

## Introduction

*Katherine L. Kraschel, I. Glenn Cohen,  
Abbe R. Gluck, and Carmel Shachar*

*There is a discussion and a delicate balance about what's the overall impact of shutting everything down completely for an indefinite period of time. So, there's a compromise. If you knock down the economy completely and disrupt infrastructure, you may be causing health issues, unintended consequences, for people who need to be able to get to places and can't. You do the best you can.*

Dr. Anthony Fauci, Chief Medical Adviser to the President of the United States  
and Director of US National Institute of Allergy and Infectious Diseases

*Normal led to this. Normal was a world ever more prone to a pandemic but ever less ready for one. To avert another catastrophe, the [United States] needs to grapple with all the ways normal failed us. It needs a full accounting of every recent misstep and foundational sin, every unattended weakness and heedless warning, every festering wound and reopened scar.*

Ed Yong, Science Journalist, *Atlantic*

*Our Constitution principally entrusts '[t]he safety and the health of the people' to the politically ac-countable officials of the States 'to guard and protect.' *Jacobson v. Massachusetts*, 197 U. S. 11, 38 (1905). When those officials 'undertake[ ] to act in areas fraught with medical and scientific uncertainties,' their latitude 'must be especially broad.' *Marshall v. United States*, 414 U. S. 417, 427 (1974). Where those broad limits are not exceeded, they should not be subject to second-guessing by an 'unelected federal judiciary,' which lacks the background, competence, and expertise to assess public health and is not accountable to the people.*

*South Bay United Pentecostal Church v. Chief Justice Roberts, concurring*

*COVID[-19] is a funhouse mirror that is amplifying issues that have existed forever. People are not dying of COVID[-19]. They are dying of racism, of economic inequality and it is not going to stop with COVID[-19].*

Dr. Shreya Kangovi, Associate Professor of Medicine, Perelman  
School of Medicine at the University of Pennsylvania

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In December 2019, a number of people experienced shortness of breath and fever in Wuhan, Hubei Province, China and would eventually be the first people identified to have the SARS-Cov-2 virus that causes Coronavirus Disease 2019 (COVID-19). By January 31, 2020, US Secretary of Health and Human Services Alex Azar and the World Health Organization (WHO) declared the SARS-Cov-2 virus a public health emergency, and by March 15, 2020, U.S. states and many countries started shutting down schools, workplaces, and restaurants to stop the spread of the virus and lethal disease. The COVID-19 pandemic was, and continues to be, a public health tragedy of unmatched proportions in our lifetime, causing more than one million deaths in the United States alone in the first two years, with that toll falling inequitably across populations. It has caused a massive disruption of daily life, the global economy, and every major institution, on a scale and at a pace not seen in generations. The pace with which COVID-19 spread and the stress it placed on institutions left no place to hide and exposed weaknesses, foundational inequalities, and opportunities for innovation and change.

As this volume goes to press in late Spring 2023, the COVID-19 national emergency has been formally ended but the effects of the pandemic are far from over. Even a book as comprehensive as this one is in a sense “a snapshot in time,” rather than the final word on the changes sparked by the pandemic. As of the time of writing, new variants continue to surface as the virus evolves. The implications of COVID-19 survivorship remain uncertain and far reaching. But the story that has unfolded is also one of resilience, unprecedented collaboration and innovation, governance challenges, and cultural inflection points.

COVID-19 has touched all aspects of daily life and countless institutions from health care to politics, to prisons, to the economy. Underlying all of these, though, is the law. Our focus in this volume is on how law has mediated and been mediated by these institutions’ interactions with COVID-19 over the last three years. It is not possible for one book to exhaustively tell COVID-19’s story; indeed, it is probably not possible for a hundred books to do so. Our aim is instead to critically reflect on some of what COVID-19 revealed about our health care system, public health policy, governance, and law. The pandemic’s disruptive pressures have exposed strengths and weakness of pre-pandemic systems and demanded changes. Those lessons will be a large part of COVID-19’s legal legacy.

As editors, we had to make some difficult decisions in determining the right time at which to stop requesting authors of this volume to update their contributions in light of new developments. The result is a volume about a focused moment in time, attentive primarily to the initial responses to an unprecedented global health disaster. Our hope is to capture the issues that, in the short term, will inform the next wave of policy interventions, while also memorializing the lessons that will inform the years to come, years when – we hope – the realities and challenges of COVID-19 are no longer as vivid as a day-to-day matter.

