ Chibundu (1997),²⁵⁷ Posner (1998),²⁵⁸ Chua (1998),²⁵⁹ Cross (2002),²⁶⁰ Davis and Trebilcock (2001),²⁶¹ Barr and Avi-Yonah (2004),²⁶² McInerney (2005),²⁶³

252. See David M. Trubek & Marc Galanter, *Scholars in Self-Estrangement: Some Reflections on the Crisis in Law and Development Studies in the United States*, WIS. L. REV. 1062 (1974) (studying the relationship between scholarship and action, with a focus on scholars' attempt to create a specialized body of knowledge).

253. See John Henry Merryman, *Comparative Law and Social Change: On the Origins, Style, Decline & Revival of the Law and Development Movement*, 25 AM. J. COMPAR. L. 457 (1977) (arguing why comparative law and social change is the field for law and development).

254. See Francis G. Snyder, *The Failure of "Law and Development,"* WIS. L. REV. 373 (1982) (reviewing JAMES A. GARDNER, *LEGAL IMPERIALISM: AMERICAN LAWYERS AND FOREIGN AID IN LATIN AMERICA* (1980)); see also Francis G. Snyder, *Law and Development in the Light of Dependency Theory*, 14 L. & SOC'Y REV. 723 (1980).

255. See Douglass C. North, *Institutions*, 5 J. ECON. PERSP. 97 (1991) (using economic history to illustrate the role of institutions in economies).

256. See Brian Z. Tamanaha, *The Lessons of Law-and-Development Studies*, 89 AM. J. INT'L L. 470 (1995) (reviewing LAW AND DEVELOPMENT (Anthony Carty ed., 1992) and LAW AND CRISIS IN THE THIRD WORLD, (Sammy Adelman & Abdul Paliwala, eds. 1993)).

257. See Maxwell O. Chibundu, *Law in Development: On Tapping, Gourding and Serving Palm-Wine*, 29 CASE W. RES. J. INT'L L. 167 (1997) (focusing on Sub-Saharan Africa to show the relevance of law in the development of Third World countries).

258. See Richard A. Posner, *Creating a Legal Framework for Economic Development*, 13 WORLD BANK OBSERVER 1 (1998) (proposing a framework of legal reform for economic growth in countries).

259. See Amy Chua, *Markets, Democracy, and Ethnicity: Toward A New Paradigm for Law and Development*, 108 YALE L. J. 1 (1998) (arguing that marketization and democratization may drive ethnic tensions).

260. See Frank B. Cross, *Law and Economic Growth*, 80 TEX. L. REV. 1737 (2002) (surveying the field of research on economic growth and the law).

261. See Kevin E. Davis & Michael J. Trebilcock, *Legal Reforms and Development*, 22 THIRD WORLD Q. 21 (2001) (examining the role of legal intuitions in the pursuit of development).

262. See Michael S. Barr & Reuven S. Avi-Yonah, *Globalization, Law and Development: Introduction and Overview (Globalization, Law and Development Conference)*, 26 MICH. J. INT'L L. 1 (2004) (providing an overview of the key issues surrounding development in the age of globalization).

263. See Thomas F. McInerney, *Law and Development as Democratic Practice*, 38 VAND. J. TRANSNAT'L L. 109 (2005) (examining law and development through a political-theoretical lens).

Chodosh (2006),²⁶⁴ Dam (2006),²⁶⁵ Chukwumerije (2009),²⁶⁶ and Prado (2009),²⁶⁷ have addressed a range of issues about law and development. These scholars have called for new approaches, including theoretical underpinnings that explain the dynamics among law, institutions, and the existing political, social, and economic conditions.²⁶⁸

The recently-developed General Theory responds to this call and provides an analytical framework to assess the impact of law, legal frameworks, and institutions (LFIs) on economic and social development.²⁶⁹ The General Theory is comprised of two parts: the first part of the theory sets the disciplinary parameters of law and development, and the second part explains the causal relationship between law and development through “the regulatory impact mechanisms,” which refers to the mechanisms by which law impacts development, with references made to institutional frameworks and socioeconomic conditions.²⁷⁰ The second part of the General Theory, namely the regulatory impact mechanisms, addresses the impact of the proposed legal and institutional reform.²⁷¹ The remainder of this section introduces the relevant part of the theory (the regulatory impact mechanisms).²⁷² Part IV applies the General Theory to the proposed legal and institutional reform and examines its impact and expected implementation issues.²⁷³

The regulatory impact mechanisms are comprised of three analytical elements: “regulatory design,” “regulatory

264. See HIRAM E. CHODOSH, *GLOBAL JUSTICE REFORM: A COMPARATIVE METHODOLOGY* (2005) (outlining the risks and benefits of the comparative methodology in global justice reform).

265. See KENNETH W. DAM, *THE LAW-GROWTH NEXUS: THE RULE OF LAW AND ECONOMIC DEVELOPMENT* (2006) (examining the underlying mechanisms through which the law, judiciary, and legal profession influence the economy).

266. See Okezie Chukwumerije, *Rhetoric Versus Reality: The Link Between the Rule of Law and Economic Development*, 23 *EMORY INT'L L. REV.* 383 (2009) (looking at the limitations of the rule of law on economic growth in developing countries).

267. See Mariana Prado, *Should We Adopt a “What Works” Approach in Law and Development?*, 104 *NW. U. L. REV.* 174 (2009).

268. *Gen. Theory*, *supra* note 46, at 417.

269. *Id.* at 418.