This book is organized into six parts. It first provides a broad view on COVID-19’s initial disruption and the kinds of challenges that would endure. Part I describes the

systems in place at the outset of the pandemic and COVID-19's initial disruptions. Part II explores the severe disparities in health that existed before the pandemic but that the pandemic further exposed and exacerbated. Part III dissects responses by the government – executive, legislative, administrative, and judicial. Part IV describes the unprecedented innovation and speed with which novel treatments and therapies, including the vaccine, were created, and the infrastructure surrounding their authorizations and approvals, as well as advances in health care access and delivery. Part V considers global responses to the pandemic. Finally, Part VI takes a broader lens, analyzing the global response to COVID-19.

Understanding COVID-19's disruptive force requires examining the structures in place at the time COVID-19 hit. While almost all chapters in this volume in part provide such insights to explain their point of view, Part I, "The Health Care System that COVID-19 Encountered," centers it explicitly. This part sketches a picture of the health care delivery system, the cultural proclivity to consume and amplify misinformation, and the structures fueling health care disparities in the United States at the outset of the pandemic.

The part begins in New York, one of the first American cities to experience the pandemic. Dr. Joseph Fins, medical ethics chief at a major academic medical center, takes us back to spring 2020 and the first surge by providing a firsthand account of the tragic choices and lack of preparedness physicians faced during that time, even as they were being applauded as "heroes." He reminds us that the lessons learned in the earliest days must be remembered moving forward so that the system can be better prepared to make equitable decisions in the face of scarcity and to prevent the need for such impossible decisions again.

Richard Saver unpacks some of the challenges Dr. Fins discusses, pointing to the ethos of clinical medicine to prioritize individual patient needs over public health and how ill suited this paradigm is for an infectious disease pandemic. Acknowledging the legal challenges inherent in expanding physicians' health duties beyond the patient, he argues for better integration between clinical medicine and public health.

Next, Dr. William Sage and Victoria Tiase focus on the protection of health care workers, also using the first surge in New York City as their subject of study. They discuss the necessity for stronger protections, not just for the sake of the workforce but also to maintain quality care standards. They applaud the call to duty many health care workers answered but note that "in a sustained and serious pandemic, a heroism-based ethical paradigm for accepting personal risk is as misleading as the myth of professional perfection has been for avoiding medical errors." They propose a number of reforms to improve protections for health care workers, including more equitable sharing of staff and supplies across hospital systems, a transition from the current individualistic culture to a community-based model, and more practical and emotional support.

Wendy Parmet and Jeremy Paul tackle a different challenge that has influenced the trajectory of the pandemic – the "post-truth" perspective that, they argue, existed

prior to the pandemic and has fueled misinformation about vaccines, treatments, and more. They provocatively explain how developments in health law and bioethics may have inadvertently contributed to building the path towards a post-truth world, with those fields' modern emphases on individual choice and the resulting devaluation of expertise.

Finally, Sadia Coreas, Erik Rodriguez, and Dr. Eliseo Pérez-Stable examine one of the most disturbing truths about the pandemic – its disproportionate impact on people of color. They outline the systemic and structural factors that have long driven health care disparities in the United States, demonstrate how these disparities have persisted through every surge of the pandemic, and demand our attention and care to address health disparities related to COVID-19 and beyond.

The authors in Part II, “COVID-19, Disparities, and Vulnerable Populations,” delve deeper into the issues faced by communities particularly vulnerable to COVID-19's impact. This part begins with a prologue by Dr. Marcella Nunez-Smith, co-chair of the Biden-Harris Transition COVID-19 Advisory Board, chair of the Biden Administration's COVID-19 Health Equity Task Force, and a member of Connecticut Governor Ned Lamont's Reopen Connecticut Advisory Group, as well as chair of its Community Committee.