270. *Id.*

271. *Id.*

272. *Id.*

273. *Id.* at 456.

compliance,” and “quality of implementation,” with additional sub-elements under each of these three elements.²⁷⁴ These elements are conceptually distinct but interrelated and influence one another.²⁷⁵ The first element of the regulatory impact mechanisms, regulatory design, analyzes how law is designed to achieve a development objective.²⁷⁶ Regulatory design is analyzed by three sub-elements: anticipated policy outcome; organization of law, legal frameworks, and institutions (LFIs); and law’s adaptation to socioeconomic conditions.²⁷⁷ The first sub-element, anticipated policy outcome, refers to the outcome of the policy that law is anticipated to deliver.²⁷⁸ For example, an increase in the number of diagnostic tests performed would be the anticipated policy outcome of a law that mandates covering the cost of testing. Examination of the anticipated policy outcome is aided by methods and analytics of relevant social sciences, which include, but are not limited to, economics, political science, anthropology, and sociology.²⁷⁹

The second sub-element, organization of LFIs, examines the dynamics and interrelations among law, applicable legal frameworks, and relevant institutions.²⁸⁰ Regulatory design is enhanced by positive synergies among the constituent elements of LFIs.²⁸¹ For example, a law that aims to ensure social distancing and mask-wearing in public places may not be effective without operative institutional frameworks, such as an enforcement mechanism against violations. The third sub-element, adaptation to socioeconomic conditions, examines whether law conforms to relevant social, political, economic, and cultural conditions (“socioeconomic conditions”).²⁸² For instance, a law that aims to provide timely public access to information related to COVID-19 will have only limited impact on improving information accessibility if the underlying socioeconomic conditions are incompatible; e.g., where a majority of the population culturally disfavor releasing their private

274. *Id.* at 418.

275. *Id.*

276. *Id.* at 419.

277. *Id.*.

278. *Id.* at 437.

279. *Id.*

280. *Id.* at 441.

281. *Id.* at 442.

282. *Id.* at 444.

information (such as the time and location of their visits after contracting the virus) even during a pandemic. Thus, adaptation to the prevailing socioeconomic conditions is essential to the successful operation of law, and in this example, a law will have to mandate extensive public engagement and education campaigns to solicit cooperation from the public.

In addition to the regulatory design which is assessed by the anticipated policy outcome, an organization of LFIs, and the law's adaptation to socioeconomic conditions, the General Theory presents two other elements to determine the impact of law: regulatory compliance and quality of implementation.²⁸³ The second element, regulatory compliance, examines compliance with law by the public.²⁸⁴ Law would not have impact without due compliance by the public, who are subject to the application of law.²⁸⁵ Regulatory compliance is analyzed under two sub-elements: general regulatory compliance and specific regulatory compliance.²⁸⁶ General regulatory compliance examines the overall level of compliance with law in a given jurisdiction.²⁸⁷ Social and political factors, such as legal culture in society and public confidence in the state implementing law, influence general regulatory compliance.²⁸⁸ Specific regulatory compliance pertains to the strength of compliance with a particular law.²⁸⁹ A key element determining specific regulatory compliance is the consistency between a particular law and the socioeconomic conditions on the ground;²⁹⁰ i.e., even in a society where general regulatory compliance is strong, a particular law may still have weak compliance when it does not conform to the socioeconomic conditions prevailing on the ground.²⁹¹ A law that mandates quarantine of those infected with COVID-19 in a CTC-type facility may not attract strong regulatory compliance without incentives, where a culture that emphasizes individual autonomy and freedom prevails.

283. *Id.* at 418.

284. *Id.* at 446, fig. 5.1.

285. *Id.*

286. *Id.*

287. *Id.*

288. *Id.* at 446–48.

289. *Id.* at 446.

290. *Id.* at 449.

291. *Id.* at 447.

The third and final element under the regulatory impact mechanisms is quality of implementation.²⁹² This element assesses the degree to which a state meets the requirements of law and undertakes its mandates to fulfill regulatory objectives.²⁹³ Laws which are otherwise well-designed and command strong compliance by the public will not have much impact if the state fails to properly implement them.²⁹⁴ In the preceding example, a law that attempts to ensure social distancing and mask-wearing in public places would not be successful unless the state implements them effectively by enforcing these laws with sufficient capacity (e.g., competent personnel, technical resources, adequate budget). State capacity, including its financial, technological, and administrative capabilities for the implementation of law, is a key determinant of the quality of implementation.²⁹⁵ The implementation of law also requires a degree of political will, particularly when implementation poses political challenges for reasons including conflicts of interest and preferences within a society and among different segments of the population.²⁹⁶ Political will would be necessary to enforce mask-wearing mandates where a significant portion of the population feels uncomfortable wearing masks, rendering such a mandate politically unpopular. These two factors, state capacity and political will, are essential elements that determine the quality of implementation.²⁹⁷

IV. APPLYING THE GENERAL THEORY OF LAW AND DEVELOPMENT

A. REGULATORY DESIGN

Under the General Theory, the impact of the proposed reform is assessed against its analytical elements, beginning with the first—regulatory design—and the three sub-elements,

292. *Id.* at 450.

293. *Id.*

294. *Id.*

295. *Id.* at 451–52.

296. *Id.* at 454.