Dr. Nunez-Smith provides a frontline view of the challenges that confronted policymakers tackling COVID-19 inequities, as well as the breakthroughs that helped ameliorate them. Testing and tracing, along with securing accurate data on COVID-19's impact on different communities, were major early challenges. After vaccines became available, ensuring equitable access became the next priority – with administration officials launching collaborative programs and partnerships meant to foster trust among diverse communities. She argues that investing in community-led solutions for ensuring health equity and creating greater accountability around health equity outcomes are some of COVID-19's most important lessons for the future

Dr. Jaimie Meyer, Marisol Orihuela, and Judith Resnik analyze the vulnerabilities of people incarcerated during the pandemic. They reveal how the plight of people in detention during the early days of the pandemic – often without adequate dedensification, access to proper hygiene, or testing – may prove an inflection point in prison reform and the abolition movement. They argue that both the Eighth Amendment and constitutional doctrines have fallen short in protecting the health of incarcerated persons – even absent a global pandemic.

Next, Scott Schweikart, Fernando De Maio, Mia Keays, Joaquin Baca, Brian Vandenberg, and Dr. Aletha Maybank argue that the role of structural racism in COVID-19's disproportionate impact on Black, Indigenous, and People of Color communities demands a reexamination of public health data systems. They argue that the United States is at a political pivot point, one which emerged from the Black Lives Matter movement and arguably swelled as a result of the inequities of the pandemic and the murder of George Floyd. Furthermore, they suggest that this

pivot point could prompt progressive reforms in health care access, criminal justice reform, housing, civil rights enforcement, and more.

Govind Persad and Jessica Roberts turn their attention to older persons and persons with disabilities, and detail the mechanisms used to allocate and distribute scarce resources during the pandemic – especially critical care services and vaccines. Persad and Roberts identify several barriers to adopting allocation policies that do not discriminate against older persons and persons with disabilities: implicit bias among even the most well-intentioned health care providers; preexisting challenges with utilizing and accessing technology; and serious transportation barriers. They propose debiasing strategies to ameliorate these harms.

Finally, Nina Kohn considers another population in a congregate living setting on which COVID-19 has shone a bright light: people in long-term care facilities. Kohn describes how regulatory failures that preceded the pandemic – such as the failure to impose minimum staffing requirements and the underreporting of health and safety threats – as well as a slow public health response to COVID-19 led to a tremendous number of deaths in long-term care facilities. She argues for regulatory reforms, including aligning payment incentives with quality care metrics, tying public funding to staffing minimums, and requiring states to provide coverage for in-home care at the same level as institutional care.

Part III, “Government Response and Reaction to COVID-19” further considers the role and powers of government in such an unprecedented public health crisis. COVID-19 is one of the most significant governance challenges in modern history; not only has it elicited responses across all levels and branches of government, it has also impacted governance infrastructures themselves.

Nicole Huberfeld’s chapter leads this part and depicts the interactions among federal, state, local, and tribal bodies that constitute the US health care governance architecture. Our national health care system is a federalist system built on structural redundancies. Each level of government has emergency powers, and each used theirs during the pandemic – at times to fill in for the lack of leadership by other levels, including by the President himself. Despite the security of overlap, Huberfeld worries that our federalist model remains a driver for inequality and ineffective emergency response.

The next two chapters of Part III take up issues of the government’s preparedness for a pandemic and its ability to respond. Matthew Lawrence describes “upstream fiscal determinants” of health – structures within the federal government, including the budget process, that fuel underinvestment in public health. Ariel Jurow Kleiman, Gabriel Scheffler, and Andrew Hammond hone in on the federal government’s expansion of existing social safety net programs during the pandemic, such as through greater appropriations for the Supplemental Nutrition Assistance Program and the provision of higher tax credits for individuals who enrolled in marketplace health insurance plans under the Affordable Care Act. They describe how the government should have done more to provide essential resources and propose

additional automatic actions that will allow a better response to future crises and mitigate inequalities that were exacerbated during the pandemic.

Ruqaiyah Yearby discusses the role of regulations. She provides a health justice critique, analyzing how the failure of federal and state governments to provide paid sick leave for all workers and the Occupational Safety and Health Administration's decision to issue advisories instead of workplace requirements to limit the spread of COVID-19 exacerbated pandemic health inequities. She also proposes a model to design emergency preparedness plans for the next emergency with greater voice from the workers themselves.

The judicial branch – the courts – also took center stage in the first few years as the United States reacted to the pandemic. Lindsay Wiley details the complexities of the legal challenges brought against government actions – such as gathering restrictions – in the name of public health. For more than a century, courts have relied on a Supreme Court precedent, *Jacobson v. Massachusetts*, in deferring to the scientific and expert judgment of government officials to exercise their public health authorities. Wiley details how the post-*Jacobson* development of individual rights doctrine creates a tension that requires courts today not to suspend judicial review in the face of a public health emergency but to incorporate *Jacobson's* core principle into new doctrines that seek to reconcile individual rights and community protection.

Part IV, “Innovation During COVID-19,” deepens our inquiry into debates about whether COVID-19 represented an exceptional concurrence of events that overwhelmed good regulatory structures or exposed structures that were already ailing.

The first chapter of this part offers an expert account of the innovation infrastructure in place at the time of the pandemic provided by Rachel Sachs, Lisa Larrimore Ouellette, W. Nicholson Price II, and Jacob Sherkow. They describe the unique pressure that COVID-19 testing placed on interagency coordination, the difficult balance of quickly getting critical therapies to market with the need to make decisions informed by reliable data, and the incentive structures and role of government funding in facilitating the “warp speed” of COVID-19 vaccine development. They suggest future policymaking be informed by the lessons learned from COVID-19 – so that it is both responsive to the next pandemic and addresses issues such as access to medicine generally.

Dr. Michael Sinha, Sven Bostyn, and Timo Minssen delve deeper into intellectual property rights for COVID-19 vaccines and treatments. They focus on exclusivity rights and, among other things, argue that “safeguards are needed to guarantee global access to sufficient vaccines at reasonable prices.”

Katharine Van Tassel and Sharona Hoffman round out this part with a chapter on vaccine injury compensation. They detail the two existing mechanisms to remedy vaccine-related harms and describe how the system places disproportionate burdens on vulnerable populations. They conclude by making the case for amending the Public Readiness and Emergency Preparedness Act to shift vaccines approved

under emergency use authorizations to the more generous and accessible compensation program available for other vaccines.

Part V, “Opening New Pathways for Health Care Delivery and Access,” considers different types of innovation – in health care delivery and access. Ryan Knox, Laura Hoffman, Asees Bhasin, and Abbe Gluck tackle the way COVID-19 accelerated one of the most significant shifts in the practice of medicine: telemedicine. After providing a concise but comprehensive background on the regulatory and legal barriers telemedicine faced in the United States prior to the pandemic, they describe the massive shifts the pandemic wrought, largely via emergency actions at both the state and federal levels. The national updating of telemedicine in the pandemic, they argue, helps make the case for lasting regulatory reforms to maintain access to telemedicine, while revealing some of the challenges – including significant access barriers for certain populations – that the pandemic telehealth experience illustrated and which must be addressed.

Dr. Zoe Adams, Taleed El-Sabawi, Dr. William H. Coe, Hannah Batchelor, Janan Wyatt, Mona Gandhi, Dr. Ida Santana, and Dr. Ayana Jordan focus on methadone for opioid use disorder, explaining the regulatory barriers that have accompanied the use of methadone for this disorder for nearly fifty years, which require patients to receive treatment in person. They tell the story of how these requirements were relaxed during the pandemic to minimize COVID-19 exposure. They then present qualitative survey data to illustrate the benefits and minimal risk that accompany the less stringent requirements and make the case for lasting reforms.

The last two chapters of Part V address abortion access during the pandemic. First, Rachel Zacharias, Elizabeth Dietz, Kimberly Mutcherson and Josephine Johnston provide an account of restrictions placed on medication abortion via the Risk Evaluation Mitigation Strategies program of the Food and Drug Administration (FDA). In contrast to treatment for opioid use disorder, the in-person provision requirements for medication abortion were not relaxed until the Biden administration came into office. And their chapter details the litigation that ensued against the FDA policy prohibiting distribution of mifepristone, the drug used for medication abortion, in an attempt to facilitate access. The authors employ a reproductive justice framework to consider these issues and critique the emphasis on personal responsibility in the discourse around abortion by providing examples of the ways it entrenches racial disparities. As this book goes to print, a case is winding its way through the court system challenging both the FDA’s 20-year-old approval of abortion medication as well as the Biden Administration’s relaxing of the REMS. Joanna Erdman’s chapter takes a socio-legal perspective on at-home abortion and points to the ways improved access during the pandemic was achieved within a system of clinical control of abortion and social norms of abortion law. Despite shifts within the clinically controlled system during the pandemic, she suggests that the normalization of abortion in the home may lead to radical changes in its practice in the long term.