297. See Yong-Shik Lee, *General Theory of Law and Development: An Overview*, 12 L. & DEV. REV. 351, 368–71 (2019) (analyzing the ways in which state capacity and political will impact the ability of the state to implement a given law).

anticipated policy outcome, organization of LFIs, and adaptation to socioeconomic conditions.²⁹⁸

1. Anticipated Policy Outcome

The proposed legal requirement to ensure timely public access to TCQT is expected to expedite the government's preparations if the law identifies each of the governmental steps to be taken and sets timelines for each of these steps. The proposed reform reduces political discretion embedded in the current law by imposing a mandatory requirement on the government to take preparatory steps in pre-set timelines.²⁹⁹ Currently, there is no recourse under the law when the government does not exercise its legal authority to mobilize resources and make preparations, as shown by the conduct of the previous Trump administration which neglected to proceed expeditiously with preparations during the early stages of the pandemic, leaving the primary responsibility of controlling the pandemic to the state and local authorities. This must be remedied by adding a legal requirement for the government to take specific steps to ensure timely public access to TCQT.³⁰⁰ The proposed amendment to link vaccination to individual tax relief and payments may also increase the rate of vaccination, although it is unclear how effective such economic incentive will be for those who object to vaccination for political reasons or concerns about possible side-effects after vaccination.³⁰¹

As for the proposed institutional reform, the anticipated policy outcome of setting a national, bi-partisan Commission headed by a politically independent agency will be the separation of the pandemic response from political considerations that may delay timely public warnings and preparations. This anticipated policy outcome will be enhanced by ensuring the political autonomy of the proposed Commission as a fully independent regulatory agency, such as the Securities

298. *Gen. Theory, supra* note 46, at 436.

299. *See* discussion *supra* Section II.A.

300. A statutory right should be granted to members of the public so that an individual may have standing to challenge a violation.

301. The CDC reports that possible side effects are likely mild. *Possible Side Effects After Getting a COVID-19 Vaccine*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sep. 30, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html> [<https://perma.cc/KME3-ZRJR>].

and Exchange Commission and the Federal Reserve. This separation will also have the effect of enhancing coordination among federal, state, and local authorities, minimizing partisan political interests and interferences in the development and implementation of measures to combat the pandemic.

2. Organization of LFIs

The second sub-element under the regulatory design is organization of LFIs.³⁰² A question may be raised whether requiring the federal government to ensure public access to TCQT would be compatible with the federal legal system in the United States, whose Constitution limits the role of the federal government.³⁰³ Some may argue that the job should be left with state and local authorities, as well as the private sector. Another potential question is whether the no cost-share requirement for TCQT will be compatible with the current private healthcare system, where a majority of the public rely on private healthcare provisions whereby the financial arrangement for the cost is to be determined by private insurance contracts. As for the first question, the lesson from the current pandemic is that irrespective of the federal system, leaving the primary responsibility to combat COVID-19 to state and local governments, whose resources may not be sufficient to deal with a pandemic on a national or an international scale, or to the private sector, whose interests may not necessarily be aligned with public health interests, does not ensure successful control of the disease. The federal government, armed with superior resources and information, must be required to take the lead and adopt the necessary steps to respond to the pandemic in pre-defined timelines. This proposed legal adjustment is necessary to ensure the federal response. The proposal is not to supersede or preempt state and local authorities; rather, it is to create a strong coordination mechanism, in conjunction with the proposed Commission, so that the policies and measures that are developed to control the pandemic are implemented through

302. *Gen. Theory, supra* note 46, at 419 (“[R]egulatory design is analyzed in the following three categories (sub-elements): anticipated policy outcome; organization of law, legal frameworks, and institutions (LFI); and adaptation to socioeconomic conditions . . .”).

303. U.S. CONST. amend. X (“The powers not delegated to the United States by the Constitution, nor [the powers] prohibited by [the Constitution] to the states, are reserved to the states . . .”).

state and local enforcement mechanisms in systematic cooperation among federal, state, and local authorities. The proposed Commission, as an institutional control center, should serve this function.

As for the second question—the federal government’s guarantee for vaccination, testing, and treatment costs—the current federal COVID-19 legislation already requires healthcare insurance providers not to impose cost-sharing on the insured for tests, vaccines, and preventive care.³⁰⁴ The proposed reform adds a requirement for the government to make an explicit guarantee to the public that they will bear no out-of-pocket cost for COVID-19 related treatment regardless of their insurance status; the objective is to ensure that the public will not be discouraged from seeking treatment because of cost concern and that this concern will not become a cause for further spread of the disease.³⁰⁵ The explicit government guarantee will be required to contain the spread of the disease by timely testing and treatment, and any personal benefit to COVID-19 patients is incidental and subordinate to the national interest to contain the pandemic. Thus, the proposed legal adjustment will be consistent with the powers granted to the federal government in the context of a national emergency.³⁰⁶

304. Families First Coronavirus Response Act, Pub. L. No. 116-127, §§ 6001–6004, 134 Stat. 178, 201–08 (waiving cost-sharing on COVID-19 testing and certain clinical visits related to testing); 42 U.S.C. §§ 1320b–5, 1395l, 1396d(a)(3)(B) (2020) (establishing authorization to waive requirements during national emergencies); Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, §§ 3201, 3203(a), 134 Stat. 184, 366–67 (ordering insurance providers to cover COVID-19 testing, preventive services, and vaccines); 41 U.S.C. § 300gg-13 (2020) (covering preventive services).

305. Witters, *supra* note 61 (presenting evidence that one in every seven Americans (14%) is deterred from seeking healthcare for themselves or a family member when experiencing COVID-19 symptoms due to high healthcare costs).

306. See Public Health Service Act, 42 U.S.C. §§ 201–300mm-61 (2018) (authorizing the Secretary of Health and Human Services to lead medical response to public health emergencies); Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121–5207 (2018) (authorizing delivery of federal assistance to states and localities during emergencies); National Emergencies Act, 50 U.S.C. §§ 1601–1651 (2018) (establishing ground rules for how the federal government responds to national emergencies).

3. Adaptation to Socioeconomic Conditions

As to the adaptation to socioeconomic conditions, the third sub-element for the regulatory design, a relevant question is whether the proposed reform can be supported by financial, technical, and cultural conditions on the ground.³⁰⁷ The legal reform, which will require the government to ensure timely public access to TCQT, necessitates securing sufficient quantities of test kits, masks, PPE, medicine, contact tracers, and medical facilities. The relevant industries reportedly have sufficient production capacities for medical supplies,³⁰⁸ but securing a needed number of contact tracers to perform contact tracing as well as treatment centers to isolate asymptomatic and mildly symptomatic patients could prove to be a challenge. The role of the federal government is to ensure, in close coordination with state and local authorities, as well as with the private sector counterparts, that sufficient quantities of medical supplies are produced, secured, and distributed in time; enough contact tracers are recruited throughout the country; and the sites for treatment centers are secured. Monitoring will be another issue, with the monitored quarantine of those who have not tested positive but have been exposed to the risk of infection. It might be a challenge to acquire the capacity for proper monitoring.

As for the proposed Commission, strong bi-partisan support will be necessary at the federal, state, and local levels to ensure the successful operation of the Commission. A question may be raised whether the current partisan and divisive political environment is conducive to the successful operation of such a bi-partisan Commission where representatives from federal, state, and local authorities must cooperate and coordinate in the development and implementation of policies and measures. There is a risk that the partisan political interests among the representatives may impede the work of the Commission, and it remains to be seen whether the unprecedented magnitude of the

307. *Gen. Theory*, *supra* note 46, at 444 (defining socioeconomic conditions as a range of social, political, economic, and cultural conditions).

308. See, e.g., *Tracker: How Businesses Are Accelerating Production of Critical Medical Supplies to Combat the Coronavirus*, U.S. CHAMBER OF COM., <https://www.uschamber.com/article/tracker-how-businesses-are-accelerating-production-of-critical-medical-supplies-combat-the> [https://perma.cc/KR7W-JXN Q] (last updated May 12, 2020) (listing efforts of forty-four American businesses to provide aid for the coronavirus response).

current pandemic will generate popular support or pressure for a bi-partisan effort to form a united front against the pandemic. The leadership role of the politically independent head agency, as well as support from political leaders, expert groups, and the general population, will be crucial for the success of the Commission.

B. REGULATORY COMPLIANCE

The second analytical element in the regulatory impact mechanisms, regulatory compliance, is also relevant to assess the proposed reform. As discussed above, regulatory compliance is analyzed by two sub-elements: general regulatory compliance and specific regulatory compliance.³⁰⁹

1. General Regulatory Compliance

The level of regulatory compliance, which refers to the general level of regulatory compliance in a given jurisdiction, can be measured by proxy indicators such as the rule of law indexes compiled by the World Justice Project and the World Bank, as the rule of law would not be feasible without regulatory compliance.³¹⁰ The ratings of the United States are high on these indexes: twenty-first among 128 countries under the Rule of Law Index 2020 by World Justice Report and 89.9 percentile under the Rule of Law Indicator 2020 by the World Bank,³¹¹ indicating a high level of general regulatory compliance. This outcome is consistent with a prevailing observation that the United States has one of the world's most advanced legislative, judicial, and law enforcement systems, the combination of which is bound to

309. *Gen. Theory*, *supra* note 46, at 446 (“Regulatory compliance can be classified into general regulatory compliance, which refers to the general level of regulatory compliance in a given jurisdiction, and specific regulatory compliance, which pertains to a particular law.”).

310. *Rule of Law Index 2020*, WORLD JUST. PROJECT (2020), https://worldjusticeproject.org/sites/default/files/documents/WJP-ROLI-2020-Online_0.pdf [<https://perma.cc/XU6Z-AE6S>] (“[M]easuring the rule of law based on the experiences and perceptions of the general public and in-country legal practitioners and experts worldwide.”); *Worldwide Governance Indicators*, WORLD BANK (2020), <https://info.worldbank.org/governance/wgi/> [<https://perma.cc/L682-PZK2>] (reporting “aggregate and individual governance indicators for over 200 countries and territories . . . for six dimensions of government.”).

311. WORLD JUST. PROJECT, *supra* note 310, at 154; WORLD BANK, *supra* note 310.

command generally a high level of regulatory compliance by the public. The long tradition of the rule of law, which began with the birth of the nation, is also conducive to general regulatory compliance.

2. Specific Regulatory Compliance

Against this backdrop, specific regulatory compliance can be assessed. Regulatory compliance does not mean only the absence of rule violations, but also the knowledge of law and participation in the processes mandated by law.³¹² There have been substantial compliance and implementation issues in pandemic management.

In the crucial weeks of February through early March of 2020, the Trump administration failed to inform the public about the danger of the disease and to present effective guidelines for mitigating its spread.³¹³ The administration had banned entry from China in January of 2020 to prevent further spread of the disease from the place that was believed to be its origin,³¹⁴ but the Trump administration neither cautioned the public about the risk of the spread of the disease within the United States nor made due preparations, such as securing a sufficient number of test kits and face masks to be made available to the public.³¹⁵ The lack of follow-up actions led the public to believe—at least until the first half of March when they witnessed the rapidly increasing number of infections and the declaration of a national emergency by the President—that the pandemic was largely a problem occurring outside the country and that it was not, therefore, necessary to make serious

312. *Gen. Theory, supra* note 46, at 446 (“[J]udicial reform would not be as effective where only a small minority of the population uses the court for dispute resolution.”).

313. See Philip Mirvis, *Reflections: US Coronavirus Crisis Management—Learning from Failure Donald Trump and More, January—April, 2020*, 20 J. CHANGE MGMT. 283 (2020) (recounting former-President Trump’s “alarmist” labeling of coronavirus warnings and partial travel ban that permitted 40,000 travelers to and from China amidst the crisis).

314. Proclamation 9984, *supra* note 92, §§ 1–2 (suspending entry from China).

315. See Mirvis, *supra* note 313, at 293–94 (“A key challenge was to come to grips with the healthcare system’s supply chain with projected shortages of hospital beds, breathing ventilators, masks, and other personal protective equipment.”).

preparations for COVID-19.³¹⁶ Until mid-March, the federal government did not issue any mandate or guideline for public compliance.