Part VI, “Global Responses to COVID-19,” takes a broader lens. The chapters in this part both compare COVID-19 responses across countries and consider what differing responses mean for a connected, global economy and information ecosystem. In their chapter, Tess Wise, Gali Katznelson, Carmel Shachar, and Andrea Louise Campbell complicate pre-COVID-19 public health preparedness evaluations by organizations such as the World Bank and the WHO. They offer an empirical analysis examining the effectiveness of early COVID-19 response, as measured by disease spread and mortality rate, and conclude that those countries identified as being best prepared for a public health crisis, based upon political, legal, social, cultural, economic, and organizational factors, did not outperform other countries in mitigating the spread of the virus and reducing the number of deaths. They urge a different global consensus on public health in which “the risks and costs associated with sickness are shared by the whole society, not only sick individuals, emphasizing that justice and efficiency must be linked together.”

In their chapter, Joelle Grogan and Alicia Ely Yamin also consider various countries’ COVID-19 responses and the risk of human rights violations that may accompany governmental responses during a public health crisis. Based upon findings from two multi-country convenings, they show that there are stronger correlations between social and political environments and human rights violations than between the formal legal regimes in which the social and political environments operate and human rights violations.

The third chapter in this part, written by Daniel Farber, situates the emergent crisis of COVID-19 alongside the longer-term crisis of climate change. He considers COVID-19’s short-term and direct impact on climate change itself by discussing the reduction of carbon emissions that accompanied the earliest stages of the pandemic, while noting that the longer-term impacts are unknown. He also contemplates two less direct ways that COVID-19 may shape climate change – leveraging COVID-19 stimulus funding to support green energy investment and what COVID-19 teaches us about governance challenges, particularly government interventions that require lasting behavioral changes to address a global collective problem.

Glenn Cohen provides the final chapter in the book. It addresses vaccine tourism – “queue jumping” by traveling from a community where vaccination is not readily available to a destination state or country where it is. Cohen first describes ethical concerns with vaccine tourism: the discordance between those who are able to participate in vaccine tourism and those who we may agree should be first to access vaccination; the displacement of those in the community with the supply of vaccines; and the concern with disease infection and transmission in the process of accessing vaccination. He then argues for communitarian principles to guide defining the groups who have compelling moral claims to vaccines in order to address the health justice and equity issues posed by vaccine tourism.

Finally, Abbe Gluck and Jacob Hutt offer an epilogue detailing the trajectory of the massive array of litigation that stemmed from COVID-19. In areas from workers’



rights to prison health and election law, the litigation shined a salutary bright light on challenges and inequities that preexisted the pandemic but that the pandemic made impossible to ignore. But beyond its effect on countless individual areas of law, Gluck and Hutt argue that the arc of the litigation reflected changes in governments' responses to the pandemic itself and also more seismic shifts in Supreme Court doctrine. Early cases focused on the tension between modern civil rights and long-standing precedents counseling judicial deference to state government policies, such as the early COVID-19 business closures, implemented to protect public health. Later cases were part of larger debates at the Supreme Court about interpreting old federal laws – such as the CDC's long-standing public health authorities – and curtailing deference to executive-branch actions, such as federal vaccination mandates, taken under those laws.

When essential workers were left to bear the risks of COVID-19 exposure so that we could “flatten the curve” and when “Zoom” entered our daily vernacular, very few could have fathomed the loss of life that has followed or predicted that we would still be fending off another surge in 2022 and waiting to see what the next variant may bring in 2023. Debate continues today about whether we are in a “new normal,” if the pandemic has evolved into its endemic phase, and how the government ought to be providing support and resolving issues that have come to the fore with COVID-19's disruption.

Yet COVID-19's impact on health, institutions, governance, and law already offers much from which we can learn. COVID-19 has taught us the limits of the designs of health care delivery and governance and demanded action to respond to the inequities in the system. It has helped to identify areas of inspiring innovations in treatment and access. It has forced us to appreciate that viruses do not respect borders. While the federal public health emergency is sunsetting, the effects of the last few years continue to be felt. But this is as good a moment as any to critically reflect on its lessons thus far with the hope that they might help mold COVID-19's legacy for the intersection of law and health.