This complacency was turned into pressing stress on the public in the following sequence. The government had been unsuccessful in conducting a sufficient number of tests and contact tracing, consequently failing to contain the spread of the pandemic. As a result, the number of infections and the death toll skyrocketed from late February to early March.³¹⁷ Unprepared to handle the pandemic, states resorted to the most drastic measures, such as stay-at-home orders and non-essential business closures, to contain the spread of the disease.³¹⁸ These measures appear to have stabilized the rate of infections by mid-April but exerted considerable economic, psychological, and social pressure on the public, as demonstrated by public objections and mass protests.³¹⁹ When states started to lift stay-at-home orders and re-open businesses in late April,³²⁰ the federal government issued guidelines for re-opening but without any mandate on essential measures, such as mask mandates.³²¹

316. See, e.g., JOHN STERNFELD, UNPREPARED: AMERICA IN THE TIME OF CORONAVIRUS (2020) (tracing the trajectory of the development of the coronavirus and analyzing the adequacy of the response of the United States government throughout); see also Ethan Epstein, *America the Complacent*, WASH. TIMES (Mar. 1, 2020), <https://www.washingtontimes.com/news/2020/mar/1/america-has-become-complacent-when-it-comes-corona/> [https://perma.cc/T3GW-CLLA] (“Americans seem blithely unaware that in just a few short weeks their lives could be upended with lockdowns . . .”).

317. See *COVID Data Tracker*, supra note 1 (accounting for the increase in the number of infection cases).

318. Lindsay K. Cloud et al., *A Chronological Overview of the Federal, State, and Local Response to COVID-19*, in ASSESSING LEGAL RESPONSES TO COVID-19, supra note 3, at 10 (“[C]hronicling the federal and state legal response from January to July 2020 . . .”).

319. See, e.g., Michael Martina & Seth Herald, *Hundreds Protest Michigan Stay-at-Home Order*, REUTERS (May 14, 2020), <https://www.reuters.com/article/us-health-coronavirus-michigan-protest/hundreds-protest-michigan-stay-at-home-order-idUSKBN22Q11L> (covering protests against state government-mandated lockdowns in Michigan in May of 2020).

320. Alaa Elassar, *This is Where Each State is During Its Phased Reopening*, CNN (May 27, 2020), <https://www.cnn.com/interactive/2020/us/states-reopen-coronavirus-trnd/> [https://perma.cc/MV94-SJF7].

321. Alana Wise, *READ: White House Guidelines to States for Reopening*, NPR (Apr. 16, 2020), <https://www.npr.org/2020/04/16/836489480/read-white-house-guidelines-to-states-for-reopening> [https://perma.cc/7JNQ-KNCN]. There is controversy as to whether the federal government has the authority to impose

Varied state and local mandates, sometimes in conflict with one another,³²² created a sub-optimal environment for public compliance with the measures adopted by state and local governments.

Under such an environment, public compliance with mask mandates, which is one of the most important measures to prevent the spread of the disease, has varied by region, with the most compliant areas in the Northeast and along the West Coast, and lower levels of compliance in the Plains and the South.³²³ There is no federal, national mask mandate in place,³²⁴ but the CDC recommends that all individuals over two years of age wear a mask in a public setting or around people who live in a separate household.³²⁵ The number of American adults wearing masks has been increasing; in June of 2020 only 65 percent of American adults reported regularly wearing face

a federal mask mandate. The government may invoke Section 361 of the Public Health Service Act (PHSA), which grants the federal government the authority to make and enforce regulations necessary “to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.” 42 U.S.C. § 264 (2018). However, a counterargument is that Section 361 authorizes the federal government to take measures against dissemination across national or state borders; thus, a federal mask mandate cannot be imposed on an individual who does not travel across national or state borders. See WEN W. SHEN, CONG. RSCH. SERV., LSB10530, *COULD THE PRESIDENT OR CONGRESS ENACT A NATIONWIDE MASK MANDATE?* (2020) (discussing potential legal issues with a federal mask mandate); see also John Yoo & James C. Phillips, *The Constitutionality of Federal Mask Mandates*, AM. ENTER. INST. (July 27, 2020), <https://www.aei.org/op-eds/the-constitutionality-of-federal-mask-mandates/> (arguing the federal government cannot implement a mask mandate).

322. See Cole, *supra* note 107; Reimann, *supra* note 108 and accompanying text (discussing disagreements and disputes among state and local authorities).

323. Josh Katz et al., *A Detailed Map of Who Is Wearing Masks in the U.S.*, N.Y. TIMES (July 17, 2020), <https://www.nytimes.com/interactive/2020/07/17/upshot/coronavirus-face-mask-map.html> [<https://perma.cc/V87J-XCZY>].

324. See WEN W. SHEN, CONG. RSCH. SERV., LSB10530, *COULD THE PRESIDENT OR CONGRESS ENACT A NATIONWIDE MASK MANDATE?* (2020) and accompanying text (discussing the lack of a federal mask mandate and potential legal issues).

325. *Guidance for Wearing Masks; Help Slow the Spread of COVID-19*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 7, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html> [<https://perma.cc/QT8D-RB3K>].

masks in public, but that number increased to 85 percent within the first two weeks of August.³²⁶

In the context of the proposed reform, the public is expected to show support and compliance with the law that requires the government to ensure timely public access to testing and treatment, as they are the beneficiary of the law reform. However, regulatory compliance may become an issue for the implementation of a law that requires timely contact tracing and isolation of COVID-19 patients. Those subject to contact tracing for exposure to infection will have to disclose the personal information required for contact tracing. Some may not be willing to disclose personal information. This means that participation in contact tracing may have to be incentivized; compulsion may not be effective and may only backfire where a culture emphasizing privacy prevails. Forms of incentives may include granting a priority for treatment.

As for the proposed treatment in isolation, some of the asymptomatic or mildly symptomatic COVID-19 patients may not accept mandatory isolated treatment in public facilities for days (i.e., five to ten days until they test negative) and may resist involuntary separation from their families and removal from their homes,³²⁷ even if it is necessary to contain the disease. An incentive offer, such as full coverage of the cost of the isolated treatment by the government, may improve compliance. Additional incentives, such as job protection during the period of isolation, care arrangements for the patient's minor children and elderly parents, and a guarantee for hospital admission if the patient's condition deteriorates while staying at the treatment center, could also be offered to improve compliance, although offering the latter incentive might be difficult in places where hospitals are reaching capacity. Also possible is an opt-out option, under which the patient is allowed to make their own arrangements for isolation if they demonstrate to the

326. Stephanie Kramer, *More Americans Say They Are Regularly Wearing Masks in Stores and Other Businesses*, PEW RSCH. CTRS. (Aug. 27, 2020), <https://www.pewresearch.org/fact-tank/2020/08/27/more-americans-say-they-are-regularly-wearing-masks-in-stores-and-other-businesses/> [https://perma.cc/2E3V-45NA].

327. See Choi et al., *supra* note 19 (detailing the use of Community Treatment Centers in South Korea); see also Gonsalves et al., *supra* note 215, at 3 (“Individuals will not cooperate with self-isolation or other voluntary social distancing measures if they are unable to provide for themselves and their families.”).

government that they can meet the criteria for effective isolation. In the latter case, a monitoring system should also be in place. Similar compliance issues may also arise for the monitored quarantine of those who have not tested positive but were exposed to the risk of infection and the public release of some of the private information acquired through contact tracing; some incentives might be necessary to enhance regulatory compliance.

C. QUALITY OF IMPLEMENTATION

Lastly, the proposed reform is assessed against the last element under the regulatory impact mechanisms, quality of implementation, which “refers to the act of a state meeting the requirements of law and undertaking mandates under the terms of law to fulfill its objectives.”³²⁸ As discussed above, state capacity and political will are essential elements that determine the quality of implementation.³²⁹

1. State Capacity

The United States has the world’s largest state capacity for the implementation of law:³³⁰ with its vast financial, technological, and administrative resources, the federal government has greater capacity than any other government to meet the requirement of the proposed reform, which mandates that the government ensure timely public access to TCQT, including setting up CTC-type facilities for the isolated treatment of all COVID-19 patients.

The proposed amendment will require financial, administrative, and technical resources to ensure the sufficient supply of test kits, PPE, vaccines, medicines, and care facilities, and to collect and release pertinent information promptly. State and local governments may not have sufficient resources to undertake these tasks, but the federal government can cooperate with state and local authorities to implement the proposed amendment across the country.

As for the proposed Commission, it is also well within the state capacity of the United States to establish such a

328. *Gen. Theory*, *supra* note 46, at 450.

329. *Id.* at 451.

330. *See id.* at 451–52 (discussing the United States’ extensive capacity for legal implementation).

Commission and support its activities: logistical requirements to set up such a Commission, such as the creation of an extensive communications facility, and providing the head agency with necessary financial, technical, and administrative resources will not likely be a challenge to the state capacity of the United States. The proposed Commission will have to coordinate with state and local health authorities in the implementation of its policies. The resources at the disposal of the federal government will likely be sufficient to support such coordination. A more likely challenge to implement the proposed reform will be a political one, rather than state capacity, as further discussed below.

2. Political Will

Political will, another important element to determine the quality of implementation, may prove to be an issue. The magnitude of the unprecedented health crisis requires extraordinary political leadership at the federal, state, and local levels for successful management. Indeed, effective political leadership has guided populations in other countries that have better managed COVID-19.³³¹ Such political leadership has been lacking in the United States, particularly at the federal level under the Trump administration. Traditionally, Presidents have accepted political responsibility and exercised leadership during periods of crisis.³³² However, the Trump administration failed to show such leadership for the management of COVID-19: the administration initially downplayed the seriousness of the pandemic and delegated the management responsibilities largely to state and local governments.³³³ As discussed above, the pandemic is a national and international emergency. As such, it requires a national response with national (federal) leadership, and state and local initiatives are insufficient to overcome the crisis.

331. See, e.g., Michael J. Ahn, *Combating COVID-19: Lessons from South Korea*, BROOKINGS (Apr. 13, 2020), <https://www.brookings.edu/blog/techtank/2020/04/13/combating-covid-19-lessons-from-south-korea/> [<https://perma.cc/2VY3-GVNQ>] (detailing the actions taken by the South Korean government against COVID-19).

332. Scott Burris et al., *Summary of Findings and Recommendations*, in ASSESSING LEGAL RESPONSES TO COVID-19, *supra* note 3, at 3.

333. *Id.* at 4.

The sharp partisan divide in United States politics, which has been deepening for decades, as well as former President Trump's dismissive attitude about the pandemic, contributed to the lacking federal leadership. As this President had been elected without majority support from the population,³³⁴ he displayed innate limits on his ability to unite Americans for a common cause. A majority of his supporters were concentrated in the midwestern and southern regions of the United States, rather than the population and economic centers on the eastern and western coasts.³³⁵ This divide, again coupled with Trump's negative attitudes and failures, created confrontations and gaps between the administration on the one hand and the economic and political elites, mass media, and scientific communities on the other, generating an adverse political environment for building a united frontline against COVID-19. The divide not only existed at the federal level but also permeated into the state and local levels, as revealed by the confrontations and disputes between state and local authorities.³³⁶

Improved leadership would be necessary to introduce an effective form of treatment that has been successful in containing the pandemic in other countries; for example, South Korea introduced the treatment of asymptomatic and mildly symptomatic COVID-19 patients in physically isolated Community Treatment Centers (CTCs) located throughout the country.³³⁷ In the United States, such patients do not receive medical treatment and are only recommended to self-quarantine at home.³³⁸ There is no monitoring of quarantine, and the patients' family members and even neighbors are exposed to the

334. *2016 US Presidential Election Map by County & Vote Share*, BRILLIANT MAPS (Nov. 29, 2016), <https://brilliantmaps.com/2016-county-election-map/> [https://perma.cc/U8YD-B2BR].

335. Snopes, *Counting Blue Counties*, in *THEORY AND PRACTICE*, *supra* note 46, at 118, n.610; *see also* Brilliant Maps, *supra* note 334 (showing vote share by county for the 2016 United States presidential election).

336. *See* Reimann *supra* note 108; Chiu, *supra* note 109 (discussing disputes and disagreements between state and local authorities).

337. *See* Choi et al., *supra* note 19 (detailing South Korea's use of Community Treatment Centers).

338. *See* *Coronavirus (COVID-19)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 9, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/index.html> [https://perma.cc/5EZJ-6HUG] (directing individuals with symptoms of COVID-19 to quarantine).

risk of infection, depending on how quarantine is done by the individual. Self-quarantine has limits and, coupled with the failure to conduct contact tracing in the early stages of the pandemic, contributed to the rapid spread of the pandemic. In contrast, South Korea was able to operate CTCs where COVID-19 patients were admitted, isolated from the rest of the population, except medical personnel, and received medical treatment and transferred to hospitals when necessary.³³⁹ Patients were released once they no longer tested COVID positive.

The isolated treatment of all COVID-19 patients was a core reason for South Korea's success in containing the disease. South Korea has been unsuccessful in securing the sufficient amount of vaccines in time due to late negotiations but has still been able to control the number of infections and deaths³⁴⁰ well below hospital capacity thanks to effective TCQT: CTCs have been set up by converting accommodation facilities, and the government assumed the cost of testing and treatment at CTCs. The introduction of this system will be instrumental to contain the disease, but substantial political leadership will be required to persuade COVID-19 patients with mild or no symptoms to stay for days in an isolated place, where many may not feel comfortable with this type of isolated treatment, even with the aforementioned incentives. It also takes considerable political leadership to secure facilities to convert to CTC-type treatment centers and make an arrangement for the cost reimbursement of accommodation and treatment under the private healthcare system, unlike South Korea with its prevailing public healthcare system.³⁴¹ The proposal will indeed be politically challenging, but effective leadership, which facilitates the isolated treatment for all COVID-19 patients, will result in saving lives.

Vaccination is also important to save lives and contain the disease, but as mentioned, as of this writing, nearly half the population has not been fully vaccinated, and over 40 percent of the population has not yet received a single dose.³⁴² Those who object to vaccination for reasons including political ones may

339. See Choi et al., *supra* note 19, at 2338 (detailing the use of community treatment centers to combat the spread of COVID-19 in South Korea).

340. KOREA DISEASE CONTROL AND PREVENTION AGENCY, *supra* note 8.

341. See, e.g., Maizland & Felter, *supra* note 12 (detailing South Korea's quick response to contain the COVID-19 pandemic).

342. U.S. COVID-19 Vaccine Tracker, *supra* note 33.

well resist and challenge the proposed financial incentives linked to the Coronavirus Tax Relief and Payments as unacceptable discrimination against them. Political leadership will be required to implement such incentives over political challenges and persuade a significant number of the population still resisting or avoiding vaccination to get vaccinated for their own protection and the protection of others. It remains to be seen whether the new Biden administration will be able to exercise such political leadership and increase vaccination.

Concerning the proposed legal reform, the federal administration may for political considerations not welcome a legal requirement to take mandatory steps to prepare for the pandemic in pre-defined timelines: the administration may well consider such a requirement to undermine its political discretion by reducing its political options in the pandemic situation. As discussed above, the Trump administration initially downplayed the seriousness of the pandemic, as demonstrated by lack of timely preparations, due to the pandemic's adverse effect on his re-election in November of 2020.³⁴³ The proposed legal requirement will remove such an expedient political option relating to the management of the pandemic. The libertarian-minded administration may also consider the part of the proposed law that requires timely quarantine and isolated treatment of COVID-19 patients, as well as mandatory contact tracing and public release of some of the private information acquired through contact tracing, as exceeding the bounds of governmental authority and politically unsupportable, even if the federal government may have legal authorities.³⁴⁴ The administration, therefore, may lack the political will to support and implement the proposed legal reform.

As for the proposed Commission, the administration may also consider such a Commission to be adversarial to its political interest; the politically independent head agency will not be subject to the control of the President, at least not directly, and may develop policies, guidelines, and mandatory measures without political considerations favoring the administration. The proposed system of coordination will also create direct

343. See Bennett, *supra* note 42 and accompanying text (discussing the political impact of COVID-19 in the United States).

344. 42 C.F.R. pts. 70 and 71 (2020) (outlining the broad powers afforded to the federal government to combat public health emergencies related to communicable diseases).

channels of cooperation and coordination with federal, state, and local authorities, which is to be headed by this politically independent agency; the administration may consider such a system as weakening its influence and control over the pandemic response. Thus, implementing the proposed law and institutional reform will require a federal administration with a strong political will to set up an optimal legal and institutional framework for the welfare of the people, rather than one embedded in a partisan political interest.

V. CONCLUSION

COVID-19 represents an unprecedented public health failure in the United States, causing over 44.8 million infections and over 720,000 deaths in less than two years of the pandemic.³⁴⁵ The infection of former President Trump with COVID-19 was a symbolic testament to this failure; the former President, who was expected to lead the national effort to combat COVID-19, failed to comply with safety guidelines, such as wearing face masks in public, and downplayed the seriousness of the pandemic for his re-election concerns,³⁴⁶ instead of encouraging the public to follow guidelines and cooperate with public health authorities. The former President may have recovered from the disease within only a few days, thanks to the state-of-the-art facilities and the then-experimental medicine made available to him, but other COVID-19 patients not in such a privileged position were dying by the thousands daily. The daily death toll has been reduced since then, but still hundreds of COVID-19 patients are losing their lives daily, and over 40 percent of the population in the United States remains unvaccinated at the time of writing.³⁴⁷

Many lives would have been saved had the federal government ensured public access to TCQT in the early stages of the pandemic. Several factors other than the conduct of the government, such as system of governance, institutional frameworks, public compliance, technological environment, and healthcare system structure, have affected the country's

345. *COVID Data Tracker*, *supra* note 1.

346. See Bennett, *supra* note 42 and accompanying text (discussing the political impact of COVID-19 in the United States).

347. *U.S. COVID-19 Vaccine Tracker*, *supra* note 33.

readiness for the pandemic. Among these factors, the United States healthcare system, which is unique among the high-income countries as reliant on job-based private health insurance, limited access to testing and treatment for tens of millions of Americans, who were either uninsured or underinsured, due to concerns about the cost,³⁴⁸ particularly in the earlier weeks of the pandemic when immediate testing and treatment were crucial for containing the disease. Subsequent COVID-19 legislation relieved some of this cost burden, including the cost of testing and vaccination,³⁴⁹ but provisions for the cost of treatment remain variant by states and localities. There is a call for overhauling the current healthcare system; scholars advocate for a single-payer system that has been instrumental to securing unfettered public access to testing and treatment in other countries adopting that system.³⁵⁰

The politicization of the COVID-19 response has also impeded efforts to control the disease. In the center of the controversy lies former President Trump's unsupportive attitude about state and local efforts to contain the disease, such as stay-at-home orders, business closures, and mask mandates, which had the effect of encouraging his supporters to defy them in mass protests.³⁵¹ The fragmented authorities among federal, state, and local governments in COVID-19 management also caused open disputes, disagreements, and even lawsuits among them, creating further confusion among the public.³⁵² The

348. See Witters, *supra* note 61 (reporting that concerns over cost deterred early testing).

349. See, e.g., The Families First Coronavirus Response Act (FFCRA) of 2020 §§ 6001–6004, 42 U.S.C. §§ 1320b–5, 1395l, 1396d(a)(3) (2020); Coronavirus Aid, Relief, and Economic Security Act (CARES Act) of 2020 § 3201 (amending FFCRA § 6001 to apply coverage without cost-sharing to out-of-network tests), § 3203(a), 41 U.S.C. § 300gg-13 (2020).

350. See, e.g., Maizland & Felter, *supra* note 12 (illustrating the discrepancy in effectiveness of pandemic response efforts between countries with public versus private healthcare systems).

351. See, e.g., Martina & Herald, *supra* note 319 (describing an anti “stay-at-home” order protest in Michigan); see also Owen Dyer, *Covid-19: Trump Stokes Protests Against Social Distancing Measures*, BMJ (Apr. 21, 2020), <https://www.bmj.com/content/369/bmj.m1596> [<https://perma.cc/9T8Y-F7V9>] (highlighting former President Trump's tweets calling for the “liberation” of states from stay-at-home orders, which spurred protests).

352. See discussion *supra* Section I.B (describing “fragmented authorities” driving public confusion as COVID-19 emerged).

vertical division of governmental power may be an essential feature of the United States federal system, but this divisive fragmentation has harmed pandemic management throughout the country. With insufficient coordination among federal, state, and local governments, the current practice has proved to be ineffective in controlling a pandemic of national and international scale.

The timely collection and public release of the information pertinent to COVID-19, including some information acquired through contact tracing information, is essential for the public to stay informed and protect themselves from the pandemic. The government largely failed to provide public access to such information, particularly in the crucial first few weeks of the pandemic.³⁵³ While there is a public interest in securing access to the information, a concern for privacy over the collection and release of personal information also exists,³⁵⁴ along with a risk of misuse by a third party or by the government.³⁵⁵ Steps must be taken to protect privacy and prevent misuse, but striking an adequate balance between the public need for information and the right to privacy is not always straightforward. On account of the unprecedented public health crisis, there is a call for reinforcing the public interests in the collection and release of information.

This article proposes legal and institutional reforms to ensure timely public access to TCQT. Legal and institutional prescriptions cannot eliminate the adverse influence of politics, but these prescriptions, at a minimum, offer a blueprint that guides the government where rule of law prevails. A core element of the proposed reform is amending existing law to not only empower, but also to *require* the federal government, with vast financial, technological, and administrative resources at its disposal, to take mandatory steps to ensure public access to TCQT in pre-defined timelines and to promptly provide the public with all pertinent information necessary to prevent the spread of disease.³⁵⁶ The proposed reform also includes the establishment of a bi-partisan Commission, headed by a

353. See Mirvis, *supra* note 313 (discussing data collection and communication failures in the United States Government's response to the COVID-19 pandemic).

354. *Id.* at 530-40.

355. *Id.*

356. *Id.*

politically independent agency in charge of controlling infectious diseases. The proposed Commission will be responsible for the development of policies and implementation of measures in systematic coordination with federal, state, and local governments, as well as the private sector. The practice adopted by the former Trump administration, which defers to the discretion of a federal administration that failed to take timely steps due to political considerations and to state and local governments with limited resources and personnel, to manage the pandemic on their own, is simply untenable for a future pandemic.